ALABAMA STATE COMMITTEE OF PUBLIC HEALTH
BUREAU OF ENVIRONMENTAL AND HEALTH SERVICE STANDARDS
DIVISION OF RADIATION CONTROL
ADMINISTRATIVE CODE

CHAPTER 420-3-26
RADIATION CONTROL

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420-3-26-.01 General Provisions.

(1) **Scope.** Except as otherwise specifically provided, these rules apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation; provided, however, that nothing in these rules shall apply to any person to the extent such person is subject to regulation by the U.S. Nuclear Regulatory Commission.[3] The provisions of Rule 420-3-26-.03 of this rule shall not be interpreted as limiting the intentional exposure of patients to radiation for the purpose of diagnosis or therapy by persons licensed to practice one or more of the healing arts within the authority granted them by healing arts statute or persons licensed to practice dentistry or podiatry within the authority granted them by licensing laws applying to dentists and podiatrists.

(2) **Definitions.**

(a) As used in these rules, these terms have the definitions set forth below. Additional definitions used only in a certain rule will be found in that rule.

1. "A1" means the maximum activity of special form radioactive material permitted in a Type A package. "A2" means the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are listed in Rule 420-3-26-.03(32) of these rules.

2. "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of an absorbed dose are the gray (Gy) and the rad.

3. "Accelerator" means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 meV.

For purposes of this definition, "particle accelerator" is an equivalent term.

4. "Accelerator-produced material" means any material made radioactive by a particle accelerator.

5. "Act" means Act No. 582, Alabama Law, Regular Session, 1963. Codified as 22-14-1 Code of Ala. 1975.

6. "Activity" means the rate of disintegration or transformation or decay of radioactive material. The units of activity are the becquerel (Bq) and the curie (Ci).

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[1] Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

7. "Adult" means an individual 18 or more years of age.

8. "Agency" means the Alabama State Board of Health.

9. "Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under subsection 274b. of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

10. "Airborne radioactive material" means any radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

11. "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

(i) In excess of the derived air concentrations (DACs) specified in Appendix B, Table I of 420-3-26-.03 of these rules.

(ii) To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

12. "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic

considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

13. "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. "Background radiation" does not include radiation from licensed or registered sources regulated by the Agency.

14. "Becquerel" (Bq) means the SI unit of activity. One becquerel is equal to 1 disintegration or transformation per second (dps or tps).

15. "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, quantities of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

16. "Brachytherapy" means a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

17. "Byproduct material" means:

(i) Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

(ii) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

(iii) Any discrete source of radium 226 that is produced, extracted or converted after extraction, for use for a commercial, medical, or research activity.

(iv) Any material that has been made radioactive by use of a particle accelerator and is produced, extracted, or converted after extraction for use in a commercial, medical, or research activity.

(v) Any discrete source of naturally occurring radioactive material, other than source material that the NRC, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium 226 to the public health and safety or common defense and security, and is extracted or converted after extraction for use in a commercial, medical, or research activity.

18. "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these rules except at the beginning of a year.

19. "Calibration" means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

20. "CFR" means Code of Federal Regulations.

21. "Chelating agent" means amine polycarboxylic acids, hydroxycarboxylic acids, gluconic acid, and polycarboxylic acids.

22. "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

23. "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

24. "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma\, w_T H_{T,50}$).

25. "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.

26. “Critical group” means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

27. "Curie" means a unit of quantity of radioactivity. One curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7E+10 transformations per second (tps).

28. "Deep dose equivalent" (Hd), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm2).

29. "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

30. "Discrete source" means a radionuclide that has been processed so that its concentration within a material has been purposely increased for commercial, medical or research activities.

31. "Dose" is a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, total organ dose equivalent, or total effective dose equivalent. For purposes of these rules, "radiation dose" is an equivalent term.

32. "Dose equivalent (HT)" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

33. "Dose limits" means the permissible upper bounds of radiation doses established in accordance with these rules. For purposes of these rules, "limits" are an equivalent term.

34. "Effective dose equivalent (HE)" means the sum of the products of the dose equivalent to each organ or tissue (HT) and the weighting factor (wT) applicable to each of the body organs or tissues that are irradiated ($HE = \Sigma\ wTHT$).

35. "Embryo/fetus" means the developing human organism from conception until the time of birth.

36. "Entrance or access point" means any opening through which an individual or extremity of an individual could gain access to radiation areas or to licensed or registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

37. "Explosive material" means any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

38. "Exposure" means being exposed to ionizing radiation or to radioactive material.

39. "Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the coulomb per kilogram (C/kg). See 420-3-26-.01(13), Units of Exposure and Dose for the special unit.

40. "Exposure rate" means the exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

41. "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

42. "Extremity" means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

43. "Eye dose equivalent" means the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter (300 mg/ cm2).

44. "Former U.S. Atomic Energy Commission (AEC) or U.S. Nuclear Regulatory Commission (NRC) licensed facilities" means nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where AEC or NRC licenses have been terminated.

45. "Generally applicable environmental radiation standards" means standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that imposes limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

46. "Gray" (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

47. "Hazardous waste" means those wastes designated as hazardous by U.S. Environmental Protection Agency regulations in 40 CFR Part 261.

48. "Healing arts" means the practice of medicine, dentistry, osteopathy, chiropractic, podiatry, and for non-humans, veterinary medicine.

49. "High radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

50. "Human use" means the internal or external administration of radiation or radioactive material to human beings.

51. "Individual" means any human being.

52. "Individual monitoring" means the assessment of:

(i) Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

(ii) Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours. [See the definition of DAC-hours in 420-3-26-.03].

53. "Individual monitoring devices" means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

54. "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with rules, orders, requirements, and conditions of the Agency.

55. "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

56. "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

57. "License" means a license issued by the Agency in accordance with the rules adopted by the Agency.

58. "Licensed material" means radioactive material received, possessed, used, transferred, or disposed of under a general or specific license issued by the Agency.

59. "Licensee" means any person who is licensed by the Agency in accordance with these rules and the Act.

60. "Licensing State" means any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NARM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

61. "Limits" [See "Dose limits"].

62. "Lost or missing licensed or registered source of radiation" means licensed or registered source of radiation whose location is unknown. This definition includes licensed or registered material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

63. "Major processor" means a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding 4 times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in Rule 420-3-26-.03(32) of these rules.

64. "Member of the public" means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

65. "Minor" means an individual less than 18 years of age.

66. "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities, or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

67. "NARM" means any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.[2]

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[2] For purposes of meeting the definition of a Licensing State by the Conference of Radiation Control Program Directors, Inc. (CRCPD), NARM refers only to discrete sources of NARM. Diffuse sources of NARM are excluded from consideration by the CRCPD for Licensing State designation purposes.

68. "Nationally tracked source" means a sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix D of Rule 420-3-26-.03. In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded in a solid form and which is not exempt from regulatory control. It does not mean radioactive material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod or fuel pellet. Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. Category 2 nationally tracked sources are those containing

radioactive material at a quantity equal to or greater than the Category 2 threshold, but less than the Category 1 threshold.

69. "Natural radioactivity" means radioactivity of naturally occurring nuclides.

70. "Nuclear Regulatory Commission" (NRC) means the U.S. Nuclear Regulatory Commission or its duly authorized representatives.

71. "Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include doses received: from background radiation, as a patient from medical practices, from voluntary participation in medical research programs, or as a member of the public.

72. "Package" means the packaging together with its radioactive contents as presented for transport.

73. "Particle accelerator" [See "Accelerator"].

74. "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing other than the U.S. Nuclear Regulatory Commission, and other Federal Government Agencies licensed by the U. S Department of Energy, and other than Federal Government Agencies licensed by the U. S. Nuclear Regulatory Commission.

75. "Personnel monitoring equipment" [See "Individual monitoring devices"].

76. "Pharmacist" means an individual licensed by this state to compound and dispense drugs, prescriptions, and poisons.

77. "Physician" means an individual licensed by the State of Alabama to dispense drugs in the practice of medicine.

78. "Public dose" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, or dose from voluntary participation in medical research programs.

79. "Pyrophoric liquid" means any liquid that ignites spontaneously in dry or moist air at or below 130°F (54.4°C). A pyrophoric solid is any solid material, other than one classed as

an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

80. "Qualified expert" means an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology or the American Board of Health Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-Ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.

81. "Quality factor" (Q) means the modifying factor, listed in Tables I and II of Rule 420-3-26-.01(13), that is used to derive dose equivalent from absorbed dose.

82. "Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 gray).

83. "Radiation" means alpha particles, beta particles, gamma rays, x rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these rules, ionizing radiation is an equivalent term. Radiation, as used in these rules, does not include non-ionizing radiation, such as radio waves or microwaves, visible, infrared, or ultraviolet light.

84. "Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

85. "Radiation dose" [See "Dose"].

86. "Radiation machine" means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

87. "Radiation safety officer" means an individual who has the knowledge and responsibility to apply appropriate radiation protection rules.

88. "Radioactive material" means any solid, liquid, or gas which emits radiation spontaneously.

89. "Radioactivity" means the transformation of unstable atomic nuclei by the emission of radiation.

90. "Radiobioassay" [See "Bioassay"].

91. "Registrant" means any person who is registered with the Agency and is legally obligated to register with the Agency pursuant to these rules and the Act.

92. "Registration" means registration with the Agency in accordance with the rules adopted by the Agency.

93. "Regulations of the U.S. Department of Transportation" means the regulations in 49 CFR Parts 100-189.

94. "Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

95. "Research and development" means (1) theoretical analysis, exploration, or experimentation; or (2) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

96. "Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

97. "Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58E-4 coulombs per kilogram of air [See "Exposure" and 420-3-26-.03(13)].

98. "Sealed source" means radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

99. "Shallow dose equivalent" (Hs), which applies to the external exposure of the skin or an extremity, means the dose equivalent at

a tissue depth of 0.007 centimeter (7 mg/cm2) averaged over an area of 1 square centimeter.

100. "SI" means the abbreviation for the International System of Units.

101. "Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem). 102. "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee or registrant. 103. “Source material" means:

(i) Uranium or thorium, or any combination thereof, in any physical or chemical form; or

(ii) Ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium or any combination of uranium and thorium. Source material does not include special nuclear material.

104. "Source material milling" means any activity that results in the production of radioactive material.

105. "Source of radiation" means any radioactive material or any device or equipment emitting, or capable of producing, radiation.

106. "Special form radioactive material" means radioactive material that satisfies the following conditions:

(i) It is either a single solid piece or contained in a sealed capsule that can be opened only by destroying the capsule;

(ii) The piece or capsule has at least one dimension not less than 5 millimeters (0.2 inch); and

(iii) It satisfies the test requirements specified by the U.S. Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the U.S. Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

107. "Special nuclear material" means:

(i) Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that 3 the U.S. Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

(ii) Any material artificially enriched by any of the foregoing but does not include source material.

108. "Special nuclear material in quantities not sufficient to form a critical mass" means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special _____

[3] This wording is provided for states that cannot automatically adopt changes made by the U.S. Nuclear Regulatory Commission. Nuclear material in combination shall not exceed 1. For example, the following quantities in combination would not exceed the limitation and are within the formula:

$$\frac{175\ (grams\ contained\ U-235)}{350} + \frac{50\ (grams\ U-233)}{220} + \frac{50\ (grams\ Pu)}{200} = 1$$

109. "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

110. "Test" means the process of verifying compliance with an applicable regulation.

111. "These rules" mean Rules 420-3-26-.01 through 420-3-26-.14, inclusive.

112. "Total effective dose equivalent" (TEDE) means the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

113. "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in Rule 420-3-26-.03(46)(a)6. of these rules.

114. "U.S. Department of Energy" means the Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, 42 U.S.C. 5814, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to

section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

115. "Unrefined and unprocessed ore" means ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

116. "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee or registrant. For purposes of these rules, "uncontrolled area" is an equivalent term.

117. "Waste" means those low-1evel radioactive wastes containing source, special nuclear or other radioactive material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-1evel radioactive waste means radioactive waste not classified as high-1evel radioactive waste, transuranic waste, spent nuclear fuel, or radioactive material as defined in paragraphs (ii), (iii), (iv), and (v) of the definition of “Byproduct material” set forth in Rule 420-3-26-.01(2)(a)17.

118. "Waste handling licensees" mean persons licensed to receive and store radioactive wastes prior to disposal and/or persons licensed to dispose of radioactive waste.

119. "Week" means 7 consecutive days starting on Sunday.

120. "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

121. "Worker" means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

122. "Working level" (WL) means any combination of short-1ived radon daughters in 1 liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-1ived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

123. "Working level month" (WLM) means an exposure to 1 working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.
124. "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(3) **Exemptions.**

(a) General Provision. The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

(b) U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this State is exempt from these rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

1. Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

2. Prime contractors of the U.S. Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

3. Prime contractors of the U.S. Department of Energy using or operating nuclear reactors or other nuclear devices in a United States Government-owned vehicle or vessel; and

4. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the State and the U.S. Nuclear Regulatory Commission jointly determine that:

(i) The exemption of the prime contractor or subcontractor is authorized by law; and

(ii) Under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

General Regulatory Requirements

(4) **Records.** Each licensee and registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in these rules. Records shall be maintained as long as specified in the rules or until the Agency authorizes disposal.

(5) **Inspections.**

(a) Each licensee and registrant shall afford the Agency at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

(b) Each licensee and registrant shall make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to these rules.

(c) The Agency may immediately impound or order the impounding of sources of radiation in the possession of any person who is not equipped to observe or fails to observe these rules or provisions of the act.

(6) **Tests and Surveys.** Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(a) Sources of radiation;

(b) Facilities wherein sources of radiation are used or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

(7) **Additional Requirements.** The Agency may, by rule, regulation, or order, impose upon any licensee or registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

Enforcement Requirements

(8) **Violations.** An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

(9) **Impounding.** Sources of radiation shall be subject to impounding pursuant to Section 15 of the Act.

(10) **Prohibited Uses.**

(a) A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the U.S. Food

and Drug Administration, Center for Devices and Radiological Health.

(b) A shoe-fitting fluoroscopic device shall not be used.

(c) It shall be unlawful for any person to use, receive, own, or possess any source of radiation unless it is registered, licensed or exempted by the Agency and is operated in accordance with all applicable provisions of Rules 420-3-26-.01 through 420-3-26-.13 inclusive.

(d) Persons shall not be exposed to the useful x-ray beam except for healing arts purposes, each exposure of which shall be authorized by:

1. A licensed practitioner of the healing arts; or

2. A licensed physician's assistant, a certified registered nurse practitioner, or a certified nurse midwife subject to the rules of his/her licensure board.

3. Notwithstanding the above, the performance of x-ray backscatter scans on detainees entering or leaving a state, county or city detention facility are exempt from the requirements of 420-3-26-.01(10)(d)1. and 2., provided the x-ray backscatter devices are used in accordance with American National Standard ANSI/HPS N.43.17-2009 entitled *Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation* (available online at www.hps.org/hpssc/N43Status.html).

(11) **Deliberate Misconduct.**

(a) Any licensee, registrant, applicant for a license or a certificate of registration, employee of a licensee, registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor or subcontractor of any licensee or certificate of registration holder or applicant for a license or registration, who knowingly provides to any licensee, registration holder, applicant, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registration holder's, or applicant's activities in these Rules, may not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule, or order; or any term, condition, or limitation of any license or registration issued by the Agency; or

2. Deliberately submit to the Agency, a licensee, registrant, an applicant, or a licensee's, registrant's, or applicant's contractor or subcontractor, information that the person

submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

(b) A person who violates paragraphs (a)1. or (a)2. of this rule will be subject to enforcement in accordance with procedures in Rule 420-3-26-.13.

(c) For the purposes of paragraph (a)1. of this rule, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, registrant, or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any license or registration issued by the Agency.

2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

(12) **Communications.** All communications and reports concerning these rules, and applications filed thereunder, should be addressed to the Agency at its mailing address as follows:

Office of Radiation Control
Alabama Department of Public Health
P. O. Box 303017
Montgomery, Alabama 36130-3017

(13) **Units of Exposure and Dose.**

(a) As used in these rules, the unit of Exposure is the coulomb per kilogram (C/kg) of air. One roentgen is equal to 2.58E-4 coulomb per kilogram of air.

(b) As used in these rules, the units of dose are:

1. Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

2. Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).

3. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 Sv).

4. Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in Table I.

TABLE I

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

TYPE OF RADIATION	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a]Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(d) If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in 420-3-26-.01(13)(c) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee or registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

TABLE II

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm-2 rem-1)	Fluence per Unit Dose Equivalent[b] (neutrons cm-2 Sv-1)
(thermal)	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8

	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8
	1E-1	7.5	170+6	170+8
	5E-1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

[a]Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

[b]Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

(14) **Units of Activity.** For purposes of these rules, activity is expressed in the SI unit of becquerel (Bq) or in the special unit of curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

(a) One becquerel (Bq) = 1 disintegration or transformation per second (dps or tps).

(b) One curie (Ci) = 3.7E+10 disintegrations or transformations per second (dps or tps) = 3.7E+10 becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (dpm or tpm).

APPENDIX B
TESTS FOR SPECIAL FORM LICENSED MATERIAL

1. Free Drop - A free drop through a distance of 30 feet onto a flat essentially unyielding horizontal surface, striking the surface in such a position as to suffer maximum damage.

2. Percussion - Impact of the flat circular end of a 1 inch diameter steel rod weighing 3 pounds, dropped through a distance of 40 inches. The capsule or material shall be placed on a sheet of lead, of hardness number 3.5 to 4.5 on the Vickers scale, and not more than 1 inch thick, supported by a smooth essentially unyielding surface.

3. Heating - Heating in air to a temperature of 1,475° F and remaining at that temperature for a period of 10 minutes.

4. Immersion - Immersion for 24 hours in water at room temperature. The water shall be at pH 6 - pH 8, with a maximum conductivity of 10 micromhos per centimeter.
Author: Karl David Walter
Statutory Authority: Code of Ala. 1975, §§22-2-1, 22-2-2, 22-2-5, 22-2-6, 22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, 22-14-14.
History: **New Rule:** June 15, 1966; Revised March 18, 1970; Repromulgated August 21, 1974; Revised May 21, 1975; September 15, 1976; January 18, 1978; **Recodified** June 11, 1978; Revised October 21, 1981; Revised December 21, 1983; Revised January 31, 1990. Revised April 22, 1994; effective May 26, 1994. **Amended:** Filed July 18, 2001; effective August 22, 2001. **Amended:** Filed July 27, 2010; effective August 31, 2010. **Amended:** Filed October 20, 2014; effective November 24, 2014; operative December 1, 2014. **Amended:** September 21, 2016; effective November 5, 2016.

Ed. Note: filed September 1, 1982. Readopted with amendments filed October 24, 1983. **Amended:** Filed December 19, 1986; January 19, 1990.

420-3-26-.02 **Licensing.**

(1) **Purpose.**

(a) This Rule, 420-3-26-.02, provides for the licensing of radioactive material.

(b) In addition to the requirements of this Rule, 420-326-.02, all specific licensees are subject to the requirements of Rules 420-3-26-.01, 420-3-26-.03, 420-3-26-.10, and 420-3-26-.13. Licensees engaged in industrial radiographic operations are subject to the requirements of Rule 420-3-26-.04, licensees using

radioactive material in the healing arts are subject to the requirements of Rule 420-3-26-.07, licensees using radioactive material for wireline service operation, subsurface tracer studies, or fishing operations are subject to Rule 420-3-26-.12, and licensees using radioactive material in irradiators are subject to the requirements of Rule 420-3-26-.14.

(c) General licensees are subject to the requirements of Rules 420-3-26-.01; 420-3-26-.02(4)(a)2; 420-3-26-.02(7)(a) through (h); 420-3-26-.02(12)(c), (e), and (g); 420-3-26-.02(18); 420-3-26-.02(19); 420-3-26-.03; 420-3-26-.10; and 420-3-26-.13.

(d) The regulations in this Rule 420-3-26-.02 also apply to any licensee authorized by specific or general license issued by the Agency to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Agency license, or transports that material on public highways.

(2) **Scope.** Except for persons exempt as provided in 420-3-26-.02(3) and (4), no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use radioactive material except as authorized in a specific or general license issued in accordance with the requirement of this rule.

Exemptions

(3) **Source Material.**

(a) Any person is exempt from this Rule, 420-3-26-.02, to the extent that such person receives, possesses, uses, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 1/20 of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy.

(b) Any person is exempt from this Rule, 420-3-26-.02, to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material, provided that the unrefined and unprocessed ore shall not be consolidated into a single physical location such that the quantity of source material exceeds the general license possession limits imposed in Rule 420-3-26-.02(6)(a). Except as authorized in a specific license, such person shall not refine or process such ore.

(c) Any person is exempt from the requirements for a license set forth in this Rule, 420-3-26-.02, to the extent that such person receives, possesses, uses, or transfers:

1. Any quantities of thorium contained in:

(i) Incandescent gas mantles,

(ii) Vacuum tubes,

(iii) Welding rods,

(iv) Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

(v) Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than 2 grams of thorium,

(vi) Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

(vii) Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium.

2. Source material contained in the following products:

(i) Glazed ceramic tableware manufactured before November 5, 2016, provided that the glaze contains not more than 20 percent by weight source material.

(ii) Piezoelectric ceramic containing not more than 2 percent by weight source material.

(iii) Glassware containing not more than 2 percent by weight source material or, for glassware manufactured before November 5, 2016, 10 percent by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction.

(iv) Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983.

3. Photographic film negatives, and prints containing uranium or thorium.

4. Any finished product or part fabricated of, or containing, tungsten or magnesium-thorium alloys; providing that, the thorium content of the alloy does not exceed 4 percent by weight and that the exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part.

5. Uranium contained in counterweights installed in aircraft rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights: provided that:

(i) Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";1

(ii) Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTH¬ORIZED ALTERATIONS PROHIBITED"; 1 and,

(iii) The exemption contained in this subparagraph shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any counterweights other than repair or restoration of any plating or other covering.

6. Natural or depleted uranium metal used as shielding constituting part of any shipping containers provided, that:

(i) The shipping container is conspicuously and legibly impressed with the legend "CAUTION--¬RADIOACTIVE SHIELDING URANIUM" and

(ii) The uranium metal is encased in milled steel, or equally fire resistant metal, of minimum wall thickness of one-eighth inch (3.2 mm).

7. Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than 10 percent by weight of thorium or uranium or, for lenses manufactured before November 5, 2016, 30 percent by weight of thorium; and that the exemption contained in this subparagraph shall not be deemed to authorize either:

(i) The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

(ii) The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments.

8. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

(i) The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide) and

(ii) The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

9. The exemptions in 420-3-26-.02(3)(c) do not authorize the manufacture of any of the products described.

10. No person may initially transfer for sale or distribution a product containing source material to persons exempt under this

subparagraph or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, unless authorized by a license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 40.52 of 10 CFR Part 40 to initially transfer products for sale or distribution.

(i) Persons initially distributing source material in products covered by the exemptions in this subparagraph before November 5, 2016, without specific authorization may continue such distribution for 1 year beyond this date. Initial distribution may also be continued until the U.S. Nuclear Regulatory Commission takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

(ii) Persons authorized to manufacture, process, or produce these materials or products containing source material by the Agency or another Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 40.52 of 10 CFR Part 40 for distribution only and are exempt from the requirements of Rules 420-3-26-.03, 420-3-26-.10, and 420-3-26-.02(9)(a) and (b).

(4) **Radioactive Materials.**

(a) Exempt Concentrations

1. Except as provided in paragraphs (a)2 and 3 below, any person is exempt from this Rule, 420-3-26-.02, to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Schedule C.

2. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons under Rule 420-3-26-.02(4)(a)1 or equivalent regulations of the U.S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, except in accordance with a license issued pursuant to 10 CFR 32.11.

3. A manufacturer, processor, or producer of a product or material is exempt from this Rule, 420-3-26-.02, to the extent that such person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in Schedule C and introduced into the product or material by a licensee holding a specific license issued by the Agency expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

4. Except as provided in Rule 420-3-26-.02(4)(e)2, any person is exempt from this Rule, 420-3-26-.02, to the extent that such person receives, possesses, uses, transfers, owns, or acquires property, structures, equipment, products, or materials containing radium such that the average concentration of the total of all radium isotopes present is less than 5.0 picocuries per gram.

5. Any person may, upon Agency review, be exempted from this Rule, 420-3-26-.02, provided the individual submits, and the Agency accepts, documentation indicating that the total radium content in the products, materials, property, structures, or equipment is not likely to result in an average member of the critical group receiving a total effective dose equivalent (TEDE) that exceeds 25 millirem (0.25 mSv) in any year, from all pathways.

6. The distribution, including custom blending, possession, and use of fertilizers containing naturally occurring radium is exempt from the requirements of this Rule, 420-3-26-.02.

7. Using purposeful dilution to lower radium concentrations to levels below 5 picocuries per gram in an attempt to render it exempt shall not be allowed without prior approval of the Agency.

8. This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

(b) Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from these rules to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:2

1. Timepieces or hands or dials containing radium or not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

(i) 25 millicuries (925 MBq) of tritium per timepiece.

(ii) 5 millicuries (185 MBq) of tritium per hand.

(iii) 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).

(iv) 100 microcuries (3.7 MBq) of promethium 147 per watch or 200 microcuries (7.4 MBq) of promethium 147 per any other timepiece.

(v) 20 microcuries (0.74 MBq) of promethium 147 per watch hand or 40 microcuries (1.48 MBq) of promethium 147 per other timepiece hand.

(vi) 60 microcuries (2.22 MBq) of promethium 147 per watch dial or 120 microcuries (4.44 MBq) of promethium 147 per other timepiece dial (bezels when used shall be considered as part of the dial).

(vii) The levels of radiation from hands and dials containing promethium 147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(I) For wrist watches, 0.1 millirad per hour at 10 centimeters from any surface.

(II) For pocket watches, 0.1 millirad per hour at 1 centimeter from any surface.

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[2] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source material or byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements, may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20545.

(III) For any other timepiece, 0.2 millirad per hour at 10 centimeters from any surface.

(viii) 1.0 microcurie (0.037 MBq) of radium 226 per timepiece in intact timepieces manufactured prior to November 30, 2007. 2.(i) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

2.(i) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device.

(ii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 500 microcuries (18.5 MBq) of polonium-210 per device or of a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

(iii) Such devices authorized before October 23, 2012, for use under the general license then provided in these rules or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Agency.

3. Balances of precision containing not more than 1 millicurie (37 MBq) of tritium per balance or not more than 0.5 millicuries of tritium per balance part manufactured prior to December 17, 2007.

4. Marine compasses containing not more than 750 millicuries (27.75 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas manufactured prior to December 17, 2007.

5. Ionization chamber smoke detectors containing not more than 1 microcurie (0.037 MBq) of americium 241 per detector in the form of a foil and designed to protect life and property from fires.

6. Electron tubes: provided that each tube does not contain more than one of the following specified quantities of radioactive material:

(i) 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries of tritium per any other electronic tube;

(ii) 1 microcurie (0.037 MBq) of cobalt 60;

(iii) 5 microcuries (0.185 MBq) of nickel 63;

(iv) 30 microcuries (1.11 MBq) of krypton 85;

(v) 5 microcuries (0.185 MBq) of cesium 137;

(vi) 30 microcuries (1.11 MBq) of promethium 147;

And provided further, that the level of radiation due to radioactive material contained in each electron tube does not exceed 1 millirad per hour at 1 centimeter from any surface when measured through 7 milligrams per square centimeters of absorber.3

7. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material provided that:

(i) Each source contains no more than one exempt quantity set forth in Schedule B of this rule.

(ii) Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's source(s) may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Schedule B of this rule, provided that the sum of such fractions shall not exceed unity.

(iii) For americium 241, 0.05 microcurie (0.185 Bq) is considered an exempt quantity under Schedule B of this Rule.

8. Any person who desires to apply radioactive material to, or incorporate radioactive material into, the products exempted in this section, or who desires to initially

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[3] For the purpose of this subparagraph, "electron tubes" include spark gap tubes, power tubes, microwave tubes, indicator tubes, pick-up tubes, radiation detection tubes, and any other complete sealed tube that is designed to conduct or control electrical currents. transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to 10 CFR 32.14 of the U.S. Nuclear Regulatory Commission which states that the product may be distributed by the licensee to persons exempt from the regulations 5pursuant to paragraph (b) of this section.

(c) Gas and Aerosol Detectors Containing Radioactive Material. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property, provided that:

1. Detectors containing byproduct material shall have been manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32 which license authorizes the transfer of the detectors to persons who are exempt from regulatory requirements;

2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under paragraph (c) of this section, should apply for a license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.26 of 10 CFR Part 32 and for a certificate of registration in accordance with 10 CFR 32.210 of 10 CFR Part 32; or,

3. Detectors containing other than byproduct, source or special nuclear material shall have been manufactured or initially transferred before November 30, 2007, in accordance with a specific license issued by the Agency, Licensing State, or any Agreement State pursuant to licensing requirements equivalent to those set forth in Section 32.26 of 10 CFR Part 32, which license authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

(d) Self-1uminous Products Containing Radioactive Material.

1. Tritium, Krypton 85, or Promethium 147. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-1uminous products containing tritium, krypton 85, or promethium 147, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton 85, or promethium 147 in self-1uminous products manufactured, processed, produced, or

initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32, which license authorizes the initial transfer of the product to persons who are exempt from regulatory requirements. The exemption in this paragraph does not apply to tritium, krypton 85, or promethium 147 used in products for frivolous purposes or in toys or adornments.

2. Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-1uminous products containing tritium, krypton 85, or promethium 147 for use under paragraph (d) of this section, should apply for a license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.22 of 10 CFR Part 32 and for a certificate of registration in accordance with Section 32.210 of 10 CFR Part 32.

(e) Certain Industrial Devices. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.30 of 10 CFR Part 32, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

1. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (e) of this section, should apply for a license issued by the U.S. Nuclear Regulatory Commission pursuant to Section 32.30 of 10 CFR Part 32 and for a certificate of registration in accordance with 10 CFR 32.210 of 10 CFR Part 32.

(f) Exempt Quantities.

1. Except as provided in subparagraphs 3, 4, and 5 of this paragraph, any person is exempt from these rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Schedule B.

2. Any person who possesses radioactive material received or acquired before September 25, 1971, under the general license formerly provided in Rule 420-3-26-.02 is exempt from the requirements for a license set forth in this Rule, 420-3-26-.02, to the extent that such person possesses, uses, transfers, or owns such radioactive material.

3. This paragraph (f) does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material into products intended for commercial distribution.

4. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this paragraph or equivalent regulations of the U.S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory commission pursuant to Section 32.18 of 10 CFR Part 32 which license states that the radioactive material may be transferred by the licensee to persons exempt under this paragraph (f) or the equivalent regulations of the U.S. Nuclear Regulatory Commission, Licensing State, or any Agreement State.

5. No person may, for the purposes of producing an increased radiation level combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in Schedule B, except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by these rules.

(g) Radioactive Drug: Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use in Humans.

1. Except as provided in paragraph 2. of this section, any person is exempt from the requirements for a license set forth in this rule provided that such person receives, possesses, uses, owns, transfers, or acquires capsules containing 1 microcurie (0.037 MBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for "in vivo" diagnostic use in humans.

2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to 420-3-26-.02(10)(e).

3. Nothing in this section relieves persons from complying with applicable FDA, other federal, and state requirements governing receipt, administration, and use of drugs.

(5) **Types of Licenses.** Licenses for radioactive materials are of two types: general and specific.

(a) The Agency issues a specific license to a named person who has filed an application for a license under the provisions of this Rule, 420-3-26-.02.

(b) A general license is provided by rule, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Agency or the issuance of a licensing document to a particular person. However, registration with the Agency may be required by the particular license.

(6) **General Licenses - Source Material.**

(a) A general license is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

1. No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of November 5, 2016, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for 1 year beyond this date, or until the Agency takes final action on a pending application submitted on or before November 5, 2017, for a specific license for such material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2017, or until the Agency takes final action on a pending application submitted on or before November 5, 2017, for a specific license for such material; and

2. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than 70 kg (154 lb) or uranium or thorium in any one calendar year. A person may not alter the chemical or physical form or the source material possessed under this paragraph until it is accounted for under the limits of subparagraph (a)1.; or

3. No more than 7 kg (15.4 lb) of uranium, removed from the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

4. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

(b) Persons who receive, possess, use, or transfer source material pursuant to the general license issued in paragraph (a) of this section:

1. Are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Agency in a specific license.

2. Shall not abandon such material. Source material may be disposed of as follows:

(i) A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this rule to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued under this rule; or

(ii) In accordance with Rule 420-3-26-.03(33).

3. Are subject to the provisions of Rules 420-3-26-.02(2), (12), (17), (18), (29), and (30).

4. Shall not export such source material except in accordance with 10 CFR Part 110.

(c) Any person who receives, possesses, uses, or transfers source material in accordance with paragraph (a) of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Agency about such contamination and may consult with the Agency as to the appropriateness of sampling and restoration activities to ensure that any contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in Rule 420-3-26-.03(60).

(d) Any person who receives, possesses, uses, or transfers source material in accordance with the general license granted in paragraph (a) of this section is exempt from the provisions of Rules 420-3-26-.01, 420-3-26-.03, and 420-3-26-10 to the extent that such receipt, possession, use, and transfer are within the terms of the general license, except that such person shall comply with the provisions of Rules 420-3-26-.03(33) and 420-3-26-.03(60) to the extent necessary to meet the provisions of paragraph (b)2 and (c) of this section. However, this exemption does not apply to any person who also holds a specific license issued under this rule.

(e) No person may initially transfer or distribute source material to persons generally licensed under paragraph (a)1 or (a)2 of this section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State unless authorized by a specific license issued in accordance with Rule 420-3-26-.02(10)(v) or equivalent provisions of the U.S. Nuclear Regulatory Commission or another Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by paragraph (a) of this section before November 5, 2016, without specific authorization may continue for 1 year beyond this date. Distribution may also be continued until the Agency takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before November 5, 2017.

(f) A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. The general license under this paragraph does not authorize any person to receive, possess, use, or transfer source material.

(g) Depleted Uranium in Industrial Products and Devices.

1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of 420-3-26-.02(6)(d)2, 3, 4, and 5, depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in 420-3-26-.02(6)(d) applies only to industrial products or devices which have been manufactured either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to 420-3-26-.02(10)(1) or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State.

3.(i) Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by 420-3-26-.02(6)(d) shall file Agency Form GLDU "Registration Certificate - Use of Depleted Uranium Under General License," with the Agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The registrant shall furnish on Agency Form GLDU the following information and such other information as may be required by that form:

(I) Name and address of the registrant.

(II) A statement that the registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in 420-3-26-.02(6)(d)1 and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium.

(III) Name and/or title, address, and telephone number of the individual duly authorized to act for and on behalf of the registrant in supervising the procedures identified in 420-3-26-.02(6) (d)3(i)(II).

(ii) The registrant possessing or using depleted uranium under the general license established by 420-3-26-.02(6)(d)1 shall report in writing to the Agency any changes in information furnished by him in Agency Form GLDU "Registration Certificate - Use of Depleted Uranium." The report shall be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by 420-3-26-.02(6)(d)1:

(i) Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium.

(ii) Shall not abandon such depleted uranium.

(iii) Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of 420-3-26-.02(18). In the case where the transferee receives the depleted uranium pursuant to the general license established by 420-3-26-.02(6) (d)1, the transferor shall furnish the transferee a copy of this Rule, 420-3-26-.02, and a copy of Agency Form GLDU. In cases where the transferee receives the depleted uranium pursuant to a general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 420-3-26-.02(6)(d)1, the transferor shall furnish the transferee a copy of the regulation and a copy of Agency Form GLDU accompanied by a note explaining that use of the product or device is regulated by the

U.S. Nuclear Regulatory Commission or Agreement State under requirements substantially the same as those in this Rule 420-3-26-.02.

(iv) Shall, within 30 days of any transfer, report in writing to the Agency the name and address of the person receiving the depleted uranium pursuant to such transfer.

(v) Shall not export such depleted uranium except in accordance with a license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR Part 110.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by 420-3-26-.02(6)(d)1 is exempt from the requirements of Rules 420-3-26-.03 and 420-3-26-.10 with respect to the depleted uranium covered by that general license.

(7) **General Licenses - Certain Detecting, Measuring, Gauging, or Controlling Devices and Certain Devices for Producing Light or an Ionized Atmosphere.**

(a)1. A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and federal, state, or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraphs 1, 2 and 3 of Rule 420-3-26-.02(7)(a), radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(i) The general license in paragraph (a) of Rule 420-3-26-.02(7) applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

(I) A specific license issued under Rule 420-3-26-.02(10)(g); or

(II) An equivalent specific license issued by the U.S. Nuclear Regulatory Commission, another Agreement State or Licensing State.

(ii) The devices must have been received from one of the specific licensees described in Rule 420-3-26-.02(7)(a)1(i) or through a transfer made under paragraph 3(xi) of Rule 420-3-26-.02(7)(a) and which will be possessed and used at a single physical location.

(iii) The general license in paragraph 1 of Rule 420-3-26-.02(7)(a) applies only to radioactive material which will be possessed and used at a single physical location.

(iv) Notwithstanding the requirements listed in 420-3-26-.02(7)(a)1(ii) and (iii), state and local emergency response agencies are exempt from requirements that devices described in 420-3-26-.02(7)(a)1 be possessed and used at a single location.

2. Any person who acquires, receives, possesses, uses, or transfers radioactive material in a device pursuant to the general license in paragraph 1 of Rule 420-3-26-.02(7)(a):

(i) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels.

(ii) Shall assure that the device is tested for leakage of radioactive material and proper operation of the on-off mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label; however:

(I) Devices containing only krypton need not be tested for leakage of radioactive material.

(II) Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta and/or gamma emitting material or 10 microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose.

(iii) Shall assure that the tests required by paragraph 2(ii) of Rule 420-3-26-.02(7)(a) and other testing, installation, servicing, and removal from installation involving the radioactive materials, its shielding or containment, are performed:

(I) In accordance with the instructions provided by the labels; or

(II) By a person holding a specific license issued by the Agency, another Agreement State, or the U.S. Nuclear Regulatory Commission to perform such activities.

(iv) Shall maintain records showing compliance with the requirements of paragraphs 2(ii) and 2(iii) of Rule 420-3-26-.02(7)(a). The records must show the results of the tests. The records also must show the dates of performance of, and the names of persons performing testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

(I) Each record of a test for leakage of radioactive material required by paragraph 2(ii) of Rule 420-3-26-.02(7)(a) must be retained for 3 years after the next required leak test is performed or until the sealed source is transferred or disposed.

(II) Each record of a test of the off-on mechanism and indicator required by paragraph 2(ii) of Rule 420-3-26-.02(7)(a) must be retained for 3 years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed.

(III) Each record that is required by paragraph 2(iii) of Rule 420-3-26-.02(7)(a) must be retained for 3 years from the date of the recorded event or until the device is transferred or disposed.

(v) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 0.005 microcurie (0.185 becquerel) or more of removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or another person holding a specific license to repair such devices that was issued by the Agency, another Agreement State, or the U.S. Nuclear Regulatory Commission. The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Agency. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie (0.185 kBq) or more removable radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished to the Director, Office of Radiation Control, P. O. Box 303017, Montgomery, Alabama 36130-3017 within 30 days. Under these circumstances, the criteria set out in Rule 420-3-26-.03(60), "Radiological Criteria for Unrestricted Use" may be applicable, as determined by the Agency on a case-by-case basis.

(vi) Shall not abandon the device containing radioactive material.

(vii) Shall not export the device containing radioactive material except in accordance with regulations of the U.S. Nuclear Regulatory Commission.

(viii) Shall transfer or dispose of the device containing radioactive material only by export as provided by paragraph 2(vii) of Rule 420-3-26-.02(7)(a), by transfer to another general licensee as authorized in paragraph 2(xi) of Rule 420-3-26-.02(7)(a), or to a person authorized to receive the device by a specific license issued under this Rule 420-3-26-.02, or to a person authorized to receive the device by a specific license issued under Rule 420-3-26-.02 that authorizes waste collection, or equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission, or as otherwise approved under paragraph 2(x) of Rule 420-3-26-.02(7)(a).

(ix) Shall, within 30 days after the transfer of a device to a specific licensee or export, furnish a report to the Director, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017. The report must contain:

(I) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number.

(II) The name, address, and license number of the person receiving the device (license number not applicable if exported).

(III) The date of the transfer.

(x) Shall obtain written Agency approval before transferring the device to any specific licensee not specifically identified in paragraph 2(viii) of Rule 420-3-26-.02(7)(a); however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval if the holder:

(I) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use.

(II) Removes, alters, covers, or clearly and unambiguously augments the existing label [otherwise required by Rule 420-3-26-.02(7)(a)2(i)] so that the device is labeled in compliance with Rule 420-3-26-.03(30); however, the manufacturer model number and serial number must be retained.

(III) Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures).

(IV) Reports the transfer as required in Rule 420-3-26-.02(7)(a)2(ix).

(xi) Shall transfer the device to another general licensee only if:

(I) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this Rule 420-3-26-.02, a copy of Rule 420-3-26-.03, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Director, Office of Radiation Control, P.O. Box 303017-3017, Montgomery, Alabama 36130-3017:

I. The manufacturer's (or initial transferor's) name.

II. The model number and the serial number of the device transferred.

III. The transferee's name, and mailing address for the location of use.

IV. The name, title, and phone number of the responsible individual identified by the licensee in accordance with paragraph 2(xiv) of Rule 420-3-26-.02(7)(a) to have knowledge of and authority to take actions to ensure compliance with the appropriate rules and requirements; or

(II) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(xii) Shall comply with the provisions of Rule 420-3-26-.03(51) and (52) for reporting stolen, lost, or missing sources or devices and reporting radiation incidents but shall be exempt, unless otherwise specified, from the other requirements of Rule 420-3-26-.03 and Rule 420-3-26-.10.

(xiii) Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017 a written justification for the request.

(xiv) Shall appoint an individual responsible for having knowledge of the appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of any responsibility in this regard.

(xv) Shall register, in accordance with paragraphs (7)(a)2(xv)(I) and (II) of Rule 420-3-26-.02(7)(a), devices containing at least 10 millicuries (370MBq) of cesium-137, 0.1 millicurie (3.7MBq) of strontium-90, 1.0 millicurie (37 MBq.) of cobalt-60, 0.1 millicurie of radium-226, or 1.0 millicurie (37MBq) of americium-241 or any other transuranic [i.e., element with atomic number greater than uranium (92)], based on the activity indicated on the label. Each address for a location of use, as described in paragraph (7)(a)2(xv)(II)IV of Rule 420-3-26-.02(7)(a), represents a separate general license and requires a separate registration.

(I) If in possession of a device meeting the criteria of paragraph (a)2(xv) of Rule 420-3-26-.02(7)(a), shall register these devices with the Agency. The registration information must be submitted to the Agency within 30 days of the date of receipt of the device(s) and annually thereafter. In addition, a general licensee holding

devices meeting the criteria of paragraph (a)2(xv) of Rule 420-3-26-.03(7)(a) is subject to the bankruptcy notification requirement in Rule 420-3-26-.02(12)(e).

(II) In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Agency:

I. Name and mailing address of the general licensee.

II. Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).

III. Name, title, and telephone number of the responsible person designated as a representative of the general licensee under paragraph (a)2(xiv) of Rule 420-3-26-.02(7)(a).

IV. Address or location at which the device(s) are used and/or stored.

V. Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

VI. Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

(xvi) Shall report changes to the mailing address for the location of use (including change in the name of licensee) to the Director, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017 within 30 days of the effective date of the change.

(xvii) May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (a)2(ii) of Rule 420-3-26-.02(7)(a) need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the 2-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(xviii) Shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States by or against:

(I) The licensee;

(II) Any entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the license or licensee as property of the estate; or

(III) An affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

3. The general license in paragraph (7)(a) of Rule 420-3-26-.02(7) does not authorize the manufacture or import of devices containing radioactive material.

(b) Certain Items and Self-Luminous Products Containing Radium 226.

1. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer in accordance with the provisions of paragraphs 2, 3 and 4 of this section, radium 226 contained in the following products manufactured prior to September 1, 2010.

(i) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanatory jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

(ii) Intact timepieces containing greater than 1 microcurie (0.037 MBq), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

(iii) Luminous items installed in air, marine, or land vehicles.

(iv) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

(v) Small radium sources containing no more than 1 microcurie (0.037 MBq) of radium 226. For the purposes of this paragraph, "small radium sources" means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the Agency or the U.S. Nuclear Regulatory Commission.

2. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in Rule 420-3-26-.02(7)(b)1 are exempt from the provisions of this rule to the extent that the receipt, use, or transfer of radioactive material is within the terms of the general license; provided,

however, that this exemption shall not be deemed to apply to any such person specifically licensed under this rule.

3. Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in Rule 420-3-26-.02(7)(b)1:

(i) Shall notify the Agency should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Agency within 30 days.

(ii) Shall not abandon products containing radium 226. The product, and any radioactive material from the product, may only be disposed of in accordance with Rule 420-3-26-.03 or by transfer to a person authorized by a specific license to receive the radium 226 in the product or as otherwise approved by the Agency.

(iii) Shall not export products containing radium 226 except in accordance with U.S. Nuclear Regulatory Commission regulations.

(iv) Shall dispose of products containing radium 226 at a disposal facility authorized to dispose of radioactive material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act of 2005, by transfer to a person authorized to receive radium 226 by a specific license issued under Rule 420-3-26-.02, or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State, or as otherwise approved by the Agency.

(v) Shall respond to written requests from the Agency to provide information relating to the general license within 30 calendar days of the written request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Agency a written justification for the request.

4. The general license in Rule 420-3-26-.02(7)(b)1. does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium 226, except that timepieces may be disassembled and repaired.

(c) Luminous Safety Devices for Aircraft.

1. A general license is hereby issued to own, receive, acquire, possess, and use tritium or promethium 147 contained in luminous safety devices for use in aircraft provided:

(i) Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium 147.

(ii) Each device has been manufactured, assembled, or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured or assembled in accordance with the specifications contained in a specific license or equivalent licensing document issued by the Agency or any Agreement State to the manufacturer or assembler of such device pursuant to licensing requirements equivalent to those in Section 32.53 of 10 CFR Part 32 of the regulations of the U.S. Nuclear Regulatory Commission.

2. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general license in subparagraph 1 of this paragraph are exempt from the requirements of Rule 420-3-26-.03 and 420-3-26-.10 except that they shall comply with the provisions of 420-3-26-.02(23) and 420-3-26-.02(24).

3. This general license does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or promethium 147.

4. This general license does not authorize the ownership, receipt, acquisition, possession, or use of promethium 147 contained in instrument dials.

5. The general license provided in this paragraph is subject to the provisions of 420-3-26-.01(6), 420-3-26-.01(7), 420-3-26-.01(8), 420-3-26-.01(10), 420-3-26-.01(11), 420-3-26-.01(12), 420-3-26-.02(12), 420-3-26-.02(18), 420-3-26-.02(21), and Rule 420-3-26-.10.

(d) Calibration and Reference Sources.

1. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of subparagraphs 3. and 4. of this paragraph (d), americium 241 and radium 226 in the form of calibration or reference sources:

(i) Any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

(ii) Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes him to receive, possess, use, and transfer special nuclear material.

2. A general license is hereby issued to receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subparagraphs 3 and 4 of this paragraph (d) to any person who holds a specific license issued by the Agency which authorizes him to receive, possess, use, and transfer radioactive material.

3. The general licenses in subparagraphs 1 and 2 of this paragraph apply only to calibration or reference sources which have been manufactured in accordance with specifications contained in a specific license issued to the manufacturer or importer of the sources by the U.S. Nuclear Regulatory Commission pursuant to Section 32.57 of 10 CFR Part 32 of Section 70.39 of 10 CFR Part 70, or which have been manufactured in accordance with the specifications contained in a specific license or equivalent licensing document issued to the manufacturer by the Agency or any Agreement State pursuant to licensing requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 of the regulations of the U.S. Nuclear Regulatory Commission.

4. The general licenses in subparagraphs 1. and 2. of this paragraph are subject to the provisions of 420-3-26-.01(6), 420-3-26-.01(7), 420-3-26-.01(8), 420-3-26-.01(10), 420-3-26-.01(11), 420-3-26-.02 (12), and 420-3-26-.02(19), Rule 420-3-26-.03 and Rule 420-3-26-.10 of these rules. In addition, persons who own, receive, acquire, possess, use, and transfer one or more calibration or reference sources pursuant to these general licenses:

(i) Shall not possess at any one time, at any one location of storage or use, more than 5 microcuries (0.185 MBq) of americium 241, 5 microcuries (0.185 MBq) of radium 226, and 5 microcuries (0.185 MBq) of plutonium in such sources.

(ii) Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS (AMERICIUM 241), (RADIUM 226). (PLUTONIUM).4 DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
(Name of Manufacturer or Initial Transferor)

_____

[4] Showing only the name of the appropriate material.

(iii) Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to receive the source.

(iv) Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium 241, radium 226, or plutonium which might otherwise escape during storage.

(v) Each person licensed under Section 32.57 of U.S. Nuclear Regulatory Commission Rule 10 CFR Part 32 shall perform a dry wipe test on each source containing more than 0.1 microcurie (3.7 kilobecquerels) of americium 241 or radium 226 before transferring the source to a general licensee as authorized in Rule 420-3-26-.02(7)(d)1 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State. This test shall be performed by wiping the entire radioactive surface of the source using a filter paper with the application of moderate finger pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.005 microcuries (0.185 kilobecquerel) of americium 241 or radium 226. If this test discloses more than 0.005 microcuries (0.185 kilobecquerel) of radioactive material, the source shall be deemed to be leaking americium 241 or radium 226 and shall not be transferred to a general licensee under Rule 420-3-26-.02(7)(d)1 or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State.

(vi) Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

5. These general licenses do not authorize the manu-facturer of calibration or reference sources containing americium 241, radium 226, or plutonium.

(e) Ownership of Radioactive Material. A general license is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this rule, this general license does not authorize the manufacture, production, transfer, receipt, possession, or use of radioactive material.

(f) Ice Detection Devices.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium 90 contained in ice detection devices, provided each device contains no more than 50 (1.85 MBq) microcuries of strontium 90 and each device has been manufactured or imported in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission or each device has been manufactured in accordance with the specifications contained in a specific license; or

2. Persons who own, receive, acquire, possess, use, or transfer strontium 90 contained in ice detection devices pursuant to the general license in subparagraph 1 of this paragraph (f);

(i) Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating the device, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the U.S. Nuclear Regulatory Commission or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of this Rule 420-3-26-.02.

(ii) Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon.

(iii) Are exempt from the requirements of Rules 420-3-26-.03 and 420-3-26-.10 except that such persons shall comply with the provisions of 420-3-26-.03(38), 420-3-26-.03(51), and 420-3-26-.03(52) of these rules.

(iv) Are exempt from the requirements of Rules 420-3-26-.02 and 420-3-26-.01 except that such persons shall comply with the provisions of 420-3-26-.02(12), 420-3-26-.02(18), 420-3-26-.02(19), 420-3-26-.02(21), 420-3-26-.01(6), 420-3-26-.01(7), 420-3-26-.01(8), 420-3-26-.01(10), 420-3-26-.01(11) and 420-3-26-.01(12).

3. This general license does not authorize the manufacture, assembly, disassembly, repair, or import of strontium 90 in ice detection devices.

(g) General License for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.

1. A general license is hereby issued to any physician, veterinarian in the practice of veterinary medicine, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests5, in accordance with the provisions of subparagraphs 2, 3, 4, 5, and 6 of this paragraph, the following radioactive materials in prepackaged units:

(i) Iodine 125, in units not exceeding 10 microcuries (0.37 MBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(ii) Iodine 131, in units not exceeding 10 microcuries (0.37 MBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(iii) Carbon-14, in units not exceeding 10 microcuries (0.37 MBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(iv) Hydrogen 3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

(v) Iron-59 in units not exceeding 20 microcuries (0.74 MBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive materials, or the radiation therefrom, to human beings or animals.

(vi) Cobalt-57, in units not exceeding 10 microcuries (0.37 MBq) each, for use in in vitro clinical or laboratory tests not involving internal or external administration of

_____

[5] The New Drug Provisions of the Federal Food, Drug, and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

radioactive materials, or the radiation therefrom, to human beings or animals.

(vii) Selenium-75, in units not exceeding 10 microcuries (0.37 MBq) each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive materials, or the radiation therefrom, to human beings or animals.

(viii) Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of Iodine-129 and 0.005 (0.185 kBq) microcurie of americium 241 each for use in in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

2. No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by 420-3-26-.02(7)(g)1 until he has filed Agency Form IV-GL "Certificate - In Vitro Testing with Radioactive Material Under General License" with the Agency and received from the Agency a validated copy of Agency Form IV-GL with certification number assigned. The physician, clinical laboratory, or hospital shall furnish on Agency Form IV-GL the following information and such other information as may be required by that form:

(i) Name and address of the physician, clinical laboratory, or hospital.

(ii) The location of use.

(iii) A statement that the physician, clinical laboratory, veterinarian, or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive materials as authorized under the general license in subparagraph 1 of this paragraph and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive materials.

3. A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by subparagraph 1 of this paragraph shall comply with the following:

(i) The general licensee shall not possess at any one time, pursuant to the general license in 420-3-26-.02(7)(g)1 at any one location of storage or use a total amount of iodine 125, iodine 131, iron 59, cobalt 57, and/or selenium 75 in excess of 200 microcuries (7.4 MBq).

(ii) The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

(iii) The general licensee shall use the radioactive material only for the uses authorized by subparagraph 1 of this paragraph.

(iv) The general licensee shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the Agency, the U.S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, nor transfer the radioactive material in any manner other than in an unopened, labeled shipping container as received from the supplier.

4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to subparagraph 1 of this paragraph:

(i) Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific license issued pursuant to 420-3-26-.02(10)(k) or in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State which authorizes the manufacture and distribution of iodine 125, iodine 131, carbon 14, hydrogen 3 (tritium), iron 59, cobalt 57, mock iodine 125, or selenium 75 for distribution to persons generally licensed pursuant to 420-3-26-.02(h) or its equivalent.

(ii) Unless the following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom to human beings or animals: Its receipt, acquisition, possession, use, and transfer are subject to the regulations and general license of the U.S. Nuclear Regulatory Commission or of a state with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of Manufacturer

5. The physician, clinical laboratory, or hospital possessing or using radioactive materials under the general license of subparagraph 1 of this paragraph shall report in writing to the Agency, any changes in the information furnished by him in Form IV-GL "Certificate - In Vitro Testing with Radioactive Material Under General License." The report shall be furnished within 30 days after the effective date of such change.

6. Any person using radioactive material pursuant to the general license of subparagraph 1 of this paragraph is exempt from the requirements of Rule 420-3-26-.03 and 420-3-26-.10 of these rules with respect to radioactive materials covered by that general license, except that such persons using the mock iodine-125 described in paragraph 1(viii) of this section shall comply with the provisions of 420-3-26-.03(38), 420-3-26-.03(51), and 420-3-26-.03(52) of Rule 420-3-26-.03.

Specific License

(8) **Filing of Application for Specific Licenses.**

(a) Applications for specific licenses shall be filed on a form prescribed by the Agency.

(b) The Agency may at any time after the filing of the original application and before the expiration of the license, require further statements in order to enable the Agency to determine whether the application should be granted or denied or whether a license should be modified or revoked.

(c) Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

(d) An application for a license may include a request for a license authorizing one or more activities.

(e) In his application, the applicant may incorporate by reference information contained in previous applications, statements, or

reports filed with the Agency provided such references are clear and specific.

(f) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

(g) An application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

1. Identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission, or with an Agreement State, in the Sealed Source and Device Registry; or

2. The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

3. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

(9) **General Requirements for the Issuance of Specific Licenses.** A license application will be approved if the Agency determines that:

(a) The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property.

(b) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety of property.

(c) The issuance of the license will not be inimical to the health and safety of the public.

(d) The applicant satisfied any applicable special requirements in this Rule 420-3-26-.02.

(10) **Special Requirements for Issuance of Specific Licenses for Radioactive Materials.**

(a) Human Use of Radioactive Materials. In addition to the requirements set forth in 420-3-26-.02(9) above, a specific license for human use of radioactive material in institutions will be issued only if:

1. The applicant has appointed a medical isotope committee, in accordance with 420-3-26-.07(19) to evaluate all proposals for research, diagnostic, and therapeutic use of radioisotopes performed under the license. Membership and functions of the committee are described in 420-3-26-.07(19).

2. The applicant possesses adequate facilities for the clinical care of patients.

3. The physician designated on the application as the individual user has substantial experience in handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients.

4. If the application is for a license to use unspecified quantities or multiple types of radioactive material, the applicant's staff has substantial experience in the use of a variety of radioactive materials for a variety of human uses.

5. An application from a medical facility or educational institution to produce Positron Emission Tomagraphy (PET) radioactive drugs for non-commercial transfer to itself for medical use under Rule 420-3-26-.07 shall include:

(i) A request for authorization for the production of PET radionuclides, or evidence of an existing license issued under Rule 420-3-26-.07 for a PET radionuclide production facility from which it receives PET radionuclides.

(ii) Evidence that the applicant is qualified to produce radioactive drugs for medical use.

(iii) Identification of individual(s) authorized to prepare PET radioactive drugs if the applicant is a pharmacy and documentation that each individual meets the requirements of authorized nuclear pharmacist as specified in Rule 420-3-26-.02(10)(t)5.

(iv) Information identified in Rule 420-3-26-.02(10)(t)1(iii) on the PET radioactive drugs for medical use to be transferred to itself.

(b) Licensing of Individual Physicians for Human Use of Radioactive Materials.

1. An application by an individual physician or groups of physicians for a specific license for human use of radioactive material will be approved if:

(i) The applicant satisfies the general requirements specified in 420-3-26-.02(9) of this Rule, 420-3-26-.02.

(ii) The application is for use in the applicant's practice in an office(s) outside a medical institution.

(iii) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable.

(iv) The applicant has extensive experience in the proposed use, the handling and administration of radioisotopes, and where applicable, the clinical management of radioactive patients. Physicians who wish to be named as authorized users for the medical use of radioactive material must submit documentation that they meet the appropriate training and experience as specified in Rule 420-3-26-.07.

2. The Agency will not approve an application by an individual physician or group of physicians for a specific license to receive, possess, or use radioactive material on the premises of a medical institution unless:

(i) The use of radioactive material is limited to:

(I) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(II) The performance of diagnostic studies on patients to whom a radiopharmaceutical has been administered;

(III) The performance of in vitro diagnostic studies; or

(IV) The calibration and quality control checks of radioactive assay instrumentation, radiation safety instrumentation, and diagnostic instrumentation;

(ii) The physician brings the radioactive material with him and removes the radioactive material when he departs. (The institution cannot receive, possess, or store radioactive material other than the amount of material remaining in the patient).

(iii) The medical institution does not hold a radioactive material license under 420-3-26-.02 (10)(a).

(c) Calibration or Reference Sources Containing Americium-241 or Radium-226: Requirements for License to Manufacture or Initially Transfer. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under Rule 420-3-26-.02(7)(a) will be approved if:

1. The applicant satisfies the general requirements of 420-3-26-.02(9).

2. The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(i) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source.

(ii) Details of construction and design.

(iii) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source.

(iv) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use.

(v) Details of quality control procedures to be followed in manufacture of the source.

(vi) Description of labeling to be affixed to the source or the storage container for the source.

(vii) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the source.

3. Each source will contain no more than 5 microcuries of americium-241 or radium-226.

4. The Agency determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that:

(i) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source.

(ii) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by subparagraph 5. of this section.

5. The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.005 microcurie of americium-241 or radium-226 to tests as follows:

(i) The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

(ii) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion.

(iii) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in subparagraph 5.(iv) of this section.

(iv) Source designs are rejected for which the following has been detected for any unit. Removal of more than 0.005 microcurie of americium-241 or radium-226 from the source or any other evidence of physical damage.

6. Each person licensed under paragraph (c) shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:

The receipt, possession, use, and transfer of this source, Model, Serial No., are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH THE RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or initial transferor

(d) Human Use of Sealed Sources. In addition to the requirements set forth in 420-3-26-.02(9) above, a specific license for human use of sealed sources will be issued only if the applicant, or if the application is made by an institution, the individual user.

1. Has specialized training in the therapeutic use of the sealed source considered (teletherapy unit, beta applicator, etc.) as specified in Rule 420-3-26-.07 or has experience equivalent to such training.

2. Is a physician.

(e) Multiple Quantities or Types of Radioactive Material for Use in Research and Development. In addition to the requirements set forth in 420-3-26-.02(9) above, a specific license for multiple

quantities or types of radioactive material for use in research and development will be issued only if:

1. The applicant's staff has substantial experience in the use of a variety of radioisotopes for a variety of research and development uses.

2. The applicant has established an isotope committee (composed of such persons as a radiological safety officer, a representative of the business office, and one or more persons trained or experienced in the safe use of radioactive materials) which will review and approve, in advance of purchase of radioisotopes, proposals for such use.

3. The applicant has appointed a radiological safety officer who will advise and assist on radiological safety issues.

(f) Serialization of Nationally Tracked Sources. Each licensee who manufactures a nationally tracked source after September 1, 2010, shall assign a unique serial number to each nationally tracked source. Serial numbers must be composed only of alphanumeric characters.

(g) Licensing the Manufacture and Initial Transfer of Devices to Persons Generally Licensed Under Rule 420-3-26-.02(7)(a).

1. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear materials to persons generally licensed under Rule 420-3-26-.02(7)(a) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) The applicant satisfies the general requirements of 420-3-26-.02(9).

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instruction, and potential hazards of the device to provide reasonable assurance that:

(I) The device can be safely operated by persons not having training in radiological protection.

(II) Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in 420-3-26-.03(6).

(III) Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems
Hands and forearms; feet and ankles, localized areas of skin averaged over areas no larger than 1 square centimeter	200 rems
Other organs	50 rems

(iii) Each device bears a durable, legible, clearly visible label or labels approved by the Agency, which contain in a clearly identified and separate statement:

(I) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information).

(II) The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity.

(III) The information called for in the following statement in the same or substantially similar form:

The receipt, possession, use, and transfer of this device, Model _____6 , are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or a State with which the U.S. Nuclear Regulatory Commission has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

_____
(Name of manufacturer or initial transferor)

(iv) Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words, “Caution - Radioactive Material,” the radiation symbol described in Rule 420-3-26-.03(27)(a), and the name of the manufacturer and initial distributor.

(v) Each device meeting the criteria of Rule 420-3-26-.02(7)(a)2(xv) bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the

device if the source housing is not separable, that includes the words, "Caution - Radioactive Material," and if practicable, the radiation symbol described in Rule 420-3-26-.03(27)(a).

(vi) The device has been registered in the Sealed Source and Device Registry.

2. In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test

_____

[6] The model, serial number, and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the devices.

for leakage of radioactive material, the Agency will consider information which includes, but is not limited to:

(i) Primary containment (source capsule).

(ii) Protection of primary containment.

(iii) Method of sealing containment.

(iv) Containment construction materials.

(v) Form of contained radioactive material.

(vi) Maximum temperature withstood during prototype tests.

(vii) Maximum pressure withstood during prototype tests.

(viii) Maximum quantity of contained radioactive material.

(ix) Radiotoxicity of contained radioactive material.

(x) Operating experience with identical devices or similarly designed and constructed devices.

3. In the event the applicant desires that the general license under 420-3-26-.02(7)(a), or under equivalent regulations of the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State, be authorized to install the device, collect the

sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated annual doses associated with such activity or activities, and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general license, is unlikely to cause that individual to receive a dose in excess of 10 percent of the limits specified in 420-3-26-.03(6).

4. Conditions of licenses.

(i) If a device containing radioactive material is to be transferred for use under a general license contained in Rule 420-3-26-.02(7)(a), each person that is licensed under this rule shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(I) A copy of the general license contained in Rule 420-3-26-.02(7)(a); if paragraphs (ii), (iii) and (iv) of Rule 420-3-26-.02(7)(a)3. do not apply to the particular device, those paragraphs may be omitted.

(II) A copy of Rule 420-3-26-.02(7)(a), Rule 420-3-26-.02(30), Rule 420-3-26-.03(51), and Rule 420-3-26-.03(52).

(III) A list of the services that can only be performed by the general licensee.

(IV) Information on acceptable disposal options including estimated costs of disposal.

(V) An indication that the policy of the Agency, other Agreement States, and the U.S. Nuclear Regulatory Commission is to issue civil penalties for improper disposal.

(ii) If radioactive material is to be transferred in a device for use under an equivalent general license of another Agreement State or the U.S. Nuclear Regulatory Commission, each person that is licensed under Rule 420-3-26-.02(10)(f) shall provide the information specified in this paragraph to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

(I) A copy of the appropriate Agreement State or U.S. Nuclear Regulatory Commission rules or regulations equivalent to Agency Rules 420-3-26-.02(7)(a), 420-3-26-.02(30), 420-3-26-.03(51), and 420-3-26-.03(52). If certain paragraphs of the regulations do not apply to a particular device, those paragraphs may be omitted.

(II) A list of the services that can only be performed by a specific licensee.

(III) Information on acceptable disposal options including estimated costs of disposal.

(IV) The name or title, address, and phone number of the contact at the Agreement State regulatory agency or U.S. Nuclear Regulatory Commission office from which additional information can be obtained.

(iii) An alternative approach to informing customers may be proposed by the licensee for approval by the Agency.

(iv) Each device that is transferred after the effective date of this rule must meet the labeling requirements in Rule 420-3-26-.02(10)(g)1.(iii) through (v).

(v) If a notification of bankruptcy has been made under Rule 420-3-26-.02(12)(e) or the license is to be terminated, each person licensed under Rule 420-3-26-.02(10)(g) shall provide, upon request, to the Agency, to the U.S. Nuclear Regulatory Commission, and to any appropriate Agreement State, records of final disposition required under paragraph (10)(g)5(ii) of Rule 420-3-26-.02(10).

5. Material Transfer Reports and Records. Each person licensed under Rule 420-3-26-.02(10)(g) to initially transfer devices to generally licensed persons shall comply with the requirements of this rule.

(i) The person shall report by letter to the Director, Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017 all transfers of such devices to persons for use under the general license in Rule 420-3-26-.02(7)(a) and all receipts of devices from persons licensed under Rule 420-3-26-.02(7)(a).The report must be submitted on a quarterly basis on a form prescribed by the Agency or in a clear and legible report containing all the data required by the form prescribed by the Agency.

(I) The required information for transfers to general licensees includes:

I. The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general

licensee shall be submitted along with information on the actual location of use.

II. The name, title, and phone number of the person identified as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements.

III. The date of transfer.

IV. The type, model number, and serial number of the device transferred.

V. The quantity and type of radioactive material contained in the device.

(II) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(III) For devices received from a Rule 420-3-26-.02(7)(a) licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(IV) If the licensee makes changes to a device possessed by a Rule 420-3-26-.02(7)(a) general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(V) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(VI) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(VII) If no transfers have been made to or from persons generally licensed under Rule 420-3-26-.02(7)(a) during the reporting period, the report must so indicate.

(ii) The person shall report all transfers of devices to persons for use under a general license in an Agreement State or in a state subject to regulations of the U.S. Nuclear Regulatory Commission that are equivalent to Rule 420-3-26-.02(7)(a) to the responsible Agreement State agency or the U.S. Nuclear Regulatory Commission, as appropriate. The report must be submitted on a form prescribed by the Agreement State or on U.S. Nuclear Regulatory

Commission Form 653 - "Transfers of Industrial Devices" or in a clear and legible report containing all of the data required by the form.

(I) The required information for transfers to general licensees includes:

I. The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

II. The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate regulations and requirements;

III. The date of transfer;

IV. The type, model number, and serial number of the device transferred; and

V. The quantity and type of radioactive material contained in the device.

(II) If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

(III) For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

(IV) If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

(V) The report must cover each calendar quarter, must be filed within 30 days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

(VI) The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

(VII) If no transfers have been made to or from a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State or the U.S. Nuclear Regulatory Commission upon request of the agency.

(iii) The person shall maintain all information concerning transfers and receipts of devices that support the reports required by this rule. Records required by this rule must be maintained for a period of 3 years following the date of the recorded event.

(h) Use of Sealed Sources in Industrial Radiography7. In addition to the requirements set forth in 420-3-26-.02(9) above, a specific license for use of sealed sources in industrial radiography will be issued only if:

1. The applicant submits an adequate program for training radiographers and radiographer's assistants that meets the requirements of Rule 420-3-26-.04(16).

2. The applicant submits procedures for verifying and documenting the certification status of radiographers and

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[7] Industrial radiography for the purpose of this paragraph means the examination of the macroscopic structure of materials by nondestructive methods of utilizing sources of radiation.

for ensuring that the certification of individuals acting as radiographers remains valid.

3. The applicant submits written operating and emergency procedures as described in Rule 420-3-26-.04(17).

4. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months as described in Rule 420-3-26-.04(16)(e).

5. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegation and responsibility.

6. The applicant identifies and lists the qualifications of the individual(s) designated as the Radiation Safety Officer 420-3-26-.04(15) and potential designees responsible for ensuring that the licensee's radiation safety program is implemented in accordance with approved procedures.

7. If an applicant intends to perform leak testing of sealed sources or exposure devices containing depleted uranium (DU)

shielding, the applicant must describe procedures for performing and the qualifications of the person(s) authorized to do the leak testing. If the applicant intends to analyze wipe samples, the application must include a description of the procedures to be followed. The description must include the following:

i. Instruments to be used.

ii. Methods of performing the analysis.

iii. Pertinent experience of the person who will analyze the wipe samples.

8. If the applicant intends to perform "in-house" calibrations of survey instruments, the applicant must describe methods to be used and the relevant experience of the person(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in 420-3-26-.04(8).

9. The applicant identifies and describes the location(s) of all field stations and permanent radiographic installations.

10. The applicant identifies the locations where all records required by these rules will be maintained.

(i) Multiple Quantities or Types of Radioactive Material for Use in Processing. In addition to the requirements set forth in 420-3-26-.02(9), a specific license for multiple quantities or types of radioactive material for use in processing for distribution to other authorized persons will be issued only if:8

1. The applicant's staff has substantial experience in the use of a variety of radioisotopes for processing and distribution.

2. The applicant has appointed a radiological safety officer who will advise and assist on radiological safety matters.

(j) Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General License. An application for a specific license to manufacture or distribute radioactive material for use under the general license of 420-3-26-.02(7)(g) will be approved if:

1. The applicant satisfies the general requirements specified in 420-3-26-.02(9).

2. The radioactive material is to be prepared for distribution in prepackaged units of:

(i) Iodine-125 in units not exceeding 10 microcuries (0.37 MBq) each.

(ii) Iodine-131 in units not exceeding 10 microcuries (0.37 MBq) each.

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[8] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material, intended for use by the general public may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C. 20545.

(iii) Carbon-14 in units not exceeding 10 microcuries (0.37 MBq) each.

(iv) Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

(v) Iron-59 in units not exceeding 20 microcuries (0.74 MBq) each.

(vi) Cobalt-57 in units not exceeding 10 microcuries (0.37 MBq) each.

(vii) Selenium-75 in units not exceeding 10 microcuries (0.37 MBq) each.

(viii) Mock Iodine-125 in units not exceeding 0.05 microcuries (1.85 kBq) of Iodine-129 and 0.005 microcuries (0.185 kBq) of americium-241 each.

3. Each prepackaged unit bears a durable, clearly visible label:

(i) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (0.37 MBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75, 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (0.74 MBq) of iron-59, or Mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (0.185kBq) of americium-241 each.

(ii) Displaying the radiation caution symbol described in 420-3-26-.03(27) and the words, "CAUTION, RADIOACTIVE MATERIAL" and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS."

4. The following statement, or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal

or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a General License of the U.S. Nuclear Regulatory Commission or a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

_____
(Name of Manufacturer)

5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in 420-3-26-.03(38) of these rules.

(k) Requirements for License to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Application.

1. An application for a specific license to manufacture industrial products and devices containing depleted uranium for use pursuant to 420-3-26-.02(6)(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

(i) The applicant satisfies the general requirements specified in 420-3-26-.02(9).

(ii) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling and marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use and transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar year a radiation dose in excess of 10 percent of the limits specified in 420-3-26-.03(6).

(iii) The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium or a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

2. In the case of an industrial product or device whose unique benefits are questionable, the Agency will approve an application for a specific license under 420-3-26-.02(10)(k) only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

3. The Agency may deny any application for a specific license under 420-3-26-.02(10)(k) if the end use of the industrial product or device cannot be reasonably foreseen.

4. Each person licensed pursuant to 420-3-26-.02(10)(k) shall:

(i) Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

(ii) Label or mark each unit to:

(I) Identify the manufacturer of the product or device and the number of the license under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device.

(II) State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State.

(iii) Assure that the depleted uranium, before being installed in each product or device, has been impressed with the following legend clearly legible through any plating of other covering: "Depleted Uranium;"

(iv)(I) Furnish a copy of the general license contained in 420-3-26-.02(6)(d) and a copy of Agency Form GLDU to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license contained in 420-3-26-.02(6)(d); or

(II) Furnish a copy of the general license contained in the U.S. Nuclear Regulatory Commission or Agreement State's regulation equivalent to 420-3-26-.02(6)(d) and a copy of the U.S. Nuclear Regulatory Commission or Agreement State's certificate; or alternatively, furnish a copy of the general license contained in 420-3-26-.02(6)(d) and a copy of Agency Form GLDU to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general license of the U.S. Nuclear Regulatory Commission or an Agreement State, with a note explaining that use of the product or device is regulated by the U.S. Nuclear Regulatory Commission or an Agreement State under requirements substantially the same as those in 420-3-26-.02(6)(d).

(v) Report to the Agency all transfers of industrial products or devices to persons for use under the general license in 420-3-26-.02(6)(d). Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of the device transferred, and

the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under 420-3-26-.02(6)(d) during the reporting period, the report shall so indicate.

(vi) (I)Report to the U.S. Nuclear Regulatory Commission all transfers of industrial products or devices to persons for use under the U.S. Nuclear Regulatory Commission general license in Section 40-25 of 10 CFR Part 40.

(II) Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to 420-3-26-.02(10)(k) for use under a general license in that state's regulations equivalent to 420-3-26-.02(6)(d).

(III) Such report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the Agency and the general licensee, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person.

(IV) If no transfers have been made to the U.S. Nuclear Regulatory Commission licensees during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission.

(V) If no transfers have been made to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the responsible Agreement State.

(vii) Keep records showing the name, address, and point of contact for each general licensee to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in 420-3--26-.02(6)(d) or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State. The records shall be main-tained for a period of 3 years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this section.

(l) Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use. An application for a specific license to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons licensed pursuant to 420-3-26-.02(10)(a) or (b) will be approved if:

1. The applicant satisfies the general requirements specified in 420-3-26-.02(9) of this Rule, 420-3-26-.02.

2. The applicant submits evidence that:

(i) The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), a biologic product license issued by FDA; or

(ii) The manufacture and distribution of the radioactive pharmaceutical containing radioactive material is not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage.

4. (i)The label affixed to each package of the radiopharmaceutical-contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is licensed by the Agency for distribution to persons licensed pursuant to 420-3-26-.02(10)(a) or (b) or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State.

(ii) The labels, leaflets or brochures required by 420-3-26-.02(10)(l)4.(i) are in addition to the labeling required by the FDA and they may be separate from or with the approval of FDA, may be combined with the labeling required by FDA.

(m) Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material. An application for a specific license to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons licensed pursuant to 420-3-26-.02(10)(a) or (b) will be approved if:

1. The applicant satisfies the general requirements specified in 420-3-26-.02(9).

2. The applicant submits evidence that:

(i) The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the FDA, or a biologic product license issued by FDA; or

(ii) The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act.

3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kits.

4. The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay.

5. The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

(i) Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit.

(ii) A statement that this generator or reagent kit (as appropriate) is approved for use by persons licensed by the Agency pursuant to 420-3-26-.02(10)(a) or (b) or under equivalent licenses of the U.S. Nuclear Regulatory Commission or an Agreement State. The labels, leaflets, or brochures required by 420-3-26-.02(10)(m) are in addition to the labeling required by FDA and they may be separate from or with the approval of FDA may be combined with the labeling required by FDA.

(n) Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use.

1. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under 420-3-26-.07 for use as a calibration, transmission, or reference sources, or for the uses listed in Rules 420-3-26-.07(60), (70), (72), and (90) will be approved if:

(i) The applicant satisfies the general requirements in Rule 420-3-26-.02(9).

(ii) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

(I) The radioactive material contained, its chemical and physical form, and amount.

(II) Details of design and construction of the source or device.

(III) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity

under stresses likely to be encountered in normal use and accidents.

(IV) For devices containing radioactive material, the radiation profile of a prototype device.

(V) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests.

(VI) Procedures and standards for calibrating sources and devices.

(VII) Legend and methods for labeling sources and devices as to their radioactive content.

(VIII) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label.

(iii) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the Agency has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in Rules 420-3-26-.07(35), (60), (70), and (72) as appropriate, and to persons who hold an equivalent license issued by the Agency, the NRC or an Agreement State.

(iv) The source or device has been registered in the Sealed Source and Device Registry.

2.(i) In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than 6 months the application shall include sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source.

(ii) In determining the acceptable interval for test of leakage of radioactive material, the Agency will consider information that includes, but is not limited to:

(I) Primary containment (source capsule).

(II) Protection of primary containment.

(III) Method of sealing containment.

(IV) Containment construction materials.

(V) Form of contained radioactive material.

(VI) Maximum temperature withstood during prototype tests.

(VII) Maximum pressure withstood during prototype tests.

(VIII) Maximum quantity of contained radioactive material.

(IX) Radiotoxicity of contained radioactive material.

(X) Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

(o) Licensing the Distribution of NARM in Exempt Quantities

1. An application for a specific license to distribute NARM to persons exempted from these rules pursuant to 420-3-26-.02(4)(e) will be approved if:

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[9] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons who are exempted from regulatory requirements may be obtained only from the U.S. Nuclear Regulatory Commission, Washington, D.C.

(i) The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to a human being.

(ii) The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity product, or device intended for commercial distribution.

(iii) The applicant submits copies of prototype labels and brochures and the Agency approves such labels and brochures.

2. The license issued under 420-3-26-.02(10)(o) is subject to the following conditions.

(i) No more than ten exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

(ii) Each exempt quantity shall be separately and individually packaged. No more than ten such packaged exempt quantities' shall be contained in any outer package for transfer to persons exempt pursuant to 420-3-26-.02(4)(e). The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

(iii) The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

(I) Identifies the radionuclide and the quantity of radioactivity.

(II) Bears the words "Radioactive Material."

(iv) In addition to the labeling information required by 420-3-26-.02(10)(o)2(iii), the label affixed to the immediate container, or an accompanying brochure shall:

(I) State that the contents are exempt from Agreement State requirements.

(II) Bear the words, "Radioactive Material-Not for Human Use--Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited--Exempt Quantities Should Not Be Combined."

(III) Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

3. Each person licensed under 420-3-26-.02(10)(o) shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under 420-3-26-.02(4)(e) or the equivalent regulations of an Agreement State, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to 420-3--26-.02(10)(o) during the reporting period, the report shall so indicate.

(p) Commercial Waste Disposal by Land Burial. In the case of an application for a license to receive and possess radioactive material for commercial waste disposal by land burial, source material milling, or for the conduct of any other activity which the Agency determines will significantly affect the quality of the environment, the Agency shall weigh the environmental, economic, technical, and other benefits against environmental costs and consider available alternatives. The Agency shall conclude that

the issuance of the proposed license, with any appropriate conditions to protect environmental values, justified before commencement of construction of the plant or facility in which the activity will be conducted. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant facility. As used in this paragraph the term "commencement of construction" means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the site or the protection of environmental values.

(q) Special Financial Surety Requirements. In the case of an application for a license or an amendment to a license listed in subparagraph 4 below, financial surety arrangements must be made for site reclamation as follows:

1. Pursuant to Act 582, and as otherwise provided, financial surety arrangements for site reclamation which may consist of surety or performance bonds, cash deposits, certificate of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of licensees listed in 420-3-26-.02(10)(q)4 shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the licensee to meet the requirements of the act and these rules.

(i) The amount of funds to be ensured by such surety arrangements shall be based on Agency approved cost estimates.

(ii) Self-insurance, or any arrangement which essentially constitutes self-insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through license requirements.

2. The arrangements required in 420-3-26-.02(10)(q)1 shall be established prior to issuance of the license to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

3. (Deleted 1998)

4. The following specific licensees are required to make financial surety arrangements:

(i) Major processors.

(ii) Waste handling licensees.

(iii) Former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed production and utilization facilities.

5. The following persons are exempt from the requirements of 420-3-26-.02(10)(q)1.

(i) All state, local, or other government agencies unless they are subject to 420-3-26-.02(10)(q)4.

(ii) Persons authorized to possess no more than 1,000 times the quantity specified in Schedule B of 420-3-26-.02 or combination of radioactive material listed therein as given in Schedule B of 420-3-26-.02.

(iii) Persons authorized to possess hydrogen-3 contained as hydrogen gas in a sealed source, or

(iv) Persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-1ife greater than 30 days.

(r) Long Term Care Requirements. Pursuant to Act 82-328 Code of Alabama and as otherwise provided, a long-term care fund shall be established by the following specific licen-sees prior to the issuance of the license or prior to the termination of the license if the applicant chooses at the time of the licensure to provide a surety in lieu of a long-term care fund:10

1. Waste handling licensees.

2. Source material milling licensees.

(s) Licensing Wireline Service Operations and Subsurface Studies. In addition to the requirements set forth in 420-3-26-.02(9) above, a specific license authorizing the use of radioactive material for wireline service operations and/or subsurface tracer studies will be issued only if:

1. The applicant has developed an adequate program for training logging supervisors and logging assistants and such program specifies the:

(i) Initial training.

(ii) On-the-job training.

(iii) Annual safety reviews provided by the licensee.

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[10] Long-term care funding may also be required for former U.S. Atomic Energy Commission or U.S. Nuclear Regulatory Commission licensed facilities.

(iv) Methods the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Agency Rules and the applicant's operating and emergency procedures.

(v) Methods the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the Agency's Rules and the applicant's operating and emergency procedures.

2. The applicant has developed and submitted to the Agency written operating and emergency procedures as described in 420-3-26-.12(16).

3. The applicant has established and submits his program for annual inspections of the job performance of each logging supervisor to ensure that Agency Rules, license requirements, and the applicant's operating and emergency procedures are followed. Records of these inspections must be maintained for 3 years.

4. The applicant submitted a description of his overall organizational structure as it applies to the radiation safety responsibilities in wireline service operations and in subsurface tracer studies, including specific delegations of authority.

5. The applicant has or can contract for personnel with experience in the recovery of equipment lodged in wells.

6. Evidence of a liability insurance policy for $1,000,000.00 to cover any liability as a result of any operations.

7. If the applicant wishes to perform leak testing of sealed sources, he shall identify the manufacturers and model numbers of the leak test kit(s) to be used. If the applicant wishes to analyze his own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures including:

(i) Instruments to be used.

(ii) Methods of performing the analysis.

(iii) Pertinent experience of the person who will analyze the wipe samples.

(t) Manufacture, Preparation, or Transfer for Commercial Distribution of Radioactive Drugs Containing Radioactive Material for Medical Use Under Rule 420-3-26-.02(10)(a) or (b).

1. An application for a specific license to manufacture, prepare or transfer for commercial distribution radiopharmaceuticals containing radioactive material for use by persons licensed

pursuant to 420-3-26-.02(10)(a) or (b) and 420-3-26-.07 will be approved if:

(i) The applicant satisfies the general requirements specified in 420-3-26-.02(9).

(ii) The applicant submits evidence that the applicant is at least one of the following:

(I) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in manufacture, preparation, propagation, compounding or processing of a drug under 21 CFR 207.20(a).

(II) Registered or licensed with the Alabama Board of Pharmacy as a drug manufacturer.

(III) Licensed as a pharmacy by the Alabama Board of Pharmacy.

(IV) Operating as a nuclear pharmacy within a federal medical institution.

(V) A positron Emission Tomography (PET) drug production facility registered with the Agency.

(iii) The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for the safe handling and storage of the radioactive drugs by medical use licensees.

(iv) The applicant commits the following labeling requirements:

(I) A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL," the name of the radioactive drug or its abbreviation, and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-1ife greater than 100 days, the time may be omitted.

(II) A label is affixed to each syringe, vial or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL" and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

2. A licensee described in paragraph 1(ii)(III) or (IV) of this rule:

(i) May prepare radioactive drugs for medical use as defined in 420-3-26-.07(2) provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph 2(ii) and (iii) of this section, or an individual under the supervision of an authorized nuclear pharmacist as described in 420-3-26-.07(22).

(ii) May allow a pharmacist to work as an authorized nuclear pharmacist if:

(I) The individual qualifies as an authorized nuclear pharmacist as defined in 420-3-26-.07(2).

(II) The individual meets the requirements in 420-3-26-.07(28)(b) and 420-3-26-.07(30) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

(III) The individual is authorized as an authorized nuclear pharmacist in accordance with paragraph (iii) of this section.

(iii) May allow a pharmacist to act as an authorized nuclear pharmacist if the individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator- produced radioactive material at a pharmacy, at a government agency, or federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009.

(iv) The actions authorized in paragraphs 2(i) and 2(ii) of this rule are permitted in spite of more restrictive language in license conditions.

3. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement, or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta- or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(i) As specified in 420-3-26-.07(32), perform tests on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary.

(ii) Check each instrument for constancy and proper operation at the beginning of each day of use.

4. Nothing in this section relieves the licensee from applying with applicable FDA other federal and state requirements governing radioactive drugs.

5. To meet the requirements of Rule 420-3-26-.07(28), the licensee shall provide to the Agency:

(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State as specified in 420-3-26.07(28); or

(ii) The Agency, U.S. Nuclear Regulatory Commission or an Agreement State license; or

(iii) A U.S. Nuclear Regulatory Commission master material licensee permit; or

(iv) The permit issued by a U.S. Nuclear Regulatory Commission master material permitee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacists; or

(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a government agency or federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009; and

(vi) A copy of the Alabama State Board of Pharmacy license, no later than 30 days after the date the license allows, under paragraphs 2(ii)(I) and 2(ii)(III) of this rule, the individual to work as an authorized nuclear pharmacist.

6. A pharmacy authorized under Rule 420-3-26-.02(10)(a)5 to produce PET radioactive drugs for non-commercial transfer to itself that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of subparagraph 5.

7. A licensee shall satisfy the labeling requirements in 420-3-26-.02(10)(t)(iv).

(u) Licensing of Irradiators. A specific license for the use of radioactive material in an irradiator will be issued if the applicant satisfies the general requirements of 420-3-26-.02(9) and the following requirements:

1. The applicant must describe the training provided to irradiator operators including:

(i) Classroom training and on-the-job simulator training.

(ii) Safety reviews.

(iii) Means employed by the applicant to test each operator's understanding of Agency rules, licensing requirements, and the operating, safety, and emergency procedures for the irradiator.

(iv) Minimum training and experience of personnel who provide training.

2. The application must include a copy of the written operating and emergency procedures listed in 420-3-26-.14(18) that describes the radiation safety aspects of the procedures.

3. The application must describe the organizational structure for managing the irradiator, specifically the radiation safety responsibilities and authority of the radiation safety officer and those management personnel who have radiation safety responsibility or authority. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

4. The application must include a description of the access control systems required by 420-3-26-.12(7), the radiation monitors described by 420-3-26-.14(10), the method of detecting leaking sources required by 420-3-26-.14(21), including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

5. If the applicant intends to perform leak testing, the applicant shall establish procedures for performing leak testing of dry-source-storage sealed sources and submit a copy of these procedures to the Agency. The procedures must include:

(i) Methods of collecting leak test samples.

(ii) Qualifications of the individual who collects the samples.

(iii) Instruments to be used.

(iv) Methods of analyzing the samples.

6. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading and unloading at its facility, the loading or unloading must be done by persons specifically authorized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State to load or unload irradiator sources.

7. The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by 420-3-26-.14(22).

(v) Initial Transfer of Source Material for Use Under Small Quantities of Source Material General License.

1. An application for a specific license to initially transfer source for use under Rule 420-3-26-.02(6), or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement State, will be approved if:

(i) The applicant satisfies the general requirements of Rule 420-3-26-.02(9).

(ii) The applicant submits sufficient information on, and the Agency approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

2. Each person licensed under paragraph (v)1. shall:

(i) Label the immediate container of each quantity of source material with the type of source material and quantity of material and the words "radioactive material."

(ii) Ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

(iii) Provide the information specified in this paragraph to each person to whom source material is transferred for use under Rule 420-3-26-.02(6) or equivalent provisions in U.S. Nuclear Regulatory Commission or another State regulation. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

(I) A copy of Rules 420-3-26-.02(6) and 420-3-26-.02(18) or equivalent regulations of the U.S. Nuclear Regulatory Commission or another Agreement States.

(II) Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

(iv) Report transfers as follows:

(I) File a report with the Agency. The report shall include the following information:

I. The name, address, and license number of the person who transferred the source material.

II. For each general licensee under Rule 420-3-26-.02(6) or equivalent U.S. Nuclear Regulatory Commission or another Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar year, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name and/or position and

phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

III. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients.

(II) File a report with the U.S. Nuclear Regulatory Commission or each responsible Agreement State that identifies all persons, operating under provisions equivalent to Rule 420-3-26-.02(6), to whom greater than 50 grams (0.111b) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers to U.S. Nuclear Regulatory Commission jurisdiction or the Agreement State being reported to:

I. The name, address, and license number of the person who transferred the source material.

II. The name and address of the general licensee to whom source material was distributed; a responsible agent, by name and/or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred.

III. The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within U.S. Nuclear Regulatory Commission and other Agreement State jurisdictions.

(III) Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under Rule 420-3-26-.02(6) during the current period, a report shall be submitted to the Agency indicating so. If no transfers have been made to general licensees in U.S. Nuclear Regulatory Commission jurisdiction or a particular Agreement State during the reporting period, this information shall be reported to the U.S. Nuclear Regulatory Commission or the responsible Agreement State agency upon their request.

3. Each person licensed under paragraph (v)1. shall maintain all information that supports the reports required by this section concerning each transfer to a general licensee for a period of 1 year after the event is included in a report to the Agency, U.S. Nuclear Regulatory Commission, or another Agreement State.

(w) Licensing of Radium in Property, Products, or Material Containing Radium in Concentrations Sufficient to Cause an Individual to Receive a Total Effective Dose Equivalent (TEDE) in Excess of 25 Millirem (0.25 mSv) in 1 Year.

1. Except as provided by Rule 420-3-26-.02(4)(a)4 and 5, any individual who receives, possesses, uses, transfers, owns, or acquires property, structures, products, or materials containing radium in concentrations exceeding 5 picocuries/gram (0.185 Bq/g), excluding background, shall make application to the Agency for a radioactive material license which authorizes the receipt, possession, transfer, and use of such property, structures, equipment, products, or materials.

(x) Requirements for Licensing the Manufacture, Assembly, Repair or Initial Transfer of Luminous Safety Devices for Use in Aircraft.

1. An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under 420-3-26-.02(7)(c), will be approved if all the following are met:

(i) The applicant satisfies the general requirements specified in 420-3-26-.02(9) of this chapter.

(ii) The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

(I) Chemical and physical form and maximum quantity of tritium or promethium-147 in each device.

(II) Details of construction and design.

(III) Details of the method of binding or containing the tritium or promethium-147.

(IV) Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most severe conditions likely to be encountered in normal use.

(V) Quality assurance procedures to be followed that are sufficient to ensure compliance with the requirements of this section.

(VI) Any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device.

(iii) Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad (5 microgray) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

(iv) The Agency determines that:

(I) The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions that are likely to be encountered in normal use and handling of the device.

(II) The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it.

(III) The device is so designed that it cannot easily be disassembled.

(IV) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (v) of this section.

(v) The applicant shall subject at least five prototypes of the device to tests as follows:

(I) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(II) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (v)(III) of this section.

(III) Device designs are rejected for which the following has been detected for any unit:

I. A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

II. Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

III. Any other evidence of physical damage.

(vi) The device has been registered in the Sealed Source and Device Registry.

2. Each person licensed under 420-3-26-.02(10)(x) shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

3. Each person licensed under this paragraph shall:

(i) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions.

(ii) Subject inspection lots to acceptance sampling procedures, by procedures specified in 420-3-26-.02(10)(x)4 of this section and in the license issued under 420-3-26-.02(10)(x), to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

4. The licensee shall subject each inspection lot to:

(i) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

(ii) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria:

(I) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device.

(II) Levels of radiation in excess of 0.5 millirad (5 microgray) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147.

(III) Any other criteria specified in the license issued under this paragraph.

5. No person licensed under this paragraph shall transfer to persons generally licensed under 420-3-25-.02, or an equivalent general license of the U.S. Nuclear Regulatory Commission or an Agreement State:

(i) Any luminous safety device tested and found defective under any condition of a license issued under 420-3-26-.02(10)(x) unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(ii) Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in 420-3-26-.02(10)(x)3.(ii) of this section, unless:

(I) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under 420-3-26-.02(10)(x).

(II) Each individual sub-lot is sampled, tested, and accepted in accordance with 420-3-26-.02(10)(x)3.(ii) and 5.(ii)(I) and any other criteria that may be required as a condition of the license issued under this paragraph.

6. Each person licensed under 420-3-26-.02(10)(x) shall file an annual report with Agency, by method specified in 420-3-26-.01(12), which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under this paragraph. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending December 31 and must be filed within 30 days thereafter. If no transfers have been made to persons generally licensed under this paragraph during the reporting period, the report must so indicate.

7. Each person licensed under this paragraph shall report annually all transfers of devices to persons in another Agreement State or the U.S. Nuclear Regulatory Commission for use under general license regulations that are equivalent to this rule. Reports shall be sent to the responsible Agreement State agency or the U.S. Nuclear Regulatory Commission. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made into a particular Agreement State or the U.S. Nuclear Regulatory Commission jurisdiction during the reporting period, this information must be reported to the responsible Agreement State agency or the U.S. Nuclear Regulatory Commission upon request.

(y) Ice Detection Devices Containing Strontium-90; Requirements for License to Manufacture or Initially Transfer.

1. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under 420-3-26-.02(7) of this chapter will be approved if all the following are met:

(i) The applicant satisfies the general requirements specified in 420-3-26-.02(9) of this chapter.

(ii) The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

(I) Chemical and physical form and maximum quantity of strontium-90 in the device.

(II) Details of construction and design of the source of radiation and its shielding.

(III) Radiation profile of a prototype device.

(IV) Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use.

(V) Details of quality control procedures to be followed in manufacture of the device.

(VI) Description of labeling to be affixed to the device.

(VII) Instructions for handling and installation of the device.

(VIII) Any additional information, including experimental studies and tests required by the Agency to facilitate a determination of the safety of the device.

(iii) Each device will contain no more than 50 microcuries of strontium-90 in an insoluble form.

(iv) Each device will bear durable, legible labeling that includes the radiation caution symbol prescribed by 420-3-26-.03(27) of this chapter, a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices.

(v) The Agency determines that:

(I) The method of incorporation and binding of the strontium-90 in the device is such that the strontium-90 will not be released from the device under the most severe conditions that are likely to be encountered in normal use and handling of the device.

(II) The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem in a year under ordinary circumstances of use.

(III) The device is so designed that it cannot be easily disassembled.

(IV) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by 420-3-26-.02(10)(y)1(vi).

(V) Quality control procedures have been established to satisfy the requirements of this section.

(vi) The applicant shall subject at least five prototypes of the device to tests as follows:

(I) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

(II) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in 420-3-26-.02(10)(y)1.(vi)(III).

(III) Device designs are rejected for which the following has been detected for any unit:

I. A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

II. Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

III. Any other evidence of physical damage.

(vii) The device has been registered in the Sealed Source and Device Registry.

(viii) Each person licensed under this paragraph shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

(ix) Each person licensed under this paragraph shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

(x) Each person licensed under this paragraph shall:

(I) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions.

(II) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph 420-3-26-.02(10)(y)1(xi) and in the license issued under 420-3-26-.02(10)(y), to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

(xi) Each person licensed under 420-3-26-.02(10)(y) shall subject each inspection lot to:

(I) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

(II) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria: A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under 420-3-26-.02(10)(y).

(xii) No person licensed under this paragraph shall transfer to persons generally licensed under 420-3-26-.02(7)(f) of this chapter, or under an equivalent general license of an Agreement State:

(I) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under this paragraph, unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

(II) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in paragraph 420-3-26-.02(10)(y)1(x)(II) of this section, unless:

I. A procedure for defining sub-1ot size, independence, and additional testing procedures is contained in the license issued under this paragraph.

II. Each individual sub-1ot is sampled, tested, and accepted in accordance with paragraphs 420-3-26-.02(10)(y)1(x)(II) and 420-3-26-.02(10)(y)1(xii)(II)I and any other criteria as may be required as a condition of the license issued under 420-3-26-.02(10)(y).

(z) Registration of product information.

1. Any manufacturer or initial distributor of a sealed source or device containing a sealed source may submit a request to the Agency for evaluation of radiation safety information about its product and for its registration.

2. The request for review must be sent to the Agency at the address specified in 420-3-26-.01(12).

3. The request for review of a sealed source or a device must include sufficient information about the design, manufacture, prototype testing, quality control program, labeling, proposed uses, and leak testing and, for a device, the request must also include sufficient information about installation, service and maintenance, operating and safety instructions, and its potential hazards, to provide reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property.

4. The Agency normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the Agency formulates reasonable standards and criteria with the help of the manufacturer or distributor. The Agency shall use criteria and standards sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property.

5. After completion of the evaluation, the Agency issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.

6. The person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with:

(i) The statements and representations, including quality control program, contained in the request.

(ii) The provisions of the registration certificate.

7. Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases:

(i) Calibration and reference sources containing no more than:

(I) 1 millicurie (37 MBq), for beta and/or gamma emitting radionuclides; or

(II) 0.01 millicurie (0.37 MBq), for alpha emitting radionuclides; or

(ii) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in unshielded form, as specified in their licenses; and

(I) The intended recipients are licensed under this chapter or comparable provisions of the U.S. Nuclear Regulatory Commission or an Agreement State; or

(II) The recipients are authorized for research and development; or

(III) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 20 curies (740 GBq) of tritium or 200 millicuries (7.4 GBq) of any other radionuclide.

8. After the certificate is issued, the Agency may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Agency will complete its evaluation in accordance with criteria specified in this section. The Agency may request such additional information as it considers necessary to conduct its review and the certificate holder shall provide the information as requested.

9. A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Agency shall request inactivation of the registration certificate. Such a request must be sent to the Agency at the address specified in 420-3-26-.01(12), and must normally be made no later than 2 years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial

transfer more than 2 years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this determination and briefly describe the circumstances of the delay.

10. If a distribution license is to be terminated in accordance with 420-3-25-.02(13), the licensee shall request inactivation of its registration certificates associated with that distribution license before the Agency will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number.

11. A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, even if the certificate is inactive.

(11) Issuance of Specific Licenses.

(a) Upon a determination that an application meets the requirements of the Act and the rules of the Agency, the Agency will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

(b) The Agency may refuse to issue a license to any person who has been refused issuance or renewal of a license, by authority of the Agency, another Agreement State, Licensing State, or the Nuclear Regulatory Commission, or whose license has been revoked, suspended, or restricted by such licensing authority, if such suspension, revocation, or restriction has occurred within 1 calendar year. If it is a repeat suspension, revocation, or restriction, then the period for refusal is 2 years.

(12) **Specific Terms and Conditions of Licenses.**

(a) Each license issued pursuant to this Rule, 420-3-26-.02, shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b)1. No license issued or granted pursuant to this rule nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily, directly or indirectly, through transfer of control of any license to any person, unless the Agency shall, after securing full information, find that the transfer is in accordance with the provisions of the act and shall give consent in writing.

2. An application for transfer of license must include:

(i) The identity, technical, and financial qualifications of the proposed transferee.

(ii) Financial assurance for decommissioning information required by 420-3-26-.02(26).

(c) Each person licensed by the Agency pursuant to this Rule, 420-3-26-.02, shall confine his use and possession of the material licensed to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to this rule shall carry with it the right to receive, acquire, own, and possess radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with transportation requirements specified in Rules 420-3-26-.02(21), (22), (23), and (24).

(d) Each licensee shall notify the Agency in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license.

(e)1. Each licensee, including licensees required to register by Rule 420-3-26-.02(7)(a)2(xv), shall notify the Agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against:

(i) The licensee.

(ii) An entity [as that term is defined in 11 U.S.C. 101(14)] controlling the licensee or listing the license or licensee as property of the estate.; or

(iii) An affiliate [as that term is defined in 11 U.S.C. 101 (2)] of the licensee.

2. This notification must indicate:

(i) The bankruptcy court in which the petition for bankruptcy was filed.

(ii) The date of the filing of the petition.

(f) Licensees required to submit emergency plans by 420-3-6-.02(27)(a) shall follow the emergency plan approved by the Agency. The licensee may change the approved plan only if the changes do not decrease the effectiveness of the plan. The licensee shall furnish the change to the Agency and to affected offsite response organizations within 6 months after the change is made. Proposed changes that decrease, or potentially decrease, the effectiveness of the approved emergency plan may not be implemented without prior application to and prior approval by the Agency.

(g) Each portable gauge licensee shall use, at a minimum, two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

(h) The Agency may incorporate, in any license issued pursuant to this rule, at the time of issuance, or thereafter by appropriate rule, license condition, or order, such additional requirements with respect to the receipt, possession, use, and transfer of radioactive material as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property.

2. Require such reports and the keeping of such records and to provide for such inspections as may be necessary or appropriate to effectuate the purpose of the act and the rules thereunder.

(i) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 420-3-26-.07(49). The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentrations listed in 420-3-26-.07(49)(a) at the time of generator elution, in accordance with 420-3-26-.07(125).

(j) Deliberate misconduct

1. This section applies to any:

(i) Licensee.

(ii) Certificate holder.

(iii) Quality assurance program approval holder.

(iv) Applicant for a license, certificate, or quality assurance program approval.

(v) Contractor (including a supplier or consultant) or subcontractor to any person identified in paragraph (j)1 of this section.

(vi) Employees of any person identified in paragraph (j)1 of this section.

2. A person identified in paragraph 1 of this section who knowingly provides to any entity, listed in paragraph 1. of this section, any components, materials, or other goods or services

that relate to a licensee's, certificate holder's, quality assurance program approval holder's, or applicant's activities subject to this part may not:

(i) Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate holder, quality assurance program approval holder, or any applicant to be in violation of any rule, regulation, or order; or any term, condition or limitation of any license, certificate, or approval issued by the Agency; or

(ii) Deliberately submit to the Agency, a licensee, a certificate holder, quality assurance program approval holder, an applicant for a license, certificate or quality assurance program approval, or a licensee's, applicant's, certificate holder's, or quality assurance program approval holder's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Agency.

3. A person who violates paragraph 2(i) or 2(ii) of this section may be subject to enforcement action in accordance with the procedures in 420-3-26-.13.

4. For the purposes of paragraph (ii)(I) of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

(i) Would cause a licensee, certificate holder, quality assurance program approval holder, or applicant for a license, certificate, or quality assurance program approval to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license or certificate issued by the Agency; or

(ii) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate holder, quality assurance program approval holder, applicant, or the contractor or subcontractor of any of them.

(13) **Renewal, Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas.**

(a) Each specific license expires at the end of the day on the expiration date stated in the license, unless the licensee has filed an application for renewal in accordance with 420-3-26-.02(8) not less than 30 days before the expiration date stated in the existing license. If an application for renewal has been filed at least 30 days before the expiration date stated in the existing license, the existing license expires at the end of the day on which the Agency makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the Agency expires at the end of the day on the date of the Agency's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Agency Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Agency notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

1. Limit actions involving radioactive material to those related to decommissioning; and

2. Continue to control entry to restricted areas until they are suitable for release in accordance with Agency requirements.

(d) Within 60 days of the occurrence of any of the following each licensee shall provide notification to the Agency in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Agency requirements, or submit within 12 months of notification a decommissioning plan, if required by 420-3-26-.02(13)(g)1, and begin decommissioning upon approval of that plan if:

1. The license has expired pursuant to 420-3-26-.02(13)(a) or (b) of this section; or

2. The licensee has decided to permanently cease principal activities, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements; or

3. No principal activities under the license have been conducted for a period of 24 months; or

4. No principal activities have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Agency requirements.

(e) Coincident with the notification required by 420-3-26-.02(13)(d), the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to Rule 420-3-26-.02 in conjunction with a license issuance or renewal or as required by this section. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to 420-3-26-.02(13)(g)(4)(v).

1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective.

2. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Commission.

(f) The Agency may grant a request to extend the time periods established in 420-3-26-.02(13)(d) if the Agency determines that this relief is not detrimental to public health and safety and is otherwise in the public interest. The request must be submitted no later than 30 days before notification pursuant to 420-3-26-.02(13)(d). The schedule for decommissioning set forth in 420-3-26-.02(13)(d) may not commence until the Agency has made a determination on the request.

(g)1. A decommissioning plan must be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Agency and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

2. The Agency may approve an alternate schedule for submittal of a decommissioning plan required pursuant to 420-3-26-.02(13)(d) if the Agency determines that the alternative schedule is necessary for the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

3. Procedures such as those listed in 420-3-26-.02(13)(g)(1) with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

4. The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan.

(ii) A description of planned decommissioning activities.

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.

(iv) A description of the planned final radiation survey.

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in 420-3-26-.02(13)(h)2.

5. The proposed decommissioning plan will be approved by the Agency if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(h)1. Except as provided in paragraph 420-3-26-.02(13)(h)2(i), licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

2. Except as provided in paragraph 420-3-26-.02(13)(h)2(i) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 24 months following the initiation of decommissioning.

(i) The Agency may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Agency determines that the alternative is warranted by consideration of the following:

1. Whether it is technically feasible to complete decommissioning within the allotted 24-month period.

2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 24-month period.

3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-1ived radionuclides to decay.

4. Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-1ived radionuclides to decay.

5. Other site-specific factors which the Agency may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(j) As the final step in decommissioning, the licensee shall:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed Agency Form DRM or equivalent information.

2. Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in Rule 420-3-26-.03(60) and (61). The licensee shall, as appropriate:

(i) Report levels of gamma radiation in units of microroentgen (millisieverts) per hour at 1 meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters (removable and fixed) for surfaces, microcuries (megabecquerels) per milliliter for water, and picocuries (becquerels) per gram for solids such as soils or concrete.

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(k) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Agency determines that:

1. Radioactive material has been properly disposed.

2. Reasonable effort has been made to eliminate residual radioactive contamination, if present.

3.(i) A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in 420-3-26-.03; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in 420-3-26-.03.

4. Records required by 420-3-26-.02(30)(d) and (f) have been received.

(14) **Reserved.**

(15) **Amendment of Licenses at Request of Licensee.** Applications for amendment of a license shall be filed in accordance with 420-3-26-.02(8) and shall specify the respects in which the licensee desires his license to be amended and the grounds for such amendment.

(16) **Agency Action on Applications to Renew or Amend.** In considering an application by a licensee to renew or amend his license, the Agency will apply criteria set forth in 420-3-26-.02(9) and 420-3-26-.02(10), as applicable.

(17) **Inalienability of Licenses.**

(a) No license issued or granted under this rule and no right to possess or utilize radioactive material granted by any license issued pursuant to this Rule 420-3-26-.02 shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Agency shall, after securing full information find that the transfer is in accordance with the provisions of the Act, give its consent in writing.

(b) An application for transfer of license must include:

1. The identity, technical, and financial qualifications of the proposed transferee.

2. Financial assurance for decommissioning information required by Rule 420-3-26-.03, as applicable.

(18) **Transfer of Material.**

(a) No licensee shall transfer radioactive material except as authorized pursuant to this section.

(b) Any licensee may transfer radioactive material:

1. To the Agency.

2. To the U.S. Department of Energy.

3. To any person exempt from the regulations in this Rule 420-3-26-.02 to the extent permitted under such exemption.

4. To any person authorized to receive such material under the terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the Agency, the U.S. Nuclear Regulatory Commission, Licensing State, or any Agreement State, or to any person otherwise authorized to receive such material by the Federal Government or any agency thereof, the Agency, or any Agreement State; or

5. As otherwise authorized by the Agency in writing.

(c) Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of 420-3-26-.02(21).

(d) Before transferring radioactive material to a specific license of the Agency, the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State, or to a general licensee who is required to register with the Agency, the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

(e) The following methods for verification required by 420-3-26-.02(18)(d) are acceptable:

1. The transferor may have in his possession and read, a current copy of the transferee's specific license;

2. The transferor may have in his possession a written certificate by the transferee that he is authorized by license to receive the type, form, and quantity of radioactive material to be transferred, specifying the license number, issuing agency, and expiration date;

3. For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license to receive the type, form, and quantity of radioactive material to be transferred, specifying the license number, issuing agency, and expiration date; provided that the oral certification is confirmed in writing within 10 days;

4. The transferor may obtain other sources of information compiled by a reporting service from official records of the Agency, the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registration; or

5. When none of the methods of verification described in 420-3-26-.02(18)(e)1 through 4, are readily available or when a

transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Agency, the U.S. Nuclear Regulatory Commission, Licensing State, or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

(19) **Modification, Revocation, and Termination of Licenses.**

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules, regulations, and orders issued by the Agency.

(b) Any license may be revoked, suspended, or modified in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by application or statement of fact of any report, record, or inspection or other means which would warrant the Agency to refuse to grant a license on an original application, or for violation of, or failure to observe any of, the terms and conditions of the Act, or the license, or of any rule, regulation, or order of the Agency.

(c) Except in cases of willfulness or those in which the public health, interest, or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, the facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) The Agency may terminate a specific license upon request submitted by the licensee to the Agency in writing.

(e) The Agency may suspend, revoke, or amend any license in the event that the person to whom such license was granted has a license revoked, suspended, or restricted by a licensing authority of another Agreement State or the U.S. Nuclear Regulatory Commission.

(f) The Agency may cause the withholding or recall of radioactive material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Agency, or who uses such materials in violation of law or regulation of the Agency, or in a manner other than disclosed in the application therefore or approved by the Agency.

(20) **Reciprocal Recognition of Licenses.**

(a) Subject to these rules, any person who holds a specific license from the U.S. Nuclear Regulatory Commission, Licensing

State, or any Agreement State, and issued by the Agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document with this state for a period not in excess of 30 days in any calendar year provided that:

1. The licensing document does not limit the activity authorized by such document to specified installations or locations.

2. The out-of-state licensee notifies the Agency in writing at least 3 days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the 3-day period would impose an undue hardship on the out-of-state licensee, he may, upon application to the Agency, obtain permission to proceed sooner. The Agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general license provided in this section.

3. The out-of-state licensee complies with the applicable rules of the Agency and with all the terms and conditions of his licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the Agency.

4. The out-of-state licensee supplies such other information as the Agency may request.

5. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in this section except by transfer to a person.

(i) Specifically licensed by the Agency or by the U.S. Nuclear Regulatory Commission, Licensing State, to receive such material; or

(ii) Exempt from the requirements for such material under 420-3-26-.02(4)(a).

(b) Notwithstanding the provisions of paragraph (a) of this section, any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State to authorize the holder to manufacture, transfer, install, or service a device described in Rule 420-3-26-.02(7)(a) within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, or service such a device in this state provided that:

1. Such person shall file a report with the Agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general license to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device.

2. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the U.S. Nuclear Regulatory Commission, Licensing State, or an Agreement State.

3. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement the "Removal of this label is prohibited."

4. The holder of the specific license shall furnish to each general licensee to whom he transfers such device or on whose premises he installs such device a copy of the general license contained in Rule 420-3-26-.02(7)(a).

(c) The Agency may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by another Agency, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazards to public health and safety or property.

(21) **Transportation of Radioactive Material.**

(a) Incorporation by reference.

1. Except as provided in this chapter, the requirements of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) are incorporated by reference.

2. Notwithstanding the requirements incorporated by reference, 10 CFR 71.2, 71.6, 71.11, 71.14(b), 71.19, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.55, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71.85 (a), (b), and (c), 71.91(b), 71.99, 71.100, 71.101(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123 and 71.125 are not incorporated by reference.

(b) Effect of incorporation of 10 CFR Part 71.

1. To reconcile differences between this chapter and the incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), the following words and phrases shall be substituted for the language in 10 CFR Part 71 as follows:

(i) Where the words "NRC," "Commission," "United States Nuclear Regulatory Commission," or "Administrator or the appropriate Regional Office" appear in 10 CFR Part 71, substitute the words "Agency" except when used in 10 CFR 71.5(b), 71.10, 71.17(c)(3) and (e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c), (c)(3)(iii) and (f).

(ii) The terms "certificate of compliance," "compliance holder," or "applicant" apply to the NRC as they are the sole authority for issuing a package Certificate of Compliance.

(iii) Notifications, reports and correspondence referenced in the incorporated parts of 10 CFR Part 71 shall be directed to the Agency.

(c) Communications. Notwithstanding the incorporation by reference of 10 CFR 71.1 (relating to communications and records), all communications concerning the requirements of this chapter should be sent to the Alabama Office of Radiation Control, P.O. Box 303017, Montgomery, Alabama 36130-3017.

(d) In addition to the incorporation by reference of 10 CFR Part 71 (relating to packaging and transportation of radioactive material), if Chapter 420-3-26-.02 (relating to transportation) or the regulations of the United States Department of Transportation in 49 CFR Parts 171—180 and 388—397 do not apply to a shipment of licensed material, the licensee shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

(22) **Exemptions.**

(a) On application of any interested person or on its own initiative, the Agency may grant any exemption from the requirements of the regulations in this part that it determines is authorized by law and will not endanger life or property nor the common defense and security.

(b) Common and contract carriers, freight forwarders, and warehousemen are exempt from these rules to the extent that they transport or store radioactive material in the regular course of their carriage for another or storage incident thereto.

(c) Any licensee who delivers radioactive material to a carrier for transport, where such transport is subject to the regulations of the U.S. Postal Service, is exempt from the provisions of 420-3-26-.02(21).

(23) **Intrastate Transport.**

(a) A general license is hereby issued to any common or contract carrier to receive, possess, transport, and store radioactive material in the regular course of their carriage for another or

storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements of the regulations appropriate to the mode of transport, of the U.S. Department of Transportation and incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) of the U.S. Nuclear Regulatory Commission insofar as such regulations relate to the loading and storage of packages, shipping papers, placarding of the transporting vehicle, and incident reporting.11

(b) A general license is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements of the regulations, appropriate to the mode of transport, of the U.S. Department of Transportation and incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) of the U.S. Nuclear Regulatory Commission insofar as such regulations relate to the loading and storage of packages, shipping papers, placarding of the transporting vehicle, and incident reporting.11

(c) Persons who transport radioactive material pursuant to the general licenses in 420-3-26-.02(23)(a) or (b) are exempt from the requirements of Rule 420-3-26-.03 and Rule 420-3-26-.10 of these rules to the extent that they transport radioactive material.

(24) **Preparation of Radioactive Material for Transport.** A general license is hereby issued to a licensee to deliver radioactive material to a carrier12 for transport provided that:

(a) The licensee complies with the applicable requirements of the regulation, appropriate to the mode of transport, of the U.S. Department of Transportation and incorporated sections of 10 CFR Part 71 (relating to packaging and transportation of radioactive material) of the U.S. Nuclear Regulatory Commission insofar as such regulations relate to the packaging of radioactive material, providing shipping papers and to the monitoring, marking, and labeling of those packages.

(b) The licensee has established procedures for safely opening and closing packages in which radioactive material is transported and to assure that prior to the delivery to a carrier for transport, each package is properly closed for transport.

(c) Prior to delivery of a package to a carrier for transport, the licensee shall assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

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[11] Any notification of incidents referred to in those requirements shall be filed with, or made to, the Agency.

[12] For the purpose of this rule, a licensee who transports his own licensed material as a private carrier is considered to have delivered such material to a carrier for transport.

(25) **Reserved.**

(26) **Financial Assurance and Recordkeeping for Decommissioning.**

Notwithstanding and in addition to the financial requirements specified in this Rule, 420-3-26-.02, the following shall apply with regard to decommissioning fund requirements:

(a) Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-1ife greater than 120 days and in quantities exceeding 105 times the applicable quantities set forth in Appendix F to Rule 420-3-26-.03 shall submit a decommissioning funding plan as described in 420-3-26-.02(26)(f). The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 105 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix F to Rule 420-3-26-.03.

(b) Each holder of, or applicant for any specific license authorizing the possession and use of sealed sources or plated foils of half-1ife greater than 120 days and in quantities exceeding 1012 times the applicable quantities specified in Appendix F of Rule 420-3-26-.03 (or when a combination of isotopes are involved if R, as defined in 420-3-26-.02(26)(a), divided by 1012 is greater than 1) shall submit a decommissioning funding plan as described in 420-3-26-.02 (26)(g).

(c) Each applicant for a specific license authorizing the possession and use of radioactive material of half-1ife greater than 120 days and in quantities specified in 420-3-26-.02(26)(e) shall either:

1. Submit a decommissioning funding plan as described in 420-3-26-.02(26)(f); or

2. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by 420-3-26-.02(26)(e) using one of the methods described in 420-3-26-.02(26)(g). For an applicant, this certification may state that the appropriate assurance will be obtained after the applicant has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirement of paragraph (g) of this section must be submitted to the Agency before receipt of licensed material. If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Agency a

signed original of the financial instrument obtained to satisfy the requirements of paragraph (g) of this section.

(d)1. Each holder of a specific license issued on or after October 1, 1991, which is of a type described in 420-3-26-.02(26)(a) or (b), shall provide financial assurance for decommissioning in accordance with the criteria set forth in this Rule 420-3-26-.02(26).

2. Each holder of a specific license issued before October 1, 1991, and of a type described in 420-3-26-.02(26)(a) shall submit, on or before January 1, 1992, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount equal to $1,125,000 in accordance with the criteria set forth in this Rule 420-3-26-.02(26). If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

3. Each holder of a specific license issued before October 1, 1991, and of the type described in 420-3-26-.02(26)(b) shall submit, on or before January 1, 1992, a certification of financial assurance for decommissioning or a decommissioning funding plan in accordance with the criteria set forth in this Rule, 420-3-26-.02(26).

4. Any licensee who has submitted an application before October 1, 1991, for renewal of license in accordance with 420-3-26-.02(14) shall provide financial assurance for decommissioning in accordance with this Rule 420-3-26-.02(26). This assurance must be submitted when this rule becomes effective October 1, 1991.

5. Waste collectors and waste processors, as defined in Appendix G to Rule 420-3-26-.03 must provide financial assurance in an amount based on a decommissioning funding plan as described in Rule 420-3-26-.02(26). The decommissioning funding plan must include the cost of disposal of the maximum amount (curies) of radioactive material permitted by license, and the cost of the disposal of the maximum quantity, by volume, of radioactive material which could be present at the licensee's facility at any time, in addition to the cost to remediate the licensee's site to meet the criteria of Rule 420-3-26-.03. The decommissioning funding plan must be submitted by December 2, 2006.

(e) Table of required amounts of financial assurance for decommissioning by quantity of material. Licensees required to submit the $1,125,000 amount must do so by December 2, 2006. Licensees required to submit the $113,000 or $225,000 amount must do so by June 2, 2007. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan. For quantities:

1.	$1,125,000

	Greater than 104 but less than or equal to 105 times the applicable quantities of Appendix F of 420-3-26-.03 in unsealed form. (For a combination of isotopes, if R, as defined in 420-3-26-.02(26)(a), divided by 104, is greater than 1 but R divided by 105 is less or equal to 1)	
2.	Greater than 10^3 but less than or equal to 104 times the applicable quantities of Appendix F of 420-3-26-.03 in unsealed form. (For a combination of isotopes, if R, as defined in 420-3-26-.02(26)(a), divided by 103 is greater than 1 but R divided by 104 is less than or equal to 1)	$ 225,000
3.	Greater than 1010 but less than or equal to 1012 times the applicable quantities of Appendix F of 420-3-26-.03 in sealed sources or plated foils. (For a combination of isotopes, if R, as defined in 420-3-26-.02(26)(a) divided by 1010 is greater than 1, but R divided by 1012 is less than or equal to 1)	$ 113,000

(f)1. Each decommissioning funding plan must be submitted for review and approval and must contain:

(i) A detailed cost estimate for decommissioning, in an amount reflecting:

I. The cost of an independent contractor to perform all decommissioning activities.

II. The cost of meeting the criteria for unrestricted use specified in 420-3-26-.03(60), provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of 420-3-26-.03(60), the cost estimate may be based on meeting the 420-3-26-.03(60) criteria.

III. The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination.

IV. An adequate contingency factor.

(ii) Identification of and justification for using the key assumptions contained in the detailed cost estimate.

(iii) A description of the method of assuring funds for decommissioning from paragraph (g) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility.

(iv) A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning.

(v) A signed original of the financial instrument obtained to satisfy the requirements of paragraph (g) of this section (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

2. At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. If the amount of financial assurance will be adjusted downward, this cannot be done until the updated decommissioning funding plan is approved. The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

(i) Spills of radioactive material producing additional residual radioactivity in onsite subsurface material.

(ii) Waste inventory increasing above the amount previously estimated.

(iii) Waste disposal costs increasing above the amount previously estimated.

(iv) Facility modifications.

(v) Changes in authorized possession limits.

(vi) Actual remediation costs that exceed the previous cost estimate.

(vii) Onsite disposal.

(viii) Use of a settling pond.

(g) The financial instrument must include the licensee's name, license number, and docket number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

1. Prepayment. Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities.

2. A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid should the licensee default. A surety method may be in the form of a surety bond, letter of credit, or a line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A to this rule. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this rule for commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on financial tests may be used if the guarantee and tests are as contained in Appendix B of this rule. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and tests are as contained in Appendix C of this rule. For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and tests are as contained in Appendix D to this rule. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this rule or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended or, if written for a specified term, such as 5 years, must be renewed automatically unless 90 days or more prior to the renewal date, the issuer notifies the Agency, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full-face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Agency within 30 days after receipt of notification of cancellation.

(ii) The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and the trust must be acceptable to the Agency. An acceptable trustee includes an appropriate state or federal government agency or an entity which has the authority to act as trustee and whose trust operations are regulated and examined by a federal or state agency.

(iii) The surety method or insurance must remain in effect until the Agency has terminated the license.

3. An external sinking fund in which deposits are made at least annually, coupled with a surety method or insurance, the value of which may decrease by the amount being accumulated in the sinking

fund. An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected. An external sinking fund may be in the form of a trust, escrow account, government fund, certificate of deposit, or deposit of government securities. The surety or insurance provision must be as stated in 420-3-26-.02(26)(g)2.

4. In the case of federal, state, or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the Table in 420-3-26-.02(26)(e), and indicating that funds for decommissioning will be obtained when necessary.

5. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(h) Each person licensed under this Rule, 420-3-26-.02, shall keep records of information important to the safe and effective decommissioning of the facility in an identi-fied location until the site is released for unrestricted use by the Agency. Before licensed activities are transferred or assigned in accordance with 420-3-26-.02(12)(b), licensees shall transfer all records described in this rule to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated. If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their location may be used. Information the Agency considers important to decommissioning consists of:

1. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contami-nants may have spread to inaccessible areas as in the case of possible seepage into porous materials such as concrete. These records must include any known information on identification of involved radionuclides, quantities, forms, and concentrations.

2. As built drawings and modifications of structures and equipment in restricted areas where radioactive materials are being used and/or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. If required drawings are referenced, each relevant document need not be indexed individually. If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

3. Except for areas containing only sealed sources (provided the sources have not leaked or no contamination remains after any leak) or radioactive materials having only half-1ives of less than 65 days, a list contained in a single document and updated every 2 years, of the following:

(i) All areas designated and formerly designated restricted areas as defined in 420-3-26-.01(2)(a)93.

(ii) All areas outside of restricted areas that require decontamination under 420-3-26-.02(26)(h)3(i).

(iii) All areas outside of restricted areas where current and previous wastes have been buried as documented under 420-3-26-.03(48).

(iv) All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 420-3-26-.03(60) or apply for approval for disposal under 420-3-26-.03(34).

4. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method used for assuring funds if either a funding plan or certification is used.

(27) **Emergency Plan for Large Quantities.**

(a) Each application to possess radioactive material in an unsealed or a sealed form, on foils or plated sources, or sealed in glass in excess of the quantities in "Schedule E-Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan," must contain either:

1. An evaluation showing that the maximum dose to a person off site due to a release of radioactive materials would not exceed 1 rem effective dose equivalent or 5 rems to the thyroid; or

2. An emergency plan responding to a release of radioactive material.

(b) One or more of the following factors may be used to support an evaluation submitted under 420-3-26-.02(27)(a)(1):

1. The radioactive material is physically separated so that only a portion could be involved in an accident;

2. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

3. The release fraction in the respirable size range would be lower than the release fraction shown in Schedule E due to the chemical or physical form of the material;

4. The solubility of the material would reduce the dose received;

5. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in Schedule E;

6. Operating restrictions or procedures would prevent a release fraction as large as shown in Schedule E; or

7. Other factors appropriate for the specific facility.

(c) An emergency plan for responding to a release of radioactive material submitted under 420-3-26-.02(27)(a)(2) must include the following information:

1. Facility description. A brief description of the licensee's facility and area near the site.

2. Types of accidents. An identification of each type of radioactive materials accident for which protective actions may be needed.

3. Classification of accidents. A classification system for classifying accidents as alerts or site area emergencies.

4. Detection of accidents. Identification of the means of detecting each type of accident in a timely manner.

5. Mitigation of consequences. A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers on site, and a description of the program for maintaining the equipment.

6. Assessment of releases. A brief description of the methods and equipment to assess releases of radioactive materials.

7. Responsibilities. A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying off site response organizations and the Agency; also responsibilities for developing, maintaining, and updating the plan.

8. Notification and coordination. A commitment to and a brief description of the means to promptly notify off site organizations and request off site assistance for the treatment of contaminated injured on site workers when appropriate. A control point must be established. The notification and coordination must be planned so that availability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination.

The licensee shall also commit to notify the Agency immediately after notification of the appropriate off site response organizations and not later than 1 hour after the licensee declares an emergency.

9. Information to be communicated. A brief description of the types of information on facility status, radioactive releases, and recommended protective actions, if necessary, to be given to off-site response organizations and to the Agency.

10. Training. A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instruction and orientation tours the licensee would offer to fire, police, medical, and other emergency personnel. The training shall familiarize personnel with site specific emergency procedures. Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

11. Restoration of safe conditions. A brief description of the means of restoring the facility to safe condition after an accident.

12. Exercises. Provisions for conducting quarterly communications checks with off-site response organizations and biennial on site exercises to test response to simulated emergencies. Quarterly communications checks with off-site response organizations must include the check and update of all necessary phone numbers. The licensee shall invite off-site response organizations to participate in the biennial exercises. Participation of off-site response organizations in biennial exercises although recommended is not required. Exercises must use accident scenarios postulated as most probable for the specific site and the scenarios shall not be known to most exercise participants. The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

13. Hazardous chemicals. A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Pub. L. 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

(d) The licensee shall allow the off-site response organizations expected to respond in case of an accident 60 days to comment on the licensee's emergency plan before submitting it to the Agency.

The licensee shall provide any comments received within the 60 days to the Agency with the emergency plan.

(28) **Emergency Plan Reporting Requirements.**

(a) Immediate report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.)

(b) Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

1. An unplanned event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area.

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Rule 420-3-26-.03.

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-1ife of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident.

(ii) The equipment is required to be available and operable when it is disabled or fails to function.

(iii) No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

(i) The quantity of material involved is greater than 5 times the lowest annual limit on intake on the material specified in Appendix B of Rule 420-3-26-.03.

(ii) The damage affects the licensed material or its container.

(c) Preparation and submission of reports. Reports made by the licensee in response to the requirements of this section must be made as follows:

1. Licensees shall make reports required by 420-3-26-.02(28)(a) and (b) by telephone to the Agency to the extent that the information is available at the time of notification. The information provided in these reports must include:

(i) The caller's name and call back telephone number.

(ii) A description of the event, including date and time.

(iii) The exact location of the event.

(iv) The isotopes, quantities, and chemical and physical form of the licensed material involved.

(v) Any personnel exposure data available.

2. Written report. Each licensee who makes a report required by 420-3-26-.02(28)(a) and (b) shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all the necessary information and appropriate distribution is made. These reports must be sent to the Director, Office of Radiation Control, Alabama Department of Public Health, P. O. Box 303017, Montgomery, Alabama 36130. The reports must include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned.

(ii) The exact location of the event.

(iii) The isotopes, quantities, and chemical and physical form of the material involved.

(iv) Date and time of the event.

(v) Corrective actions taken or planned and the results of any evaluations or assessments.

(vi) The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

(29) **Reporting Requirements.**

(a) Immediate Report. Each licensee shall notify the Agency as soon as possible but no later than 4 hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposure to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits (events may include fires, explosions, toxic gas releases, etc.).

(b) Twenty-four hour report. Each licensee shall notify the Agency within 24 hours after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that:

(i) Requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area.

(ii) Involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of Rule 420-3-26-.03 for the material.

(iii) Has access to the area restricted for a reason other than to allow isotopes with a half-1ife of less than 24 hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

(i) The equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident.

(ii) The equipment is required to be available and operable when it is disabled or fails to function.

(iii) No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable contamination on the individuals clothing or body.

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment involving radioactive material when:

(i) The quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Rule 420-3-26-.03 for the material.

(ii) The damage affects the integrity of the licensed material or its container.

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

1. Licensees shall make reports required by paragraphs (a) and (b) of this section by telephone to the Agency. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) The caller's name and call back number.

(ii) A description of the event, including date and time.

(iii) The exact location of the event.

(iv) The isotopes, quantities, and chemical and physical form of the licensed material involved.

(v) Any personal radiation exposure data available.

2. Written report. Each licensee who makes a report required by paragraphs (a) and (b) of this section shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These reports must be sent to the Agency at the address specified in Rule 420-3-26-.01(12). The reports must include the following:

(i) A description of the event, including the probable cause and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned.

(ii) The exact location of the event.

(iii) The isotopes, quantities, and chemical and physical form of the licensed material involved.

(iv) Date and time of the event.

(v) Corrective actions taken or planned and the results of any evaluations or assessments.

(vi) The extent of exposures of individuals to radiation or to radioactive materials without identification of individuals by name.

(30) **Records.**

(a) Each person who receives radioactive material pursuant to a license issued pursuant to these rules shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

1. The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for 3 years following transfer or disposal of the material.

2. The licensee who transferred the material shall retain each record of transfer of radioactive material until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

3. The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Agency terminates each license that authorizes disposal of the material.

(b) The licensee shall retain each record that is required by this rule for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Agency terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c) Records which must be maintained pursuant to this rule may be the original or a reproduced copy. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(d) Prior to license termination, each licensee authorized to possess radioactive material with a half-1ife greater than 120 days, in an unsealed form, shall forward the following records to the Agency:

1. Records of disposal of licensed material made under 420-3-26-.03(34) (including burials authorized before January 28, 1981), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37).

2. Records required by 420-3-26-.03(42)(b)4.

(e) If licensed activities are transferred or assigned in accordance with 420-3-26-.02(12)(b), each licensee authorized to possess radioactive material, with a half-1ife greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

1. Records of disposal of licensed material made under 420-3-26-.03(34) (including burials authorized before January 28, 1981), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37).

2. Records required by 420-3-26-.03(42)(b)4.

(f) Prior to license termination, each licensee shall forward the records required by 420-3-26-.02(11)(b) to the Agency.

SCHEDULE A

(OMITTED)

SCHEDULE B EXEMPT QUANTITIES

Radioactive Material Microcuries

Antimony-122 (Sb 122) 100

Antimony-124 (Sb 124) 10

Antimony-125 (Sb 125) 10

Arsenic-73 (As 73) 100

Arsenic-74 (As 74) 10

Arsenic-76 (As 76) 10

Arsenic-77 (As 77) 100

Barium-131 (Ba 131) 10

Barium-133 (Ba 133) 10

Barium-140 (Ba 140) 10

Bismuth-210 (Bi 210) 1

Bromine-82 (Br 82) 10

Cadmium-109 (Cd 109) 10

Cadmium-115m (Cd 115m) 10

Cadmium-115 (Cd 115) 100

Calcium-45 (Ca 45) 10

Calcium-47 (Ca 47) 10

Carbon-14 (C 14) 100

Cerium-141 (Ce 141) 100

Cerium-143 (Ce 143) 100

Cerium-144 (Ce 144) 1

Cesium-129 (Cs 129) 100

Cesium-131 (Cs 131) 1,000

Cesium-134m (Cs 134m) 100

Cesium-134 (Cs 134) 1

Cesium-135 (Cs 135) 10

Cesium-136 (Cs 136) 10

Cesium-137 (Cs 137) 10

Chlorine-36 (Cl 36) 10

Chlorine-38 (Cl 38) 10

Chromium-51 (Cr 51) 1,000

Cobalt-57 (Co 57) 100

Cobalt-58m (Co 58m) 10

Cobalt-60 (Co 60) 1

Copper-64 (Cu 64) 100

Dysprosium-165 (Dy 165) 10

Dysprosium-166 (Dy 166) 100

Erbium-169 (Er 169) 100

Erbium-171 (Er 171) 100

Europium-152 (Eu 152)9.2h 100

Europium-152 (Eu 152)13 yr 1

Europium-154 (Eu 154) 1

Europium-155 (Eu 155) 10

Fluorine-18 (F 18) 1,000

Gadolinium-153 (Gd 153) 10

Gadolinium-159 (Gd 159) 100

Gallium-67 (Ga 67) 100

Gallium-72 (Ga 72) 10

Radioactive Material Microcuries

Germanium-68 (Ge 68) 10

Germanium-71 (Ge 71) 100

Gold-195 (Au 195) 10

Gold-198 (Au 198) 100

Gold-199 (Au 199) 100

Hafnium-181 (Hf 181) 10

Holmium-166 (Ho 166) 100

Hydrogen-3 (H 3) 1,000

Indium-111 (In 111) 100

Indium-113m (In 113m) 100

Indium-114m (In 114m) 10

Indium-115m (In 115m) 100

Indium-115 (In 115) 10

Iodine-123 (I 123) 100

Iodine-125 (I 125) 1

Iodine-126 (I 126) 1

Iodine-129 (I 129) 0.1

Iodine-131 (I 131) 1

Iodine-132 (I 132) 10

Iodine-133 (I 133) 1

Iodine-134 (I 134) 10

Iodine-135 (I 135) 10

Iridium-192 (Ir 192) 10

Iridium-194 (Ir 194) 100

Iron-52 (Fe 52) 10

Iron-55 (Fe 55) 100

Iron-59 (Fe 59) 10

Krypton-85 (Kr 85) 100

Krypton-87 (Kr 87) 10

Lanthanum-140 (La 140) 10

Lutetium-177 (Lu 177) 100

Manganese-52 (Mn 52) 10

Manganese-54 (Mn 54) 10

Manganese-56 (Mn 56) 10

Mercury-197m (Hg 197m) 100

Mercury-197 (Hg 197) 100

Mercury-203 (Hg 203) 10

Molybdenum-99 (Mo 99) 100

Neodymium-147 (Nd 147) 100

Neodymium-149 (Nd 149) 100

Nickel-59 (Ni 59) 100

Nickel-63 (Ni 63) 10

Nickel-65 (Ni 65) 100

Niobium-93m (Nb 93m) 10

Niobium-95 (Nb 95) 10

Niobium-97 (Nb 97) 10

Osmium-185 (Os 185) 10

Osmium-191M (Os 191m) 100

Osmium-191 (Os 191) 100

Radioactive Material Microcuries

Osmium-193 (Os 193) 100

Palladium-103 (Pd 103) 100

Palladium-109 (Pd 109) 100

Phosphorus-32 (P 32) 10

Platinum-191 (Pt 191) 100

Platinum-193m (Pt 193m) 100

Platinum-193 (Pt 193) 100

Platinum-197m (Pt 197m) 100

Platinum-197 (Pt 197) 100

Polonium-210 (Po 210) 0.1

Potassium-42 (K 42) 10

Potassium-43 (K 43) 10

Praseodymium-142 (Pr 142) 100

Praseodymium-143 (Pr 143) 100

Promethium-147 (Pm 147) 10

Promethium-149 (Pm 149) 10

Rhenium-186 (Re 186) 100

Rhenium-188 (Re 188) 100

Rhodium-103m (Rh 103m) 100

Rhodium-105 (Rh 105) 100

Rubidium-81 (Rb 81) 10

Rubidium-86 (Rb 86) 10

Rubidium-87 (Rb 87) 10

Ruthenium-97 (Ru 97) 100

Ruthenium-103 (Ru 103) 10

Ruthenium-105 (Ru 105) 10

Ruthenium-106 (Ru 106) 1

Samarium-151 (Sm 151) 10

Samarium-153 (Sm 153) 100

Scandium-46 (Sc 46) 10

Scandium-47 (Sc 47) 100

Scandium-48 (Sc 48) 10

Selenium-75 (Se 75) 10

Silicon-31 (Si 31) 100

Silver-105 (Ag 105) 10

Silver-110m (Ag 110m) 1

Silver-111 (Ag 111) 100

Sodium-22 (Na 22) 10

Sodium-24 (Na 24) 10

Strontium-85 (Sr 85) 10

Strontium-89 (Sr 89) 1

Strontium-90 (Sr 90) 0.1

Strontium-91 (Sr 91) 10

Strontium-92 (Sr 92) 10

Sulphur-35 (S 35) 100

Tantalum-182 (Ta 182) 10

Technetium-96 (Tc 96) 10

Technetium-97m (Tc 97m) 100

Technetium-99m (Tc 99m) 100

Technetium-99 (Tc 99) 10

Radioactive Material Microcuries

Tellurium-125m (Te 125m) 10

Tellurium-127 (Te 127) 100

Tellurium-129m (Te 129m) 10

Tellurium-129 (Te 129) 100

Tellurium-127m (Te 127m) 10

Tellurium-131m (Te 131m) 10

Tellurium-132 (Te 132) 10

Terbium-160 (Tb 160) 10

Thallium-200 (Tl 200) 100

Thallium-201 (Tl 201) 100

Thallium-202 (Tl 202) 100

Thallium-204 (Tl 204) 10

Thulium-170 (Tm 170) 10

Thulium-171 (Tm 171) 10

Tin-113 (Sn 113) 10

Tin-125 (Sn 125) 10

Tungsten-181 (W 181) 10

Tungsten-185 (W 185) 10

Tungsten-187 (W 187) 100

Vanadium-48 (V 48) 10

Xenon-131m (Xe 131m) 1,000

Xenon-133 (Xe 133) 100

Xenon-135 (Xe 135) 100

Ytterbium-175 (Yb 175) 100

Yttrium-87 (Y 87) 10

Yttrium-88 (Y 88) 10

Yttrium-90 (Y 90) 10

Yttrium-91 (Y 91) 10

Yttrium-92 (Y 92) 100

Yttrium-93 (Y 93) 100

Zinc-65 (Zn 65) 10

Zinc-69m (Zn 69m) 100

Zinc-69 (Zn 69) 1,000

Zirconium-93 (Zr 93) 10

Zirconium-95 (Zr 95) 10

Zirconium-97 (Zr 97) 10

Any radioactive material not listed above other than alpha-emitting radioactive material	0.1

Schedule C

Exempt Concentrations

Element (atomic number)	Isotope	Column I Gas concentration µCi/ml 1/	Column II Liquid and solid concentration µCi/ml 2/
Antimony (51)	Sb-122		$3x10^{-4}$
	Sb-124		$2x10^{-4}$
	Sb-125		$1x10^{-3}$
Argon (18)	Ar-37	$1x10^{-3}$	
	Ar-41	$4x10^{-7}$	
Arsenic (33)	As-73		$5x10^{-3}$
	As-74		$5x10^{-4}$
	As-76		$2x10^{-4}$
	As-77		$8x10^{-4}$
Barium (56)	Ba-131		$2x10^{-3}$
	Ba-140		$3x10^{-4}$
Beryllium (4)	Be-7		$2x10^{-2}$
Bismuth (83)	Bi-206		$4x10^{-4}$
Bromine (35)	Br-82	$4x10^{-7}$	$3x10^{-3}$
Cadmium (48)	Cd-109		$2x10^{-3}$
	Cd-115m		$3x10^{-4}$
	Cd-115		$3x10^{-4}$
Calcium (20)	Ca-45		$9x10^{-5}$
	Ca-47		$5x10^{-4}$
Carbon (6)	C-14	$1x10^{-6}$	$8x10^{-3}$
Cerium (58)	Ce-141		$9x10^{-4}$
	Ce-143		$4x10^{-4}$
	Ce-144		$1x10^{-4}$
Cesium (55)	Cs-131		$2x10^{-2}$
	Cs-134m		$6x10^{-2}$
	Cs-134		$9x10^{-5}$
Chlorine (17)	Cl-38	$9x10^{-7}$	$4x10^{-3}$
Chromium (24)	Cr-51		$2x10^{-2}$
Cobalt (27)	Co-57		$5x10^{-3}$

	Co-58		$1x10^{-3}$
	Co-60		$5x10^{-4}$
Copper (29)	Cu-64		$3x10^{-3}$
Dysprosium (66)	Dy-165		$4x10^{-3}$
	Dy-166		$4x10^{-4}$
Erbium (68)	Er-69		$9x10^{-4}$
	Er-171		$1x10^{-3}$
Europium (63)	Eu-152 (.2h)		$6x10^{-4}$
	Eu-155		$2x10^{-3}$
Fluorine (9)	F-18	$2x10^{-6}$	$8x10^{-3}$
Gadolinium (64)	Gd-153		$2x10^{-3}$
	Gd-159		$8x10^{-4}$
Gallium (31)	Ga-72		$4x10^{-4}$
Germanium (32)	Ge-71		$2x10^{-2}$
Gold (79)	Au-196		$2x10^{-3}$
	Au-198		$5x10^{-4}$
	Au-199		$2x10^{-3}$
Hafnium (72)	Hf-181		$7x10^{-4}$
Hydrogen (1)	H-3	$5x10^{-6}$	$3x10^{-2}$
Indium (49)	In-113m		$1x10^{-2}$
	In-114m		$2x10^{-4}$
Iodine (53)	I-126	$3x10^{-9}$	$2x10^{-5}$
	I-131	$3x10^{-9}$	$2x10^{-5}$
	I-132	$8x10^{-8}$	$6x10^{-4}$
	I-133	$1x10^{-8}$	$7x10^{-5}$
	I-134	$2x10^{-7}$	$1x10^{-3}$
Iridium (77)	Ir-190		$2x10^{-3}$
	Ir-192		$4x10^{-4}$
	Ir-194		$3x10^{-4}$
Iron (26)	Fe-55		$8x10^{-3}$
	Fe-59		$6x10^{-4}$
Krypton (36)	Kr-85m	$1x10^{-6}$	
	Kr-85	$3x10^{-6}$	
Lanthanum (57)	La-140		

			$2x10^{-4}$
Lead (82)	Pb-203		$4x10^{-3}$
Lutetium (71)	Lu-177		$1x10^{-3}$
Manganese (25)	Mn-52		$3x10^{-4}$
	Mn-54		$1x10^{-3}$
	Mn-56		$1x10^{-3}$
Mercury (80)	Hg-197m		$2x10^{-3}$
	Hg-197		$3x10^{-3}$
	Hg-203		$2x10^{-4}$
Molybdenum (42)	Mo-99		$2x10^{-3}$
Neodymium (60)	Nd-147		$6x10^{-4}$
	Nd-149		$3x10^{-3}$
Nickel (28)	Ni-65		$1x10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1x10^{-3}$
	Nb-97		$9x10^{-3}$
Osmium (76)	Os-185		$7x10^{-4}$
	Os-191m		$3x10^{-2}$
	Os-191		$2x10^{-3}$
	Os-193		$6x10^{-4}$
Palladium (46)	Pd-103		$3x10^{-3}$
	Pd-109		$9x10^{-4}$
Phosphorus (15)	P-32		$2x10^{-4}$
Platinum (78)	Pt-191		$1x10^{-3}$
	Pt-193m		$1x10^{-2}$
	Pt-197m		$1x10^{-2}$
	Pt-197		$1x10^{-3}$
Potassium (19)	K-42		$3x10^{-3}$
Praseodymium (59)	Pr-142		$3x10^{-4}$
	Pr-143		$5x10^{-4}$
Promethium (61)	Pm-147		$2x10^{-3}$
	Pm-149		$4x10^{-4}$
Rhenium (75)	Re-183		$6x10^{-3}$
	Re-186		$9x10^{-4}$

	Re-188		$6x10^{-4}$
Rhodium (45)	Rh-103m		$1x10^{-1}$
	Rh-105		$1x10^{-3}$
Rubidium (37)	Rb-86		$7x10^{-4}$
Ruthenium (44)	Ru-97		$4x10^{-3}$
	Ru-103		$8x10^{-4}$
	Ru-105		$1x10^{-3}$
	Ru-106		$1x10^{-4}$
Samarium (62)	Sm-153		$8x10^{-4}$
Scandium (21)	Sc-46		$4x10^{-4}$
	Sc-47		$9x10^{-4}$
	Sc-48		$3x10^{-4}$
Selenium (34)	Se-75		$3x10^{-3}$
Silicon (14)	Si-31		$9x10^{-3}$
Silver (47)	Ag-105		$1x10^{-3}$
	Ag-110m		$3x10^{-4}$
	Ag-111		$4x10^{-4}$
Sodium (11)	Na-24		$2x10^{-3}$
Strontium (38)	Sr-85		$1x10^{-3}$
	Sr-89		$1x10^{-4}$
	Sr-91		$7x10^{-4}$
	Sr-92		$7x10^{-4}$
Sulfur (16)	S-35	$9x10^{-8}$	$6x10^{-4}$
Tantalum (73)	Ta-182		$4x10^{-4}$
Technetium (43)	Tc-96m		$1x10^{-1}$
	Tc-96		$1x10^{-3}$
Tellurium (52)	Te-125m		$2x10^{-3}$
	Te-127m		$6x10^{-4}$
	Te-127		$3x10^{-3}$
	Te-129m		$3x10^{-4}$
	Te-131m		$6x10^{-4}$
	Te-132		$3x10^{-4}$
Terbium (65)	Tb-160		$4x10^{-4}$
Thallium (81)	Tl-200		$4x10^{-3}$

	Tl-201		$3x10^{-3}$
	Tl-202		$1x10^{-3}$
	Tl-204		$1x10^{-3}$
Thulium (69)	Tm-170		$5x10^{-4}$
	Tm-171		$5x10^{-3}$
Tin (50)	Sn-113		$9x10^{-4}$
	Sn-125		$2x10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4x10^{-3}$
	W-187		$7x10^{-4}$
Vanadium (23)	V-48		$3x10^{-4}$
Xenon (54)	Xe-131m	$4x10^{-6}$	
	Xe-133	$3x10^{-6}$	
	Xe-135	$1x10^{-6}$	
Ytterbium (70)	Yb-175		$1x10^{-3}$
Yttrium (39)	Y-90		$2x10^{-4}$
	Y-91m		$3x10^{-2}$
	Y-91		$3x10^{-4}$
	Y-92		$6x10^{-4}$
	Y-93		$3x10^{-4}$
Zinc (30)	Zn-65		$1x10^{-3}$
	Zn-69m		$7x10^{-4}$
	Zn-69		$2x10^{-2}$
Zirconium (40)	Zr-95		$6x10^{-4}$
	Zr-97		$2x10^{-4}$
Beta- and/or gamma emitting radioactive material not listed above with half-life of less than 3 years		$1x10^{-10}$	$1x10^{-6}$

NOTE 1: Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule C, the activity stated is that of the parent isotope and takes into account the daughters.

1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/g for solids

NOTE 2: For purposes of 420-3-26-.02(4) where there is involved a combination of isotopes, the limit for the combination should be derived as follows: Determine for each isotope in the product the ratio between the concentrations present in the product and the exempt concentration established in Schedule C for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

EXAMPLE:

$$\frac{Concentration\ of\ Isotope\ A\ in\ Product}{Exempt\ concentration\ of\ Isotope\ A} + \frac{Concentration\ of\ Isotope\ B\ in\ Product}{Exempt\ concentration\ of\ Isotope\ B} = 1$$

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1/ Values are given in Column I only for those materials normally used as gases.
2/ µCi/g for solids.

SCHEDULE D

(Deleted 1998)

SCHEDULE E

QUANTITIES OF RADIOACTIVE MATERIAL REQUIRING

CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN

Radioactive Material	Release Fraction	Quantity (Curies)
Actinium-228	0.001	4,000
Americium-241	.01	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14	.01	50,000
Non CO		
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000

Cobalt-60 .001 5,000

Copper-64 .01 20,000

Curium-242 .001 60

Curium-243 .001 3

Curium-244 .001 4

Curium-245 .001 2

Europium-152 .01 500

Europium-154 .01 400

Europium-155 .01 3,000

Germanium-68 .01 2,000

Gadolinium-153 .01 5,000

Gold-198 .01 30,000

Hafnium-172 .01 400

Holmium-166m .01 7,000

Hydrogen-3 .5 100

Iodine-125 .5 20,000

Iodine-131 .5 10

Indium-114m .01 1,000

Iridium-192 .001 40,000

Radioactive Material Release Fraction Quantity (Curies)

Iron-55 .01 40,000

Krypton-85 1.01 6,000,000

Lead-210 .01 8

Manganese-56 .01 60,000

Mercury-203 .01 10,000

Molybdenum-99 .01 30,000

Neptunium-237 .001 2

Nickel-63 .01 20,000

Niobium-94 .01 300

Phosphorus-32 .5 100

Phosphorus-33 .5 1,000

Polonium-32 .01 10

Potassium-42 .01 9,000

Promethium-145 .01 4,000

Promethium-147 .01 4,000

Radium-226 .001 100

Ruthenium-106 .01 200

Samarium-151 .01 4,000

Scandium-46 .01 3,000

Selenium-75 .01 10,000

Silver-110m .01 1,000

Sodium-22 .01 9,000

Sodium-24 .01 10,000

Strontium-89 .01 3,000

Strontium-90 .01 90

Sulfur-35 .5 900

Technetium-99 .01 10,000

Technetium-99m .01 400,000

Tellurium-127m .01 5,000

Tellurium-129m .01 5,000

Terbium-160 .01 4,000

Thulium-170 .01 4,000

Tin-113 .01 10,000

Tin-123 .01 3,000

Tin-126 .01 1,000

Titanium-44 .01 100

Vanadium-48 .01 7,000

Xenon-133 1.0 900,000

Yttrium-91 .01 2,000

Zinc-65 .01 5,000

Zirconium-63 .01 400

Zirconium-95 .01 5,000

Any other beta/gamma emitter .01 10,000

Mixed fission products .01 1,000

Decontaminated equipment,

beta/gamma .001 10,000

Radioactive Material Release Fraction Quantity (Curies)

Irradiated material, any form other than solid combustible .01 1,000

Mixed radioactive waste,

beta/gamma .01 1,000

Packaged mixed waste,

beta/gamma[2] .001 10,000

Any other alpha emitter .001 2

Contaminated equipment,

alpha .0001 20

Packaged waste, alpha[2] .0001 20

Combinations of radioactive

materials listed above[1]

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1. For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule C exceeds one.

2. Waste packaged in Type B containers does not require an emergency plan.

APPENDIX A

Criteria Relating to Use of Financial Tests and Parent Company Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction:

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial tests of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test and establishes the terms for obtaining the parent company guarantee.

II. Financial Test:

A. To pass the financial test, the parent company must meet the criteria of either A.1 or A. 2 of this appendix:

1. The parent company must have:

(i) Two of the following three ratios: A ratio of total liabilities to net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5.

(ii) Net working capital and tangible net worth each at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

(iii) Tangible net worth of at least $10 million.

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

2. The parent company must have:

(i) A current rating for its most recent bond issuance of AAA, AA, A, or BBB as issued by Standard and Poor’s or Aaa, Aa, A, or Baa as issued by Moody’s.

(ii) Tangible net worth at least 6 times the total current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if a certification is used).

(iii) Tangible net worth of at least $10 million.

(iv) Assets located in the United States amounting to at least 90 percent of the total assets or at least six times the current decommissioning cost estimates for all facilities or parts thereof (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must have compared the data used by the parent company in the financial test which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1.After the initial financial test, the parent company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

2. If the parent company no longer meets the requirements of Section A of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in Agency Rules within 120 days of such notice.

III. Parent Company Guarantee:

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Agency, as evidenced by the return receipt.

B. If the licensee fails to provide alternative financial assurance as specified in Agency Rules within 90 days following receipt by the licensee and Agency of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide such alternative financial assurance in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put into effect by the licensee.

D. If a trust is established for decommissioning costs, the trustee and trust must be acceptable to the Agency. An acceptable

trustee includes an appropriate state or federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a federal or state agency.

E. The licensee will promptly forward to the Agency and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

F. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor's and Moody's, the licensee no longer meets the requirements of Section II.A of this appendix.

G. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.
Health

APPENDIX B

Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. A.To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

(2) Assets located in the United States amounting to at least 90 percent of total assets or at least ten times the total current decommissioning cost estimate for the total of all facilities or parts thereof (or the current amount required if certification is used).

(3) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poor’s (S & P), or Aaa, Aa, or A as issued by Moody’s.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company’s independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within
90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this appendix, the licensee must send immediate notice to the Agency of its intent to establish alternate financial assurance as specified in Agency rules within 120 days of such notice.

III. Company Self-Guarantee. The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Agency. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Agency, as evidenced by the return receipt.

B. The licensee shall provide alternative financial assurance as specified in Agency rules within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The licensee will promptly forward to the Agency and the licensee’s independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of Section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee’s most recent bond issuance ceases to be rated in any category of “A” or above by either Standard and Poor’s or Moody’s, the licensee will provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service. If the licensee’s most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor’s and Moody’s, the licensee no longer meets the requirements of Section II.A. of this appendix.

F. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

APPENDIX C

Criteria Relating to Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance of Funds for Decommissioning by Commercial Companies That Have No Outstanding Rated Bonds

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based of furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial tests of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms of a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet the following criteria:

(1) Tangible net worth greater than $10 million, or at least ten times the current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(2) Assets located in the United States amounting to at least ten times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

(3) A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following requirements:

(1) The company’s independent certified public accountant must have compared the data used by the company in the financial test, which is required to be derived from the independently audited year-end financial statement based on United States generally accepted accounting practices for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform the Agency within 90 days of any matters that may cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(2) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(3) If the licensee no longer meets the requirements of paragraph II.A. of this appendix, the licensee must send notice to the Agency of intent to establish alternative financial assurance as specified in Agency rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur until an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the rules within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

APPENDIX D

Criteria Relating to Use of Financial Tests and Self-Guarantee for Providing Reasonable Assurance for Decommissioning by Nonprofit Colleges, Universities, and Hospitals

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this appendix. The terms of the self-guarantee are in Section III of this appendix. This appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. For colleges and universities, to pass the financial test a college or university must meet either the criteria in paragraph II.A.(1) or the criteria in paragraph II.A.(2) of this appendix.

(1) For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor’s (S&P) or Aaa, Aa, or A as issued by Moody’s.

(2) For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located within the United States of at least $50 million, or at least 30 times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater for all decommissioning activities for which the college or university is responsible as a self-guaranteeing licensee.

B. For hospitals, to pass the financial test a hospital must meet either the criteria in paragraph II.B.(1) or the criteria in paragraph II.B.(2) of this appendix:

(1) For applicants or licensees that issue bonds, a current rating for its most current uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A as issued by Standard and Poor’s (S&P) or Aaa, Aa, or A as issued by Moody’s.

(2) For applicants or licensees that do not issue bonds, all of the following tests must be met:

(Total revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

(b) Long term debt divided by net fixed assets must be less than or equal to 0.67.

(c) (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

(d) Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as a self-guaranteeing license.

C. In addition, to pass the financial test, a licensee must meet all of the following requirements:

1. The licensee's independent certified public accountant must have compared the data used by the licensee in the financial test, which is required to be derived from the independently audited year-end financial statements, based on United States generally accepted accounting practices, for the latest fiscal year, with the amounts in such financial statement. In connection with procedure, the licensee shall inform the Agency within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

2. After the initial financial test, the licensee must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section I of this appendix, the licensee must send notice to the Agency of its intent to establish alternative financial assurance as specified in Agency rules. The notice must be sent by certified mail, return receipt requested, within 90 days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial data requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee shall remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Agency. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in Agency rules within 90 days following receipt by the Agency of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Agency has terminated the license or until another financial assurance method acceptable to the Agency has been put in effect by the licensee.

D. The applicant or licensee must provide to the Agency a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Agency, the licensee will set up and fund a trust in the amount of the current cost estimates for decommissioning.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall provide notice in writing of such fact to the Agency within 20 days after publication of the change by the rating service.
Author: Karl David Walter, David A. Tuberville
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, 22-14-14, 22-2-1, 22-2-2, 22-2-5, and 22-2-6; Act 82-328 Section 5.b.l.
History: **New Rule:** June 15, 1966. Revised June 17, 1968, March 18, 1970, March 17, 1970, September 19, 1973. Repromulgated August 21, 1974. Revised May 21, 1975, September 15, 1976, January 18, 1978. **Recodified** June 11, 1978; Revised November 21, 1979. Repromulgated and Revised October 21, 1981. Revised and Repromulgated effective December 31, 1983. Revised and Repromulgated effective January 31, 1990. Revised Effective October 1, 1991. Revised and Repromulgated Filed: April 22, 1994; effective May 26, 1994. **Amended:** Filed March 20, 1998; effective April 24, 1998. **Amended:** Filed April 20, 2000; effective May 25, 2000. **Amended (Text and Appendices):** Filed May 19, 2006; effective June 23, 2006. **Amended (Text and Appendices):** Filed July 27, 2010; effective August 31, 2010. **Repealed and New Rule (Text, Schedules and Appendices):** Filed October 20, 2014; effective November 24, 2014; operative December 1, 2014. **Amended:** Filed September 21, 2016; effective November 5, 2016. **Amended:** Filed December 13, 2018; effective January 27, 2019. **Amended:** Published September 30, 2021; effective November 14, 2021.

420-3-26-.03 **Standards For Protection Against Radiation.**

GENERAL PROVISIONS

(1) Purpose.

(a) This Rule, 420-3-26-.03, establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Agency. These rules are issued pursuant to Act No. 582, Regular Session, 1963, as amended.

(b) The requirements of this Rule are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any licensee or registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this Rule. However, nothing in this Rule shall be construed as limiting actions that may be necessary to protect health and safety.

(2) Scope. Except as specifically provided in other parts of these rules, this Rule applies to persons licensed or registered by the Agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this Rule do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, to exposure from individuals administered radioactive material and released in accordance with 420-3-26-.07(29), or to voluntary participation in medical research programs.

(3) Definitions. As used in this Rule:

(a) "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

(b) "Activity" is the rate of disintegration (transformation) or decay of radioactive material. The units of activity are the curie (Ci) and the becquerel (Bq).

(c) "Adult" means an individual 18 or more years of age.

(d) "Airborne radioactive material" means radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

(e) "Airborne radioactivity area" means a room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:

1. In excess of the derived air concentrations (DACS) specified in Appendix B, Table I of this Rule.

2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours the individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

(f) “Air-purifying respirator” means a respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

(g) "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interests.

(h) "Annual limit on intake" (ALI) means the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (5 rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix B.

(i) “Assigned protection factor (APF)” means the expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

(j) “Atmosphere-supplying respirator” means a respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere , and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

(k) "Background radiation" means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, including global fallout as it exists in the environment, from the testing of nuclear explosive devices, or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. "Background radiation" does not include sources of radiation from radioactive materials regulated by the Agency.

(l) "Bioassay" means the determination of kinds, quantities or concentrations, and, in some cases, the location of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or

removed from the human body. For purposes of these rules, "radiobioassay" is an equivalent term.

(m) "Class" means a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, Days, of less than 10 days, for Class W, Weeks, from 10 to 100 days, and for Class Y, Years, of greater than 100 days. For purposes of these rules, "lung class" and "inhalation class" are equivalent terms.

(n) "Collective dose" is the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

(o) "Committed dose equivalent" ($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(p) "Committed effective dose equivalent" ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs that are irradiated and the committed Σdose equivalent to these organs or tissues ($H_{E,50} = w_T H_{T,50}$).

(q) "Constraint (dose commitment)" means a value above which specified licensee actions are required.

(r) "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

(s) "Critical group" means the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

(t) "Declared pregnant woman" means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

(u) "Decommission" means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits (1) release of the property for unrestricted use and termination of the license or (2) release of the property under restricted conditions and termination of the license.

(v) "Deep-dose equivalent" (H), which applies to dexternal whole-body exposure, is the dose equivalent at a tissue depth of 1 cm. (1000 mg/cm2).

(w) “Demand respirator” means an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

(x) "Derived air concentration" (DAC) means the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of these rules, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table I, Column 3, of Appendix B.

(y) "Derived air concentration-hour" (DAC-hour) means the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (5 rem).

(z) “Disposable respirator” means a respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-1ife renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

(aa) “Distinguishable from background” means that the detectable concentration of a radionuclide is statistically different from background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

(bb) "Dosimetry processor" means an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

(cc) "Effective dose equivalent" (HE) is the sum of the products of the dose equivalent to the organ or tissue (HT) and the weighting factors (wT) applicable to each of the body organs Σor tissues that are irradiated (HE = wTHT).

(dd) "Embryo/fetus" means the developing human organism from conception until the time of birth.

(ee) "Entrance or access point" means any location through which an individual could gain access to radiation areas or to radioactive materials or machines which produce radiation. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

(ff) "Exposure" means being exposed to ionizing radiation or to radioactive material.

(gg) "External dose" means that portion of the dose equivalent received from radiation sources outside the body.

(hh) "Extremity" means hand, elbow, arm below the elbow, foot, knee, or leg below the knee.

(ii) “Filtering facepiece (dust mask)” means a negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable straps.

(jj) “Fit factor” means a quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

(kk) “Fit test” means the use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

(ll) “Generally applicable environmental radiation standards” means standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

(mm) Helmet” means a rigid respiratory inlet covering that also provides head protection against impact and penetration.

(nn) "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

(oo) “Hood” means a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

(pp) "Individual" means any human being.

(qq) "Individual monitoring "means:

1. The assessment of dose equivalent by the use of devices designed to be worn by an individual;

2. The assessment of committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

3. The assessment of dose equivalent by the use of survey data.

(rr) "Individual monitoring devices" (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of these rules, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal air sampling devices.

(ss) "Inhalation class" [see "Class"].

(tt) "Internal dose" means that portion of the dose equivalent received from radioactive material taken into the body.

(uu) “Lens dose equivalent” (LDE) applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeters (300 mg/cm2).

(vv) "License" means a license issued by the Agency in accordance with the rules adopted by the Agency

(ww) "Licensed material" means radioactive material received, possessed, used, transferred or disposed of under a general or specific license issued by the Agency.

(xx) "Licensee" means any person who is licensed by the Agency in accordance with the rules and the Act.

(yy) "Limits (dose limits)" means the permissible upper bounds of radiation doses.

(zz) “Loose-fitting facepiece” means a respiratory inlet covering that is designed to form a partial seal with the face.

(aaa) "Lost or missing licensed or registered source of radiation" means licensed or registered source of radiation whose location is unknown. This definition includes licensed or registered source that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

(bbb) "Member of the public" means an individual in a controlled or unrestricted area. However, an individual is not a member of the public during any period in which the individual receives an occupational dose.

(ccc) "Minor" means an individual less than 18 years of age.

(ddd) "Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of these rules, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

(eee) “Negative pressure respirator (tight fitting)” means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

(fff) "Nonstochastic effect" means a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of these rules, "deterministic effect" is an equivalent term.

(ggg) "Occupational dose" means the dose received by an individual in a restricted area or in the course of employment in which the individual's assigned duties involve exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. Occupational dose does not include dose received from background radiation, as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with 420-3-26-.07(29), from voluntary participation in medical research programs, or as a member of the public.

(hhh) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing other than the U. S. Nuclear Regulatory Commission, and other federal government agencies licensed by the U. S. Department of Energy, and other than federal government agencies licensed by the U. S. Nuclear Regulatory Commission.

(iii) "Planned special exposure" means an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

(jjj) “Positive pressure respirator” means a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

(kkk) “Powered air-purifying respirator (PAPR)” means an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

(lll) “Pressure demand respirator” means a positive pressure atmosphere-supplying respirator that admits breathing air to the

facepiece when the positive pressure is reduced inside the facepiece by inhalation.

(mmm) "Public dose" means the dose received by a member of the public from exposure to sources of radiation either within a licensee's or registrant's controlled area or in unrestricted areas. It does not include occupational dose, dose received from background radiation, dose received as a patient from medical practices, from exposure to individuals administered radioactive material and released in accordance with 420-3-26-.07(29), or dose from voluntary participation in medical research programs.

(nnn) "Qualitative fit test (QLFT)" means a pass/fail test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

(ooo) "Quality factor" means the modifying factor listed in the table below that is used to derive dose equivalent from absorbed dose:

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Quality Factor Absorbed Dose Equal to a Unit	
TYPE OF RADIATION (Q)	**Dose Equivalent[a]**
X, gamma, or beta radiation and high-speed electrons	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20
Neutrons of unknown energy	10
High-energy protons	10
	0.05
	0.1
	0.1

[a]Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

(ppp) "Quantitative fit test (QNFT)" means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

(qqq) "Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

(rrr) "Radiation" means alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. Radiation, as used in this part, does not include non-ionizing radiation, such as radio or microwaves, or visible, infrared, or ultraviolet light.

(sss) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (5 millirem) (0.05 Msv) in one hour at 30 centimeters from the radiation source or from the surface that the radiation penetrates.

(ttt) "Reference man" means a hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

(uuu) “Residual radioactivity” means radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee’s control. This includes radioactivity from all licensed and unlicensed sources, used by the licensee, but excludes background radiation. It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if those burials were made in accordance with the provisions of this rule.

(vvv) "Respiratory protective equipment" means an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

(www) "Sanitary sewerage" means a system of public sewers for carrying off waste water and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the licensee.

(xxx) “Self-contained breathing apparatus (SCBA)” means an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

(yyy) "Shallow-dose equivalent (H), which applies to sthe external exposure of the skin or an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm2) averaged over an area of one square centimeter.

(zzz) "Site boundary" means that line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

(aaaa) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of these rules, "probabilistic effect" is an equivalent term.

(bbbb) "Supplied-air respirator (SAR) or airline respirator" means an atmosphere supplying respirator for which the source of breathing air is not designed to be carried by the user.

(cccc) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive materials present.

(dddd) "Tight-fitting facepiece" means a respiratory inlet covering that forms a complete seal with the face.

(eeee) "Total effective dose equivalent (TEDE)" means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

(ffff) "Unrestricted area" means an area, access to which is neither limited nor controlled by the licensee.

(gggg) "User seal check (fit check)" means an action conducted by the respirator user to determine if the respirator is properly seated to the face. Examples include negative pressure check, positive pressure check, irritant smoke check, isoamyl acetate check.

(hhhh) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rad (5 Grays) in 1 hour at 1 meter from a source of radiation or 1 meter from any surface that the radiation penetrates.[13]

(iiii) "Week" means 7 consecutive days starting on Sunday.

(jjjj) "Weighting factor" wT for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly.

[11]At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert and rem. For calculating the effective dose equivalent, the values of wT are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue w_T	
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

[a] 0.30 results from 0.06 for each of 5 "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, wT = 1.0, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

(kkkk) "Whole body" means, for purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

(llll) "Working level (WL)" is any combination of short lived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 meV of potential alpha particle

energy. The short-1ived radon daughters are -- for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212.

(mmmm) "Working level month (WLM)" means an exposure to 1 working level for 170 hours (2,000 working hours per year/12 months per year equals approximately 170 hours per month).

(nnnn) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

(4) Implementation.

(a) Any existing license or registration condition that is more restrictive than this Rule remains in force until there is an amendment or renewal of the license or registration.

(b) If a license or registration condition exempts a licensee or registrant from a provision of this Rule in effect on or before January 1, 1994, it also exempts the licensee or registrant from the corresponding provision of this Rule.

(c) If a license or registration condition cites provisions of this Rule in effect prior to January 1, 1994, which do not correspond to any provisions of this Rule, the license or registration condition remains in force until there is an amendment or renewal of the license or registration that modifies or removes this condition.

RADIATION PROTECTION PROGRAMS

(5) Radiation Protection Programs.

(a) Each licensee or registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of this Rule. See 420-3-26-.03(41) for recordkeeping requirements relating to these programs.

(b) The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

(c) The licensee or registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of 420-3-26-.03(5)(b) and notwithstanding the requirements of 420-3-26-.03(14), a constraint

on air emissions of radioactive material to the environment, excluding radon-222 and daughters of radon, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 millirem (0.1 mSv) per year from those emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall file a report with the Agency as provided by 420-3-26-.03(53) and promptly take appropriate corrective action to ensure against recurrence.

OCCUPATIONAL DOSE LIMITS

(6) Occupational Dose Limits for Adults.

(a) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to 420-3-26-.03(11), to the following dose limits:

1. An annual limit, which is the more limiting of:

(i) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

(ii) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

2. The annual limits to the lens of the eye, to the skin, and to the extremities which are:

(i) A lens dose equivalent of 0.15 Sv (15 rem), and

(ii) A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See 420-3-26-.03(11)(e)1. and 2.

(c) The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure determined as follows:

1. The deep dose equivalent, lens dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

2. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a method approved by the Agency. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

3. When a protective apron is worn and monitoring is conducted as specified in 420-3-26-.03(18)(c), the effective dose equivalent for external radiation shall be determined as follows:

(i) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in 420-3-26-.03(6)(a), the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

(ii) When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose (see 420-3-26-.03(46) and to demonstrate compliance with the occupational dose limits.

(e) Notwithstanding the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. See footnote 3 of Appendix B.

(f) The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person. See 420-3-26-.03(10)(e).

(7) Compliance with Requirements for Summation of External and Internal Doses.

(a) If the licensee or registrant is required to monitor pursuant to both 420-3-26-.03(18)(a) and (b), the licensee or registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee or registrant is required to monitor only pursuant to 420-3-26-.03(18)(a) or only pursuant to 420-3-26-.03(18)(b), then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to 420-3-26-.03(7)(b),(c), and (d). The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

(b) Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

1. The sum of the fractions of the inhalation ALI for each radionuclide, or

2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factor, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of H_{50} (i.e. $w_T H_{T,50}$, per unit intake for any organ or tissue).

(c) Intake by Oral Ingestion. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

(d) Intake through Wounds or Absorption through Skin. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be evaluated or accounted for pursuant to 420-3-26-.03(7)(d).

(8) Determination of External Dose from Airborne Radioactive Material.

(a) Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Appendix B, footnotes 1 and 2.

(b) Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

(9) Determination of Internal Exposure.

(a) For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required pursuant to 420-3-26-.03(18), take suitable and timely measurements of:

1. Concentrations of radioactive materials in air in work areas; or

2. Quantities of radionuclides in the body; or

3. Quantities of radionuclides excreted from the body; or

4. Combinations of these measurements.

(b) Unless respiratory protective equipment is used, as provided in 420-3-26-.03(24), or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

(c) When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the licensee may:

1. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

2. Upon prior approval of the Agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Appendix B.

(d) If the licensee chooses to assess intakes of Class Y material using the measurements given in 420-3-26-.03(9)(a)2. and 3., the licensee may delay the recording and reporting of the assessments for periods up to 7 months, unless otherwise required by 420-3-26-.03(52) or 420-3-26-.03(53). This delay permits the licensee to make additional measurements basic to the assessments.

(e) If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

1. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

(f) If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

(g) When a mixture of radionuclides in air exists, a licensee may disregard certain radionuclides in the mixture if:

1. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in 420-3-26-.03(6) and in complying with the monitoring requirements in 420-3-26-.03(17)(b) and (c), and

2. The concentration of any radionuclide disregarded is less than 10 percent of its DAC, and

3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

(h) When determining the committed effective dose equivalent, the following information may be considered:

1. In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (5 rem) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

2. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (5 rem), that is, the stochastic ALI, is listed in parentheses in Table I of Appendix B. The licensee may, as a simplifying assumption, use the stochastic ALI to determine

committed effective dose equivalent. However, if the licensee uses the stochastic ALI, the licensee shall also demonstrate that the limit in 420-3-26-.03(6)(a)1.(ii) is met.

(10) Determination of Prior Occupational Dose.

(a) For each individual who is likely to receive, in a year, an occupational dose requiring monitoring pursuant to 420-3-26-.03(18), the licensee or registrant shall:

1. Determine the occupational radiation dose received during the current year; and

2. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

(b) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

1. The internal and external doses from all previous planned special exposures; and

2. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual; and

3. All lifetime cumulative occupational radiation dose.

(c) In complying with the requirements of 420-3-26-.03(10)(a), a licensee or registrant may:

1. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

2. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Agency Form Y or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant; and

3. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the licensee or registrant, by telephone, telegram, facsimile, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

(d)1. The licensee or registrant shall record the exposure history as required by 420-3-26-.03(10)(a), on Agency Form Y, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing Agency Form Y or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or registrant shall place a notation on Agency Form Y or equivalent indicating the periods of time for which data are not available.

2. Licensees are not required to reevaluate the separate external dose equivalents and internal committed dose equivalents or intakes of radionuclides assessed pursuant to the rules in this Rule in effect before January 1, 1994. Further, occupational exposure histories obtained and recorded on Agency Form Y or equivalent before January 1, 1994, would not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

(e) If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

1. In establishing administrative controls pursuant to 420-3-26-.03(6)(f) for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

2. That the individual is not available for planned special exposures.

(f) The licensee or registrant shall retain the records on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made.

(11) Planned Special Exposures. A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in 420-3-26-.03(6) provided that each of the following conditions is satisfied:

(a) The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that

might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

(b) The licensee or registrant, and employer if the employer is not the licensee or registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs.

(c) Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

1. Informed of the purpose of the planned operation; and

2. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

3. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

(d) Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by 420-3-26-.03(6)(b) during the lifetime of the individual for each individual involved.

(e) Subject to 420-3-26-.03(6)(b), the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

1. The numerical values of any of the dose limits in 420-3-26-.03(6)(a) in any year; and

2. Five times the annual dose limits in 420-3-26-.03(6)(a) during the individual's lifetime.

(f) The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with 420-3-26-.03(45) and submits a written report in accordance with 420-3-26-.03(54).

(g) The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to 420-3-26-.03(6)(a) but shall be included in evaluations required by 420-3-26-.03(11)(d) and (e).

(12) Occupational Dose Limits for Minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in 420-3-26-.03(6).

(13) Dose Equivalent to an Embryo/Fetus.

(a) The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See 420-3-26-.03(46) for recordkeeping requirements.

(b) The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in 420-3-26-.03(13)(a).

(c) The dose equivalent to an embryo/fetus shall be taken as the sum of:

1. The deep dose equivalent to the declared pregnant woman; and

2. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If by the time the woman declares pregnancy to the licensee or registrant, the dose equivalent to the embryo/fetus has exceeded 4.5 mSv (0.45 rem), the licensee or registrant shall be deemed to be in compliance with 420-3-26-.03(13)(a) if the additional dose to the embryo/fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

RADIATION DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC

(14) Dose Limits for Individual Members of the Public.

(a) Each licensee or registrant shall conduct operations so that:

1. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 1 mSv (0.1 rem) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposures to individuals administered radioactive material and released in accordance with 420-3-26-.07(29), from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with 420-3-26-.03(35)14 and

2. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with 420-3-26-.07(29), does not exceed 0.02 mSv (0.002 rem) in any one hour.

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[14] Retrofit shall not be required for locations within facilities where only radiation machines existed prior to January 1, 1994, and met the previous requirements of 5 mSv (0.5 rem) in a year.

(b) If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

(c) A licensee, registrant, or an applicant for a license or registration may apply for prior Agency authorization to operate up to an annual dose limit for an individual member of the public of 5 mSv (0.5 rem). This application shall include the following information:

1. Demonstration of the need for and the expected duration of operations in excess of the limit in 420-3-26-.03(14)(a); and

2. The licensee's or registrant's program to assess and control dose within the 5 mSv (0.5 rem) annual limit; and

3. The procedures to be followed to maintain the dose ALARA.

(d) In addition to the requirements of this Rule, a licensee subject to the provisions of the U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190 shall comply with those standards.

(e) The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

(15) Compliance with Dose Limits for Individual Members of the Public.

(a) The licensee or registrant shall make or cause to be made surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in 420-3-26-.03(14).

(b) A licensee or registrant shall show compliance with the annual dose limit in 420-3-26-.03(14) by:

1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit or

2. Demonstrating that:

(i) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix B; and

(ii) If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

(c) Upon approval from the Agency, the licensee may adjust the effluent concentration values in Appendix B, Table II, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as, aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

TESTING FOR LEAKAGE OR CONTAMINATION OF SEALED SOURCES

(16) Testing for Leakage or Contamination of Sealed Sources.

(a) The licensee in possession of any sealed source shall assure that:

1. Each sealed source, except as specified in 420-3-26-.03(16)(b), is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within 6 months before transfer to the licensee.

2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 6 months or at alternative intervals approved by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission.

3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed 3 months or at alternative intervals approved by the Agency, an Agreement State, a Licensing State, or the Nuclear Regulatory Commission.

4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the licensee shall assure that the sealed source is tested for leakage or contamination before further use.

5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 µCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position.

6. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 µCi) of radon-222 in a 24 hour period when the collection efficiency for radon-222 and its daughters has been determined with respect to collection method, volume and time.

7. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 µCi) of a radium daughter which has a half-1ife greater than 4 days.

(b) A licensee need not perform test for leakage or contamination on the following sealed sources:

1. Sealed sources containing only radioactive material with a half-1ife of less than 30 days;

2. Sealed sources containing only radioactive material as a gas;

3. Sealed sources containing 3.7 MBq (100 µCi) or less of beta or photon-emitting material or 370 kBq (10 µCi) or less of alpha-emitting material;

4. Sealed sources containing only hydrogen-3;

5. Seeds of iridium-192 encased in nylon ribbon; and

6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The licensee shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within 6 months before the date of use or transfer.

(c) Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the Agency, an Agreement State, a Licensing State, or the U.S. Nuclear Regulatory Commission to perform such services.

(d) Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency.

(e) The following shall be considered evidence that a sealed source is leaking:

1. The presence of 185 Bq (0.005 µCi) or more of removable contamination on any test sample.

2. Leakage of 37 Bq (0.001 µCi) of radon-222 per 24 hours for brachytherapy sources manufactured to contain radium.

3. The presence of removable contamination resulting from the decay of 185 Bq (0.005 µCi) or more of radium.

(f) The licensee shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this Rule.

(g) Reports of test results for leaking or contaminated sealed sources shall be made pursuant to 420-3-26-.03(58).

SURVEYS AND MONITORING

(17) General.

(a) Each licensee or registrant shall make, or cause to be made, surveys that:

1. Are necessary for the licensee or registrant to comply with this Rule; and

2. Are necessary under the circumstances to evaluate:

(i) The magnitude and extent of levels; and

(ii) Concentrations or quantities of radioactive material; and

(iii) The potential radiological hazards.

(b) The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured.

(c) All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with 420-3-26-.03(6), with other applicable provisions of these, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

(d) The licensee or registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

(18) Conditions Requiring Individual Monitoring of External and Internal Occupational Dose. Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this Rule. As a minimum:

(a) Each licensee or registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

1. Adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in 420-3-26-.03(6)(a); and

2. Minors likely to receive, in 1 year from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem(1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv); and

3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv); and (4) Individuals entering a high or very high radiation area.

(b) Each licensee shall monitor, to determine compliance with 420-3-26-.03(9), the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

1. Adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Appendix B; and

2. Minors and declared pregnant women likely to receive, in 1 year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

(c) For individuals working with medical fluoroscopic equipment:

1. An individual monitoring device used to determine the dose to an embryo/fetus of a declared pregnant woman, pursuant to 420-3-26-.03(18)(a)2., shall be located under the protective apron at the waist. (Note: It is recognized that, in the specific work environment of medical fluoroscopic equipment, the dose to the embryo/fetus is overestimated by the individual monitoring device because of the overlying tissue of the pregnant individual. A certified expert, such as a medical physicist who is certified by the American Board of Radiology in Diagnostic Radiological Physics or in Radiological Physics should be consulted to determine the

dose to the embryo/fetus for the occasions in which this individual monitoring device has a monthly reported dose equivalent value in excess of 0.5 mSv (50 mrem). Therefore, for purposes of these rules, the value to be used for determining the dose to the embryo/fetus pursuant to 420-3-26-.03(13), for occupational exposure to radiation from medical fluoroscopic equipment may be the value reported by the individual monitoring device worn at the waist underneath the protective apron which has been corrected for the particular individual and her work environment by a qualified expert.)

2. An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron.

3. When only one individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to 420-3-26-.03(6)(C)2., it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. (Note: The second individual monitoring device is required for a declared pregnant woman.)

CONTROL OF EXPOSURE FROM EXTERNAL SOURCES IN RESTRICTED AREAS

(19) Control of Access to High Radiation Areas.

(a) The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

1. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from the source of radiation from any surface that the radiation penetrates; or

2. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

3. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

(b) In place of the controls required by 420-3-26-.03(19)(a) for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

(c) The licensee or registrant may apply to the Agency for approval of alternative methods for controlling access to high radiation areas.

(d) The licensee or registrant shall establish the controls required by 420-3-26-.03(19)(a) and (c) in a way that does not prevent individuals from leaving a high radiation area.

(e) The licensee is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation provided that:

1. The packages do not remain in the area longer than 3 days; and

2. The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

(f) The licensee is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that personnel are in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in this Rule and to operate within the ALARA provisions of the licensee's radiation protection program.

(g) A registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in 420-3-26-.06 for x-rays in the healing arts, and 420-3-26-.09 for particle accelerators. Entrance or access to rooms is required to be controlled when equipment is in operation.

(20) Control of Access to Very High Radiation Areas.

(a) In addition to the requirements in 420-3-26-.03(19), the licensee or registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 Gy (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

(b) The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in 420-3-26-.03(20)(a) if the registrant has met all the specific requirements for access and control specified in other applicable rules, such

as, 420-3-26-.04 for industrial radiography, 420-3-26-.06 for x-rays in the healing arts, and 420-3-26-.09 for particle accelerators.

(21) Control of Access to Very High Radiation Areas -- Irradiators.

(a) This rule applies to licensees with sources of radiation in non-self-shielded irradiators. This rule does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

(b) Each area in which there may exist radiation levels in excess of 5 Gy (500 rad) in 1 hour at 1 meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

1. Each entrance or access point shall be equipped with entry control devices which:

(i) Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

(ii) Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(iii) Prevent operation of the source of radiation if it would produce radiation levels in the area that would result in a deep dose equivalent to an individual in excess of 1 mSv (0.1 rem) in 1 hour.

2. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by 420-3-26-.03(21)(b)1.:

(i) The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to

render or summon assistance, aware of the failure of the entry control devices.

3. The licensee shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

(i) The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour; and

(ii) Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

4. When the shield for stored sealed sources is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

5. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of 420-3-26-.03(21)(b)3. and 4.

6. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

7. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

8. Each area shall be checked by a radiation measurement to ensure, that prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour.

9. The entry control devices required in 420-3-26-.03(21)(b)1. shall be tested for proper functioning. See 420-3-26-.03(49) for recordkeeping requirements.

(i) Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

(ii) Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

(iii) The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

10. The licensee or registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

11. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

(c) Licensees, registrants, or applicants for licenses or registrations for sources of radiation within the purview of 420-3-26-.03(21)(b) which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of 420-3-26-.03(21)(b), such as those for the automatic control of radiation levels, may apply to the Agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in 420-3-26-.03(21)(b). At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

(d) The entry control devices required by 420-3-26-.03(21)(b) and (c) shall be established in such a way that no individual will be prevented from leaving the area.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

(22) Use of Process or Other Engineering Controls. The licensee shall use, to the extent practicable, process or other engineering

controls, such as, containment or ventilation, to control the concentrations of radioactive material in air.

(23) Use of Other Controls. When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

(a) Control of access; or

(b) Limitation of exposure times; or

(c) Use of respiratory protection equipment; or

(d) Other controls.

RESPIRATORY PROTECTION AND CONTROLS TO RESTRICT INTERNAL EXPOSURE IN RESTRICTED AREAS

(24.1) Use of Individual Respiratory Protection Equipment.

(a) If the licensee uses respiratory protection equipment to limit intakes pursuant to 420-3-26-.03(23):

1. Except as provided in 420-3-26-.03(24)(a)2., the licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

2. If the licensee wishes to use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of reliable test information, that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use.

3. The licensee shall implement and maintain a respiratory protection program that includes:

(i) Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

(ii) Surveys and bioassays, as appropriate, to evaluate actual intakes; and

(iii) Testing of respirators for operability immediately prior to each use; and

(iv) Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and recordkeeping; and

(v) Determination by a physician prior to initial fitting of respirators, and every 12 months thereafter, that the individual user is medically fit to use the respiratory protection equipment.

4. The licensee shall issue a written policy statement on respirator usage covering:

(i) The use of process or other engineering controls, instead of respirators; and

(ii) The routine, nonroutine, and emergency use of respirators; and

(iii) The length of periods of respirator use and relief from respirator use.

5. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

6. The licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

(b) When estimating exposure of individuals to airborne radioactive materials, the licensee may make allowance for respiratory protection equipment used to limit intakes pursuant to 420-3-26-.03(23), provided that the following conditions, in addition to those in 420-3-26-.03(24)(a), are satisfied:

1. The licensee selects respiratory protection equipment that provides a protection factor, specified in Appendix A, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Appendix B, Table I, Column 3. However, if the selection of respiratory protection equipment with a

protection factor greater than the peak concentration is inconsistent with the goal specified in 420-3-26-.03(23) of keeping the total effective dose equivalent ALARA, the licensee may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used.

2. The licensee shall obtain authorization from the Agency before assigning respiratory protection factors in excess of those specified in Appendix A. The Agency may authorize a licensee to use higher protection factors on receipt of an application that:

(i) Describes the situation for which a need exists for higher protection factors, and

(ii) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

(c) In an emergency, the licensee shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

(d) The licensee shall notify the Agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either 420-3-26-.03(24)(a) or (b).

(24.2) Use of Process or Other Engineering Controls. The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

(24.3) Use of Other Controls.

(a) When it is not practical to apply process or other engineering controls to control the concentrations of radioactive material in the air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

1. Control of access;

2. Limitation of exposure time;

3. Use of respiratory protection equipment; or

4. Other controls.

(b) If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' individual health and safety.

(24.4) Use of Individual Respiratory Protection Equipment. If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material:

(a) The licensee shall use only respiratory protection equipment that is tested and certified by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this Rule.

(b) If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application to the Agency for authorized use of this equipment except as provided in this Rule. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

(c) The licensee shall implement and maintain a respiratory protection program that includes:

1. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

2. Surveys and bioassays, as necessary, to evaluate actual intakes;

3. Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

4. Written procedures regarding:

(i) Monitoring, including air sampling and bioassays;

(ii) Supervision and training of respirator users;

(iii) Fit testing;

(iv) Respirator selection;

(v) Breathing air quality;

(vi) Inventory and control;

(vii) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(viii) Recordkeeping; and

(ix) Limitations on periods of respirator use and relief from respirator use;

5. Determination by a physician that the individual user is medically fit to use respiratory protection equipment; before:

(i) The initial fitting of a face sealing respirator;

(ii) Before the first field use of non-face sealing respirators, and

(iii) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

(6) Fit testing, with fit factor greater than or equal to 10 times the APF for negative pressure devices, and a fit factor greater tan or equal to 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed 1 year. Fit testing must be performed with the face-piece operating in a negative pressure mode.

(d) The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

(e) The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

(f) Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection devices and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be

equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress. A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

(g) Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

1. Oxygen content (v/v) of 19.5-23.5%;

2. Hydrocarbon (condensed) content of 5 milligrams per cubic meter of air or less;

3. Carbon monoxide (CO) content of 10 ppm or less;

4. Carbon dioxide content of 1,000 ppm or less; and

5. Lack of a noticeable odor.

(h) The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face - facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

(i) In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

(24.5) Further Restrictions on the Use of Respiratory Protection Equipment. The Agency may impose restrictions in addition to the provisions of 420-3-26-.03(23), 420-3-26-.03(24), and Appendix A to Rule 420-3-26-.03, in order to:

(a) Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne

radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

(b) Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

(24.6) Application for Use of Higher Assigned Protection Factors. The licensee shall obtain authorization from the Agency before using assigned protection factors in excess of those specified in Appendix A of Rule 420-3-26-.03. The Agency may authorize a licensee to use higher assigned protection factors upon receipt of an application that:

(a) Describes the situation for which a need exists for higher protection factors; and

(b) Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

STORAGE AND CONTROL OF LICENSED OR REGISTERED SOURCES OF RADIATION

(25) Security of Stored Sources of Radiation. The licensee or registrant shall secure from unauthorized removal or access licensed or registered sources of radiation that are stored in controlled or unrestricted areas.

(26) Control of Sources of Radiation not in Storage.

(a) The licensee shall control and maintain constant surveillance of licensed radioactive material that is in a controlled or unrestricted area and that is not in storage or in a patient.

(b) The registrant shall maintain control of radiation machines that are in a controlled or unrestricted area and that are not in storage.

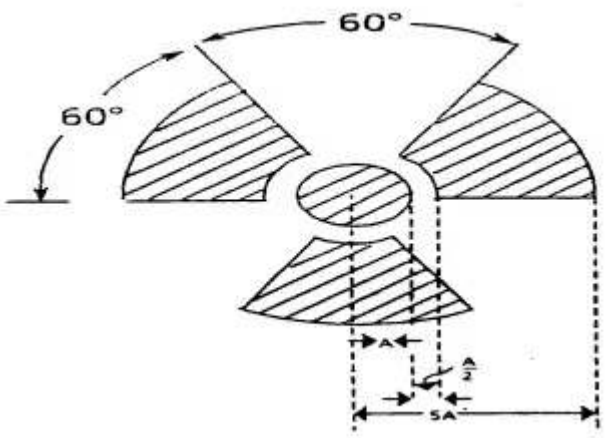
PRECAUTIONARY PROCEDURES

(27) Caution Signs.

(a) Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by 420-3-26-.03(27) shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows: RADIATION SYMBOL

1. Cross-hatched area is to be magenta, or purple, or black, and

2. The background is to be yellow.



(b) Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of 420-3-26-.03(27)(a), licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

(c) Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in this Rule, the licensee or registrant shall provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

(28) Posting Requirements.

(a) Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

(b) Posting of High Radiation Areas. The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

(c) Posting of Very High Radiation Areas. The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA." For each very high radiation area, created in a medical institution by the use of a registered medical particle accelerator, the word "Danger" may be substituted for the words "GRAVE DANGER."

(d) Posting of Airborne Radioactivity Areas. The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION,

AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

(e) Posting of Areas or Rooms in Which Licensed Radioactive Material is Used or Stored. The licensee shall post each area or room in which there is used or stored an amount of licensed or registered material exceeding 10 times the quantity of such material specified in Appendix C with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

(29) Exceptions to Posting Requirements.

(a) A licensee or registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than 8 hours, if each of the following conditions is met:

1. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in this Rule; and

2. The area or room is subject to the licensee's or registrant's control.

(b) Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to 420-3-26-.03(28) provided that the patient could be released from confinement pursuant to 420-3-26-.07(29) of these rules.

(c) A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

(d) A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

(30) Labeling Containers and Radiation Machines.

(a) The licensee shall ensure that each container of licensed or registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

(b) Each licensee, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

(c) Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

(31) Exemptions to Labeling Requirements. A licensee is not required to label:

(a) Containers holding licensed or registered material in quantities less than the quantities listed in Appendix C; or

(b) Containers holding licensed or registered material in concentrations less than those specified in Table III of Appendix B; or

(c) Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Rule; or

(d) Containers when they are in transport and packaged and labeled in accordance with the regulations of the U.S. Department of Transportation;15 or

(e) Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

(f) Installed manufacturing or process equipment, such as piping and tanks.

(32) Procedures for Receiving and Opening Packages.

(a) Each licensee who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in 420-3-26-.03(32)(b) of these rules shall make arrangements to receive:

1. The package when the carrier offers it for delivery; or

2. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

(b) Each licensee shall:

1. Monitor the external surfaces of a labeled[16] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 420-3-26-.01(2)(a)103 of these rules; and

2. Monitor the external surfaces of a labeled[3] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal

_____

[15] Labeling of packages containing radioactive materials is required by the U.S. Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by U.S. Department of Transportation regulations 49 CFR 173.403(m) and (w) and 173.421-424. 16 Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U.S. Department of Transportation regulations 49 CFR 172.403 and 172.436-440.

to the Type A quantity as defined in 420-3-26-.03(32)(b) of these rules; and

3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

Table of Exempt and Type A Quantities

Exempt Quantity Limit (in millicuries)[17]	**Type A Quantity Limit (in curies)**
A_2 x 0.001	A_2

(c) The licensee shall perform the monitoring required by 420-3-26-.03(32)(b) as soon as practicable after receipt of the package, but not later than 3 hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

(d) The licensee shall immediately notify the final delivery carrier and, by telephone and telegram, mailgram, or facsimile, the Agency when:

1. Removable radioactive surface contamination that exceeds 0.01 microcurie (22,200 disintegrations per minute) per 100 square centimeters of package surface is found on the external surfaces of the package; or

2. Radiation levels are found on the external surface of the package in excess of 200 millirem per hour, or at three feet from the external surfaces of the package in excess of 10 millirem per hour.

(e) Each licensee shall:

1. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

_____

[17] These quantities are defined as determined in 10 CFR Part 71, Appendix A. See footnote 3 on page 8.

2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

(f) Licensees transferring special form sources in vehicles owned or operated by the licensee to and from a work site are exempt from the contamination monitoring requirements of 420-3-26-.03(32)(b), but are not exempt from the monitoring requirement in 420-3-26-.03(32)(b) for measuring radiation levels that ensures that the source is still properly lodged in its shield.

WASTE DISPOSAL

(33) General Requirements.

(a) A licensee shall dispose of licensed or registered material only:

1. By transfer to an authorized recipient as provided in 420-3-26-.03(38) of these rules, or to the U.S. Department of Energy; or

2. By decay in storage; or

3. By release in effluents within the limits in 420-3-26-.03(14); or

4. As authorized pursuant to 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), or 420-3-26-.03(37.1); or

5. By transfer for disposal at a disposal facility authorized to dispose of such material in accordance with any federal or state solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

6. Licensed material as defined in paragraphs (iii),(iv) and (v) of the definition of Byproduct material set forth in 420-3-26-.01(2)(a)17. may be disposed of in accordance with this chapter,

even though it is not defined as low-1evel radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 420-3-26-.02 or equivalent Agreement State or NRC rules, must meet the requirements of 420-3-26-.03(38).

(b) A person shall be specifically licensed to receive waste containing licensed material from other persons for:

1. Treatment prior to disposal; or

2. Treatment or disposal by incineration; or

3. Decay in storage; or

4. Disposal at a land disposal facility licensed pursuant to 420-3-26-.02(10)(p) of these rules; or

5. Storage until transferred to a storage or disposal facility authorized to receive the waste.

(34) Method for Obtaining Approval of Proposed Disposal Procedures. A licensee or applicant for a license may apply to the Agency for approval of proposed procedures, not otherwise authorized in these rules, to dispose of licensed material generated in the licensee's operations. Each application shall include:

(a) A description of the waste containing licensed material to be disposed of, including the physical and chemical properties that have an impact on risk evaluation, and the proposed manner and conditions of waste disposal; and

(b) An analysis and evaluation of pertinent information on the nature of the environment; and

(c) The nature and location of other potentially affected facilities; and

(d) Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this Rule.

(35) Disposal by Release into Sanitary Sewerage.

(a) A licensee may discharge licensed or registered material into sanitary sewerage if each of the following conditions is satisfied:

1. The material is readily soluble, or is readily dispersible biological material, in water; and

2. The quantity of licensed or registered radioactive material that the licensee releases into the sewer in 1 month divided by

the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix B; and

3. If more than one radionuclide is released, the following conditions must also be satisfied:

(i) The licensee shall determine the fraction of the limit in Table III of Appendix B represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix B; and

(ii) The sum of the fractions for each radionuclide required by 420-3-26-.03(35)(a)3.(i) does not exceed unity; and

4. The total quantity of licensed radioactive material that the licensee releases into the sanitary sewerage in a year does not exceed 185 GBq (5 Ci) of hydrogen-3, 37 GBq (1 Ci) of carbon-14, and 37 GBq (1 Ci) of all other radioactive materials combined.

(b) Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in 420-3-26-.03(35)(a).

(36) Treatment or Disposal by Incineration. A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in 420-3-26-.03(37) or as specifically approved by the Agency pursuant to 420-3-26-.03(34).

(37) Disposal of Specific Wastes.

(a) A licensee may dispose of the following licensed material as if it were not radioactive:

1. 1.85 kBq (0.05 µCi), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

2. 1.85 kBq (0.05 µCi), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

(b) A licensee shall not dispose of tissue pursuant to 420-3-26-.03(37)(a)2. in a manner that would permit its use either as food for humans or as animal feed.

(c) The licensee shall maintain records in accordance with 420-3-26-.03(48).

(37.1) Disposal of Certain Radioactive Material

(a) Licensed material as defined in paragraphs (iii), Byproduct material (iv) and (v) of the definition of set forth in 420-3-26-.01(2)(a)17. may be disposed of in accordance with 10 CFR Part 61 of the Code of Federal Regulations18, even though it is not defined as low-1evel radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under 10 CFR Part 61, must meet the requirements of 420-3-26-.03(38).

(b) A licensee may dispose of radioactive material, as defined in paragraphs (iii), (iv) and (v) of the definition of *Byproduct material* set forth in 420-3-26-.01(2)(a)17., at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

(38) Transfer for Disposal and Manifests

(a) The requirements of this section and Appendix G to this rule, 420-3-26-.03, are designed to:

1. Control transfers of low-1evel radioactive waste by any waste generator, waste collector, or waste processor licensee, as defined in this rule, who ships low-1evel radioactive waste either directly, or indirectly through a waste collector or waste processor, to a low-1evel waste land disposal facility;

2. Establish a manifest tracking system; and

3. Supplement existing requirements concerning transfers and recordkeeping for those wastes.

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[18] Available at the **U.S. Government Printing Office Bookstore**, 710 North Capitol Street N.W., Washington, DC

(b) Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G of this rule.

(c) Each shipment manifest must include a certification by the waste generator as specified in section II Appendix G to this rule.

(d) Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in section III of Appendix G to this rule.

(39) Compliance with Environmental and Health Protection Regulations. Nothing in 420-3-26-.03(33), 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), or 420-3-26-.03(38) relieves the licensee from complying with other applicable Federal, State and local regulations governing any other toxic or hazardous properties of materials that may be disposed of to 420-3-26-.03(33), 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), or 420-3-26-.03(38).

RECORDS

(40) General Provisions.

(a) Each licensee or registrant shall use the units curie, rad, rem and roentgen, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Rule.

(b) In the records required by this rule, the licensee may record quantities in SI units in parentheses following each of the units specified in 420-3-26-.03(40)(a) of this rule. However, all quantities must be recorded as stated in rule 420-3-26-.03(40)(a) of this rule.

(c) Not withstanding requirements of rule 420-3-26-.03(40)(a), when recording information on shipment manifests, as required by rule 420-3-26-.03(38)(b), information must be recorded in the International System of Units (SI) or in SI and units as specified in rule 420-3-26-.03(40)(a).

(d) The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Rule, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, lens dose equivalent, deep dose equivalent, or committed effective dose equivalent.

(41) Records of Radiation Protection Programs.

(a) Each licensee or registrant shall maintain records of the radiation protection program, including:

1. The provisions of the program; and

2. Audits and other reviews of program content and implementation.

(b) The licensee or registrant shall retain the records required by 420-3-26-.03(41)(a)1. until the Agency terminates each pertinent license or registration requiring the record. The licensee or registrant shall retain the records required by 420-3-26-.03(41)(a)2. for 3 years after the record is made.

(42) Records of Surveys.

(a) Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by 420-3-26-.03(17) and 420-3-26-.03(32)(b). The licensee or registrant shall retain these records for 3 years after the record is made.

(b) The licensee or registrant shall retain each of the following records until the Agency terminates each pertinent license or registration requiring the record:

1. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

2. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

3. Records showing the results of air sampling, surveys, and bioassays required pursuant to 420-3-26-.03(24)(a)3.(i) and(ii); and

4. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

(c) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

(43) Records of Tests for Leakage or Contamination of Sealed Sources. Records of tests for leakage or contamination of sealed sources required by 420-3-26-.03(16) shall be kept in units of becquerel or microcurie and maintained for inspection by the Agency for 5 years after the records are made.

(44) Records of Prior Occupational Dose.

(a) The licensee or registrant shall retain the records of prior occupational dose and exposure history as specified in 420-3-26-.03(10) on Agency Form Y or equivalent until the Agency terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing Agency Form Y or equivalent for 3 years after the record is made.

(b) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

(45) Records of Planned Special Exposures.

(a) For each use of the provisions of 420-3-26-.03(11) for planned special exposures, the licensee or registrant shall maintain records that describe:

1. The exceptional circumstances requiring the use of a planned special exposure; and

2. The name of the management official who authorized the planned special exposure and a copy of the signed authorization; and

3. What actions were necessary; and

4. Why the actions were necessary; and

5. What precautions were taken to assure that doses were maintained ALARA; and

6. What individual and collective doses were expected to result; and

7. The doses actually received in the planned special exposure.

(b) The licensee or registrant shall retain the records until the Agency terminates each pertinent license or registration requiring these records.

(c) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

(46) Records of Individual Monitoring Results.

(a) Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to 420-3-26-.03(18), and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before January 1, 1994 need not be changed. These records shall include, when applicable:

1. The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

2. The estimated intake of radionuclides. See 420-3-26-.03(7); and

3. The committed effective dose equivalent assigned to the intake of radionuclides; and

4. The specific information used to calculate the committed effective dose equivalent pursuant to 420-3-26-.03(9)(a) and (c); and 420-3-26-.03(18); and

5. The total effective dose equivalent when required by 420-3-26-.03(7); and

6. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) Recordkeeping Frequency. The licensee or registrant shall make entries of the records specified in 420-3-26-.03(46)(a) at intervals not to exceed 1 year.

(c) Recordkeeping Format. The licensee or registrant shall maintain the records specified in 420-3-26-.03(46)(a) on Agency Form Z, in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by Agency Form Z.

(d) The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

(e) The licensee or registrant shall retain each required form or record until the Agency terminates each pertinent license or registration requiring the record.

(f) Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency.

(47) Records of Dose to Individual Members of the Public.

(a) Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. (See 420-3-26-.03(14).

(b) The licensee or registrant shall retain the records required by 420-3-26-.03(3)(48)(b) until the Agency terminates each pertinent license or registration requiring the record.

(48) Records of Waste Disposal.

(a) Each licensee shall maintain records of the disposal of licensed radioactive material made pursuant to 420-3-26-.03(34), 420-3-26-.03(35), 420-3-26-.03(36), 420-3-26-.03(37), and disposal by burial in soil, including burials authorized before January 1, 1994.

(b) The licensee shall retain the records required by 420-3-26-.03(48)(a) until the Agency terminates each pertinent license requiring the record.

(49) Records of Testing Entry Control Devices for Very High Radiation Areas.

(a) Each licensee or registrant shall maintain records of tests made pursuant to 420-3-26-.03(21)(b)9. on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

(b) The licensee or registrant shall retain the records required by 420-3-26-.03(49)(a) for 3 years after the record is made.

(50) Form of Records. Each record required by this Rule shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

REPORTS

(51) Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

(a) Telephone Reports. Each licensee or registrant shall report to the Agency by telephone as follows:

1. Immediately after its occurrence becomes known to the licensee stolen, lost, or missing licensed radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the licensee that an exposure could result to individuals in unrestricted areas; or

2. Within 30 days after its occurrence becomes known to the licensee lost, stolen, or missing licensed radioactive material in an aggregate quantity greater than 10 times the quantity specified in Appendix C that is still missing.

3. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

(b) Written Reports. Each licensee or registrant required to make a report pursuant to 420-3-26-.03(51)(a) shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

1. A description of the licensed or registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and,

2. A description of the circumstances under which the loss or theft occurred; and

3. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

5. Actions that have been taken, or will be taken, to recover the source of radiation; and

6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

(c) Subsequent to filing the written report, the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

(d) The licensee or registrant shall prepare any report filed with the Agency pursuant to 420-3-26-.03(51) so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

(52) Notification of Incidents.

(a) Immediate Notification. Notwithstanding other requirements for notification, each licensee or registrant shall immediately report each event involving a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

1. An individual to receive:

(i) A total effective dose equivalent of 0.25 Sv (25 rem) or more; or

(ii) An eye dose equivalent of 0.75 Sv (75 rem) or more; or

(iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent of 2.5 Gy (250 rad) or more; or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24

hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(b) Twenty-Four Hour Notification. Each licensee or registrant shall, within 24 hours of discovery of the event, report to the Agency each event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of 24 hours:

(i) A total effective dose equivalent exceeding 0.05 Sv (5 rem); or

(ii) An eye dose equivalent exceeding 0.15 Sv (15 rem); or

(iii) A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.

(c) The licensee or registrant shall prepare each report filed with the Agency pursuant to 420-3-26-.03(52) so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

(d) Licensees or registrants shall make the reports required by 420-3-26-.03(52)(a) and (b) to the Agency by telephone, telegram, mailgram, or facsimile to the Agency.

(e) The provisions of 420-3-26-.03(52) do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to 420-3-26-.03(54).

(53) Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits.

(a) Reportable Events. In addition to the notification required by 420-3-26-.03(52), each licensee or registrant shall submit a written report within 30 days after learning of any of the following occurrences:

1. Incidents for which notification is required by 420-3-26-.03(52); or

2. Doses in excess of any of the following:

(i) The occupational dose limits for adults in 420-3-26-.03(6); or

(ii) The occupational dose limits for a minor in 420-3-26-.03(12); or

(iii) The limits for an embryo/fetus of a declared pregnant woman in 420-3-26-.03(13); or

(iv) The limits for an individual member of the public in 420-3-26-.03(14); or

(v) Any applicable limit in the license or registration; or

(vi) The ALARA constraints for air emissions established under 420-3-26-.03(5)(d).

3. Levels of radiation or concentrations of radioactive material in:

(i) A restricted area in excess of applicable limits in the license or registration; or

(ii) An unrestricted area in excess of 10 times the applicable limit set forth in this Rule or in the license or registration, whether or not involving exposure of any individual in excess of the limits in 420-3-26-.03(14); or

4. For licensees subject to the provisions of U.S. Environmental Protection Agency's generally applicable environmental radiation standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

5. Lost or altered radiation dosimetry reports.

(b) Contents of Reports.

1. Each report required by 420-3-26-.03(53)(a) shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

(i) Estimates of each individual's dose; and

(ii) The levels of radiation and concentrations of radioactive material involved; and

(iii) The cause of the elevated exposures, dose rates, or concentrations; and

(iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with

applicable limits, ALARA constraints generally applicable environmental standards, and associated license or registration conditions.

2. Each report filed pursuant to 420-3-26-.03(53)(a) shall include for each occupationally overexposed individual: the name, Social Security account number, and date of birth. With respect to the limit for the embryo/fetus in 420-3-26-.03(13), the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

(c) All licensees or registrants who make reports pursuant to 420-3-26-.03(53)(a) shall submit the report in writing to the Agency.

(54) Reports of Planned Special Exposures. The licensee or registrant shall submit a written report to the Agency within 30 days following any planned special exposure conducted in accordance with 420-3-26-.03(11), informing the Agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by 420-3-26-.03(45).

(55) [Reserved].

(56) Reports of Individual Monitoring.

(a) This section applies to each person licensed or registered by the Agency to:

1. Possess or use sources of radiation for purposes of industrial radiography pursuant to 420-3-26-.02(10)(g) and 420-3-26-.04 of these rules; or

2. Receive radioactive waste from other persons for disposal pursuant to 420-3-26-0.03(10)(p) of these rules; or

3. Possess or use at any time, for processing or manufacturing for distribution pursuant to 420-3-26-.02 or 420-3-26-.07 of these rules, radioactive material in quantities exceeding any one of the following quantities:

Radionuclide	**Activity[a]**	
	Ci	**Gbq**
Cesium-137	1	37
Cobalt-60	1	37

Gold-198 100 3,700

Iodine-131 1 37

Iridium-192 10 370

Krypton-85 1,000 37,000

Promethium-147 10 370

Technetium- 99m 1,000 37,000

[a]The Agency may require as a license condition, or by rule, or order pursuant to 420-3-26-.03(60), reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

(b) Each licensee or registrant in a category listed in 420-3-26-.03(56) shall submit an annual report of the results of individual monitoring carried out by the licensee or registrant for each individual for whom monitoring was required by 420-3-26-.03(18) during that year. The licensee or registrant may include additional data for individuals for whom monitoring was provided but not required. The licensee or registrant shall use Agency Form Z or equivalent or electronic media containing all the information required by Agency Form Z.

(c) The licensee or registrant shall file the report required by 420-3-26-.03(56)(b), covering the preceding year, on or before April 30 of each year. The licensee or registrant shall submit the report to the Agency.

(57) Notifications and Reports to Individuals.

(a) Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in 420-3-26-.10(4) of these rules.

(b) When a licensee or registrant is required pursuant to 420-3-26-.03(53) to report to the Agency any exposure of an individual to radiation or radioactive material, the licensee or registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the Agency, and shall comply with the provisions of 420-3-26-.10(4)(a) of these rules.

(58) Reports of Leaking or Contaminated Sealed Sources. The licensee shall file a report within 5 days with the Agency if the test for leakage or contamination required pursuant to 420-3-26-.03(16) indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

(58.1) Reports of transactions Involving Nationally Tracked Sources. Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs (a) through (e) of this section for each type of transaction.

(a) Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of the source;

4. The radioactive material in the source;

5. The initial source strength in becquerels (curies) at the time of manufacture; and

6. The manufacture date of the source.

(b) Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The name and license number of the recipient facility and the shipping address;

4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

5. The radioactive material in the source;

6. The initial or current source strength in becquerels (curies);

7. The date for which the source strength is reported;

8. The shipping date;

9. The estimated arrival date; and

10. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest

number and the container identification of the container with the nationally tracked source.

(c) Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The name, address, and license number of the person that provided the source;

4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

5. The radioactive material in the source;

6. The initial or current source strength in becquerels (curies);

7. The date for which the source strength is reported;

8. The date of receipt; and

9. For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

(d) Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

4. The radioactive material in the source;

5. The initial or current source strength in becquerels (curies);

6. The date for which the source strength is reported;

7. The disassemble date of the source.

(e) Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The waste manifest number;

4. The container identification with the nationally tracked source.

5. The date of disposal; and

6. The method of disposal.

(f) The reports discussed in paragraphs (a) through (e) of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

1. The on-1ine National Source Tracking System;

2. Electronically using a computer readable format;

3. By facsimile;

4. By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

5. By telephone with follow-up by facsimile or mail.

(g) Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within 5 business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by regulation. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee’s data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs (a) through (e) of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

(h) Each licensee that possesses Category 1 and Category 2 nationally tracked sources shall report its initial inventory of such nationally tracked sources to the National Source Tracking System. The information may be submitted by using any of the methods identified by paragraph (f)(1) through (f)(4) of this

section. The initial inventory report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of each nationally tracked source or, if not available, other information to uniquely identify the source;

4. The radioactive material in the sealed source;

5. The initial or current source strength in becquerels (curies); and

6. The date for which the source strength is reported.

RADIOLOGICAL CRITERIA FOR LICENSE TERMINATION

(59) General Provisions.

(a) The criteria in this rule apply to the decommissioning of facilities licensed under 420-3-26-.02

(b) After a site has been decommissioned and the license terminated in accordance with the criteria in this rule, the Agency will require additional cleanup only if, based on new information, it determines that the criteria of this rule were not met and residual radioactivity remaining at the site could result in a significant threat to public health and safety.

(c) When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

(60) Radiological Criteria for Unrestricted Use. A site will be acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 millirem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

(61) Criteria for License Termination Under Restricted Conditions. A site will be considered acceptable for license termination under restricted conditions if:

(a) The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of 420-3-26-.03(60) would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

(b) The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) per year;

(c) The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

1. Funds placed into an account segregated from the licensee's assets and outside the licensee's administrative control as described in rule 420-3-26-.02(26)(g)1.

2. Surety method, insurance, or other guarantee method as described in rule 420-3-26-.02(26)(g)2.

3. A statement of intent in the case of Federal, State, or local Government licensees, as described in rule 420-3-26-.02(26)(g)4. or

4. When a governmental entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

(d) The licensee has submitted a decommissioning plan to the Agency indicating the licensee's intent to decommission in accordance with rule 420-3-26-.02(13)(d) and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

1. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

(i) Whether provisions for institutional controls proposed by the licensee:

I. Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 millirem (0.25 mSv) TEDE per year;

II. Will be enforceable; and

III. Will not impose undue burdens on the local community or other affected parties.

(ii) Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site;

2. In seeking advice on the issues identified in rule 420-3-26-.03(61)(d)1., the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

(e) Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

1. 100 millirem (1 mSv) per year; or

2. 500 millirem (5 mSv) per year provided the licensee does the following:

(i) Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem per year (1mSv per year) value of rule 420-3-26-.03(61)(e)1. Are not technically achievable, would be prohibitively expensive, or would result in net public or environmental harm;

(ii) Makes provisions for durable institutional controls;

(iii) Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out

periodic rechecks of the site no less frequently than every five years to assure that the institutional controls remain in place as necessary to meet the criteria of Rule 420-3-26-.03(61)(b) and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those listed in rule 420-3-26-.03(61)(c).

(62) **Alternate Criteria for License Termination.**

(a) The Agency may terminate a license using alternate criteria greater than the dose criterion listed in rules 420-3-26-.03(60), 420-3-26-.03(61)(b), and 420-3-26-.03(61)(d)1.(a), if the licensee:

1. Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than 100 millirem per year (1mSv per year), by submitting an analysis of possible sources of exposure;

2. Has employed to the extent practical restrictions on site use in accordance with Rule 420-3-26-.03(61) in minimizing exposures at the site; and

3. Reduces doses to ALARA levels, taking into account consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

4. Has submitted a decommissioning plan to the Agency indicating the licensee’s intent to decommission in accordance with 420-3-26-.02(13)(d), and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

(i) Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

(ii) An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

(iii) A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

5. Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out

responsibilities for any necessary control and maintenance of the site.

(b) The use of alternate criteria to terminate a license requires the approval of the Agency after consideration of Agency staff recommendations that will address any comments provided by Federal and other State Agencies including comments submitted by the public.

(63) **Public Notification and Public Participation.** Upon the receipt of a decommissioning plan from the licensee, or a proposal by the licensee, for release of a site pursuant to 420-3-26-.03(60) or 420-3-26-.03(61), or whenever the Agency deems such notice to be in the public interest, the Agency shall:

(a) Notify and solicit comments from:

1. Local and State government agencies in the vicinity of the site and other individuals who could be affected by the decommissioning of the site; and

2. Alabama Department of Environmental Management for cases where the licensee proposes to release a site pursuant to 420-3-26-.03(62).

(b) Publish a notice in local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to the individuals in the vicinity of the site, and solicit comments from affected parties.

(64) **Minimization of Contamination.**

(a) Applicants for licenses, other than renewals, after May 25, 2000, shall describe in the application how facility design and procedures for operation will minimize, to the extent practical, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, generation of radioactive waste.

(b) Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in 420-3-26-.03(5) and radiological criteria for license termination in 420-3-26-.03(60), (61), (62), and (63).

Author: Karl David Walter

Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-8, 22-14-9.

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420-3-26-.03-AA **Rule 3 - Appendix A - Assigned Protection Factors for Respirators.**

	Operating Mode	Assigned Protection factors
I. Air Purifying Respirators (Particulateb only)[c] :		
Filtering faceplate disposable[d] ...	Negative Pressure.....	([d])
Facepiece, half[c].....	Negative pressure	10
Facepiece, full.....	Negative pressure	100
Facepiece, half.....	Powered air-purifying respirators ..	50
Facepiece, full.....	Powered air-purifying respirators ..	1000
Helmet/ hood.....	Powered air-purifying respirators ..	1000
Facepiece, loose-fitting	Powered air-purifying respirators ..	25
II. Atmosphere supplying respirators (particulate, gases, and vaporsf):	Demand	
1. Air-line respirator:	Continuous flow	
Facepiece, half	Pressure demand	10
Facepiece, half	Demand	50
Facepiece, half	Continuous flow	50
Facepiece, full	Pressure demand	100
Facepiece, full	Continuous flow	1000
Facepiece, full	Continuous flow	1000
Helmet/hood	Continuous flow	1000
Facepiece, loose-fitting		25
Suit		([g])
2. Self-contained breathing Apparatus (SCBA):	Demand	
Facepiece, full	Pressure demand	
Facepiece, full	Demand, Recirculating	
Facepiece, full	Positive pressure Recirculating	[h]100
Facepiece, full		[i]10,000
III. Combination Respirators: Any combination of air-purifying and atmosphere-supplying respirators.	Assigned protection factor for type and mode of operation as listed above.	[h]100
		[i]10,000

FOOTNOTES:

[a] These assigned radiation protection factors apply only in a respiratory protection program that meets the requirements of this

rule. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead or, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations.

Radioactive contaminants for which the concentration values in Table 1, Column 3 of Appendix B of Rule 420-3-26-.03 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

[b] Air purifying respirators with APF less than 100 must be equipped with particulate filters that are at least 95 percent efficient. Air purifying respirators with APF equal to 100 must be equipped with particulate filters that are at least 99 percent efficient. Air purifying respirators with APFs greater than 100 must be equipped with particulate filters that are at least 99.97 percent efficient.

[c] The licensee may apply to the Agency for the use of an APF greater than 1 for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

[d] Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for use of the devices in estimating intake of dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use user check on this type of device. All other respiratory protection requirements listed in 10 CFR 20.1703 apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to 10 may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

[e] Under-chin only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of self-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least 95 percent efficient and all other requirements of Rule 420-3-26-.03 are met.

[f] The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption

or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of 3 is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

[g] No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., 10 CFR 20.1703).

[h] The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

[i] This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

Author:
Statutory Authority:
History:

420-3-26-.03-AB **Rule 3 - Appendix B - Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage.**

Introduction. For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 æm, micron, and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note: The values in Tables I, II, and III are page 1resented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6 x 10-2 or 0.06, 6E+2 represents 6 x 1O2 or 600, and 6E+0 represents 6 x 100 or 6.

Table I "Occupational Values"

Note that the columns in Table I of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "Reference Man" which would result in either (1) a committed effective dose equivalent of 0.05 Sv (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 Sv (50 rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 0.05 Sv (5 rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, wT. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of wT are listed under the definition of weighting factor in 420-3-26-.03(3)(q). The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $w_T = 0.06$ is applicable to each of the five organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining

tissues may be disregarded. The following portions of the GI tract -- stomach, small intestine, upper large intestine, and lower large intestine -- are to be treated as four separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;
St. wall = stomach wall;
Blad wall = bladder wall; and
Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 0.5 Sv (50 rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALIns) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, (intake (in µCi) of each radionuclide/ALIns) ó 1.0. If there is an external deep dose equivalent contribution of Hd, then this sum must be less than 1 - (Hd/50), instead of ó 1.0.

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

DAC = ALI(in æCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute) = [ALI/2.4 x 10^9] æCi/ml,

where 2×10^4 ml is the volume of air breathed per minute at work by Reference Man under working conditions of light work.

The DAC values relate to one of two modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See 420-3-26-.03(7). When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table II "Effluent Concentrations"

The columns in Table II of this appendix captioned "Effluents," "Air" and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of 420-3-26-.03(15). The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.5 mSv (0.05 rem).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not

always proportional as they were in Appendix A of this Rule of the eighth edition of Volume I of the Suggested State Regulations for Control of Radiation.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4 x 109, relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 0.05 Sv (5 rem) annual occupational dose limit to the 0.1 rem limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of Reference Man.

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

Table III "Releases to Sewers"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in 420-3-26-.03(35). The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3 x 106 (ml). The factor of 7.3 x 106 (ml) is composed of a factor of 7.3 x 105 (ml), the annual water intake by Reference Man, and a factor of 10, such that the concentrations, if the sewage released

by the licensee were the only source of water ingested by a Reference Man during a year, would result in a committed effective dose equivalent of 0.5 rem.

LIST OF ELEMENTS

	Atomic			Atomics	
Name	**Symbol**	**Number**	**Name**	**Symbol**	**Number**
Actinium	Ac	89	Mercury	Hg	80
Aluminum	Al	13	Molybdenum	Mo	42
Americium	Am	95	Neodymium	Nd	60
Antimony	Sb	51	Neptunium	Np	93
Argon	Ar	18	Nickel	Ni	28
Arsenic	As	33	Niobium	Nb	41
Astatine	At	85	Nitrogen	N	7
Barium	Ba	56	Osmium	Os	76
Berkelium	Bk	97	Oxygen	O	8
Beryllium	Be	4	Palladium	Pd	46
Bismuth	Bi	83	Phosphorus	P	15
Bromine	Br	35	Platinum	Pt	78
Cadmium	Cd	48	Plutonium	Pu	94
Calcium	Ca	20	Polonium	Po	84
Californium	Cf	98	Potassium	K	19
Carbon	C	6	Praseodymium	Pr	59
Cerium	Ce	58	Promethium	Pm	61
Cesium	Cs	55	Protactinium	Pa	91
Chlorine	Cl	17	Radium	Ra	88
Chromium	Cr	24	Radon	Rn	86
Cobalt	Co	27	Rhenium	Re	75
Copper	Cu	29	Rhodium	Rh	45
Curium	Cm	96	Rubidium	Rb	37
Dysprosium	Dy	66	Ruthenium	Ru	44
Einsteinium	Es	99	Samarium	Sm	62
Erbium	Er	68	Scandium	Sc	21
Europium	Eu	63	Selenium	Se	34
Fermium	Fm	100	Silicon	Si	14
Fluorine	F	9	Silver	Ag	47
Francium	Fr	87	Sodium	Na	11
Gadolinium	Gd	64	Strontium	Sr	38
Gallium	Ga	31	Sulfur	S	16
Germanium	Ge	32	Tantalum	Ta	73
Gold	Au	79	Technetium	Tc	43
Hafnium	Hf	72	Tellurium	Te	52
Holmium	Ho	67	Terbium	Tb	65
Hydrogen	H	1	Thallium	Tl	81
Indium	In	49	Thorium	Th	90
Iodine	I	53	Thulium	Tm	69
Iridium	Ir	77	Tin	Sn	50
Iron	Fe	26	Titanium	Ti	22
Krypton	Kr	36	Tungsten	W	74
Lanthanum	La	57	Uranium	U	92
Lead	Pb	82	Vanadium	V	23
Lutetium	Lu	71	Xenon	Xe	54
Magnesium	Mg	12	Ytterbium	Yb	70

	Atomic			Atomics	
Name	**Symbol**	**Number**	**Name**	**Symbol**	**Number**
Manganese	Mn	25	Yttrium	Y	39
Mendelevium	Md	101	Zinc	Zn	30
			Zirconium	Zr	40

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T_2) Submersion[1]: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	-	2E+4	8E-6	3E-8	-	-
4	Beryllium-10	W, see ^{7}Be	1E+3	2E+2	6E-8	2E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{7}Be	-	1E+1	6E-9	2E-11	-	-
6	Carbon-11[2]	Monoxide	-	1E+6	5E-4	2E-6	-	-
		Dioxide	-	6E+5	3E-4	9E-7	-	-
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	-	2E+6	7E-4	2E-6	-	-
		Dioxide	-	2E+5	9E-5	3E-7	-	-
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
8	Oxygen-15[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
9	Fluorine-18[2]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	-	9E+4	4E-5	1E-7	-	-
		Y, lanthanum fluoride	-	8E+4	3E-5	1E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	1E+3	5E-7	2E-9	-	-
13	Aluminum-26	D, all compounds excep those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	9E+1	4E-8	1E-10	-	-
14	Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and nitrates	-	3E+4	1E-5	5E-8	-	-
		Y, aluminosilicate glass	-	3E+4	1E-5	4E-8	-	-
14	Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	-	-
			LLI wall (3E+3)	-	--	4E-5	4E-4	
		W, see ^{31}Si	-	1E+2	5E-8	2E-10	-	-
		Y, see ^{31}Si	-	5E+0	2E-9	7E-12	-	-
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
		W, phosphates of Zn^{2+}, S^{3+}, Mg^{2+}, Fe^{3+}, Bi^{3+}, and lanthanides	-	4E+2	2E-7	5E-10	-	-
15	Phosphorus-33	D, see ^{32}P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
		W, see ^{32}P	-	3E+3	1E-6	4E-9	-	-
16	Sulfur-35	Vapor	-	1E+4	6E-6	2E-8	-	-
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	-	-
			LLI wall (8E+3)	-	--	1E-4	1E-3	

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
		W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3 -	2E+3	9E-7	3E-9	-	-
17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	-	2E+2	1E-7	3E-10	-	-
17	Chlorine-38[2]	D, see ^{36}Cl	2E+4 St wall (3E+4)	4E+4 -	2E-5 -	6E-8 -	- 3E-4	- 3E-3
		W, see ^{36}Cl	-	5E+4	2E-5	6E-8	-	-
17	Chlorine-39[2]	D, see ^{36}Cl	2E+4 St wall (4E+4)	5E+4 -	2E-5 -	7E-8 -	- 5E-4	- 5E-3
		W, see ^{36}Cl	-	6E+4	2E-5	8E-8	-	-
18	Argon-37	Submersion[1]	-	-	1E+0	6E-3	-	-
18	Argon-39	Submersion[1]	-	-	2E-4	8E-7	-	-
18	Argon-41	Submersion[1]	-	-	3E-6	1E-8	-	-
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
19	Potassium-44[2]	D, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
		St wall	(4E+4)	-	-	-	5E-4	5E-3
19	Potassium-45[2]	D, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
		St wall	(5E+4)	-	-	-	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+3	4E+3	2E-6	-	-	-
			Bone surf (4E+3)	Bone surf (4E+3)	-	5E-9	6E-5	6E-4
20	Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20	Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21	Scandium-49[2]	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
22	Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	-	3E+1	1E-8	4E-11	-	-
		Y, SrTi0	-	6E+0	2E-9	8E-12	-	-
22	Titanium-45	D, see ^{44}Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{44}Ti	-	4E+4	1E-5	5E-8	-	-
		Y, see ^{44}Ti	-	3E+4	1E-5	4E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
23	Vanadium-47[2]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, oxides, hydroxides, carbides, and halides	-	1E+5	4E-5	1E-7	-	-
23	Vanadium-48	D, see ^{47}V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
		W, see ^{47}V	-	6E+2	3E-7	9E-10	-	-
23	Vanadium-49	D, see ^{47}V	7E+4	3E+4	1E-5	-	-	-
			LLI wall (9E+4)	Bone surf (3E+4)	-	5E-8	1E-3	1E-2
		W, see ^{47}V	-	2E+4	8E-6	2E-8	-	-
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	-	7E+3	3E-6	1E-8	-	-
		Y, oxides and hydroxides	-	7E+3	3E-6	1E-8	-	-
24	Chromium-49[2]	D, see ^{48}Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{48}Cr	-	1E+5	4E-5	1E-7	-	-
		Y, see ^{48}Cr	-	9E+4	4E-5	1E-7	-	-
24	Chromium-51	D, see ^{48}Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see ^{48}Cr	-	2E+4	1E-5	3E-8	-	-
		Y, see ^{48}Cr	-	2E+4	8E-6	3E-8	-	-
25	Manganese-51[2]	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	8E-8	-	-
25	Manganese-52m[2]	D, see ^{51}Mn	3E+4	9E+4	4E-5	1E-7	--	
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{51}Mn	-	1E+5	4E-5	1E-7	-	-
25	Manganese-52	D, see ^{51}Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
		W, see ^{51}Mn	-	9E+2	4E-7	1E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
25	Manganese-53	D, see ^{51}Mn	5E+4	1E+4	5E-6	-	7E-4	7E-3
				Bone surf				
			-	(2E+4)	-	3E-8	-	-
		W, see ^{51}Mn	-	1E+4	5E-6	2E-8	-	-
25	Manganese-54	D, see ^{51}Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see ^{51}Mn	-	8E+2	3E-7	1E-9	-	-
25	Manganese-56	D, see ^{51}Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{51}Mn	-	2E+4	9E-6	3E-8	-	-
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	-	2E+3	1E-6	3E-9	-	-
26	Iron-55	D, see ^{52}Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see ^{52}Fe	-	4E+3	2E-6	6E-9	-	-
26	Iron-59	D, see ^{52}Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see ^{52}Fe	-	5E+2	2E-7	7E-10	-	-
26	Iron-60	D, see ^{52}Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see ^{52}Fe	-	2E+1	8E-9	3E-11	-	-
27	Cobalt-55	W, all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
27	Cobalt-56	W, see ^{55}Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see ^{55}Co	4E+2	2E+2	8E-8	3E-10	-	-
27	Cobalt-57	W, see ^{55}Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see ^{55}Co	4E+3	7E+2	3E-7	9E-10	-	-
27	Cobalt-58m	W, see ^{55}Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see ^{55}Co	-	6E+4	3E-5	9E-8	-	-
27	Cobalt-58	W, see ^{55}Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see ^{55}Co	1E+3	7E+2	3E-7	1E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
27	Cobalt-60m[2]	W, see ^{55}Co	1E+6 St wall (1E+6)	4E+6 -	2E-3 -	6E-6 -	- 2E-2	- 2E-1
		Y, see ^{55}Co	-	3E+6	1E-3	4E-6	-	-
27	Cobalt-60	W, see ^{55}Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see ^{55}Co	2E+2	3E+1	1E-8	5E-11	-	-
27	Cobalt-61[2]	W, see ^{55}Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{55}Co	2E+4	6E+4	2E-5	8E-8	-	-
27	Cobalt-62m[2]	W, see ^{55}Co	4E+4 St wall (5E+4)	2E+5 -	7E-5 -	2E-7 -	- 7E-4	- 7E-3
		Y, see ^{55}Co	-	2E+5	6E-5	2E-7	-	-
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		W, oxides, hydroxides, and carbides	-	1E+3	5E-7	2E-9	-	-
		Vapor	-	1E+3	5E-7	2E-9	-	-
28	Nickel-57	D, see ^{56}Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{56}Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	6E+3	3E-6	9E-9	-	-
28	Nickel-59	D, see ^{56}Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
		W, see ^{56}Ni	-	7E+3	3E-6	1E-8	-	-
		Vapor	-	2E+3	8E-7	3E-9	-	-
28	Nickel-63	D, see ^{56}Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
		W, see ^{56}Ni	-	3E+3	1E-6	4E-9	-	-
		Vapor	-	8E+2	3E-7	1E-9	-	-
28	Nickel-65	D, see ^{56}Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{56}Ni	-	3E+4	1E-5	4E-8	-	-
		Vapor	-	2E+4	7E-6	2E-8	-	-
28	Nickel-66	D, see ^{56}Ni	4E+2 LLI wall	2E+3	7E-7	2E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
			(5E+2)	-	-	-	6E-6	6E-5
		W, see ^{56}Ni	-	6E+2	3E-7	9E-10	-	-
		Vapor	-	3E+3	1E-6	4E-9	-	-
29	Copper-60[2]	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	4E-5	1E-7	-	-
29	Copper-61	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	-	4E+4	2E-5	6E-8	-	-
		Y, see ^{60}Cu	-	4E+4	1E-5	5E-8	-	-
29	Copper-64	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	-	2E+4	1E-5	3E-8	-	-
		Y, see ^{60}Cu	-	2E+4	9E-6	3E-8	-	-
29	Copper-67	D, see ^{60}Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see ^{60}Cu	-	5E+3	2E-6	7E-9	-	-
		Y, see ^{60}Cu	-	5E+3	2E-6	6E-9	-	-
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-63[2]	Y, all compounds	2E+4	7E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	3E-4	3E-3
30	Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-69[2]	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
31	Gallium-65[2]	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	-	2E+5	8E-5	3E-7	-	-
31	Gallium-66	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-67	D, see ^{65}Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see ^{65}Ga	-	1E+4	4E-6	1E-8	-	-
31	Gallium-68[2]	D, see ^{65}Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{65}Ga	-	5E+4	2E-5	7E-8	-	-
31	Gallium-70[2]	D, see ^{65}Ga	5E+4	2E+5	7E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		W, see ^{65}Ga	-	2E+5	8E-5	3E-7	-	-
31	Gallium-72	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{65}Ga	-	3E+3	1E-6	4E-9	-	-
31	Gallium-73	D, see ^{65}Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{65}Ga	-	2E+4	6E-6	2E-8	-	-
32	Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
		W, oxides, sulfides, and halides	-	2E+4	8E-6	3E-8	-	-
32	Germanium-67[2]	D, see ^{66}Ge	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, see ^{66}Ge	-	1E+5	4E-5	1E-7	-	-
32	Germanium-68	D, see ^{66}Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see ^{66}Ge	-	1E+2	4E-8	1E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
32	Germanium-69	D, see ^{66}Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see ^{66}Ge	-	8E+3	3E-6	1E-8	-	-
32	Germanium-71	D, see ^{66}Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
		W, see ^{66}Ge	-	4E+4	2E-5	6E-8	-	-
32	Germanium-75[2]	D, see ^{66}Ge	4E+4	8E+4	3E-5	1E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see ^{66}Ge	-	8E+4	4E-5	1E-7	-	-
32	Germanium-77	D, see ^{66}Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see ^{66}Ge	-	6E+3	2E-6	8E-9	-	-
32	Germanium-78[2]	D, see ^{66}Ge	2E+4	2E+4	9E-6	3E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, see ^{66}Ge	-	2E+4	9E-6	3E-8	-	-
33	Arsenic-69[2]	W, all compounds	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
33	Arsenic-70[2]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	6E-5	6E-4
33	Arsenic-78[2]	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
34	Selenium-70[2]	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	-	-
34	Selenium-73m[2]	D, see ^{70}Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	6E-5	2E-7	-	-
34	Selenium-73	D, see ^{70}Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
		W, see ^{70}Se	-	2E+4	7E-6	2E-8	-	-
34	Selenium-75	D, see ^{70}Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
		W, see ^{70}Se	-	6E+2	3E-7	8E-10	-	-
34	Selenium-79	D, see ^{70}Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
		W, see ^{70}Se	-	6E+2	2E-7	8E-10	-	-
34	Selenium-81m[2]	D, see ^{70}Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{70}Se	2E+4	7E+4	3E-5	1E-7	-	-
34	Selenium-81[2]	D, see ^{70}Se	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		W, see ^{70}Se	-	2E+5	1E-4	3E-7	-	-
34	Selenium-83[2]	D, see ^{70}Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	5E-5	2E-7	-	-
35	Bromine-74m[2]	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	-	-
			St wall (2E+4)	-	-	-	3E-4	3E-3
		W, bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	-	4E+4	2E-5	6E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
35	Bromine-74[2]	D, see ^{74m}Br	2E+4	7E+4	3E-5	1E-7	-	-
		St wall	(4E+4)	-	-	-	5E-4	5E-3
		W, see ^{74m}Br	-	8E+4	4E-5	1E-7	-	-
35	Bromine-75[2]	D, see ^{74m}Br	3E+4	5E+4	2E-5	7E-8	-	-
		St wall	(4E+4)	-	-	-	5E-4	5E-3
		W, see ^{74m}Br	-	5E+4	2E-5	7E-8	-	-
35	Bromine-76	D, see ^{74m}Br	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see ^{74m}Br	-	4E+3	2E-6	6E-9	-	-
35	Bromine-77	D, see ^{74m}Br	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see ^{74m}Br	-	2E+4	8E-6	3E-8	-	-
35	Bromine-80m	D, see ^{74m}Br	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see ^{74m}Br	-	1E+4	6E-6	2E-8	-	-
35	Bromine-80[2]	D, see ^{74m}Br	5E+4	2E+5	8E-5	3E-7	-	-
		St wall	(9E+4)	-	-	-	1E-3	1E-2
		W, see ^{74m}Br	-	2E+5	9E-5	3E-7	-	-
35	Bromine-82	D, see ^{74m}Br	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{74m}Br	-	4E+3	2E-6	5E-9	-	-
35	Bromine-83	D, see ^{74m}Br	5E+4	6E+4	3E-5	9E-8	-	-
		St wall	(7E+4)	-	-	-	9E-4	9E-3
		W, see ^{74m}Br	-	6E+4	3E-5	9E-8	-	-
35	Bromine-84[2]	D, see ^{74m}Br	2E+4	6E+4	2E-5	8E-8	-	-
		St wall	(3E+4)	-	-	-	4E-4	4E-3
		W, see ^{74m}Br	-	6E+4	3E-5	9E-8	-	-
36	Krypton-74[2]	Submersion[1]	-	-	3E-6	1E-8	-	-
36	Krypton-76	Submersion[1]	-	-	9E-6	4E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
36	Krypton-77[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
36	Krypton-79	Submersion[1]	-	-	2E-5	7E-8	-	-
36	Krypton-81	Submersion[1]	-	-	7E-4	3E-6	-	-
36	Krypton-83m[2]	Submersion[1]	-	-	1E-2	5E-5	-	-
36	Krypton-85m	Submersion[1]	-	-	2E-5	1E-7	-	-
36	Krypton-85	Submersion[1]	-	-	1E-4	7E-7	-	-
36	Krypton-87[2]	Submersion[1]	-	-	5E-6	2E-8	-	-
36	Krypton-88	Submersion[1]	-	-	2E-6	9E-9	-	-
37	Rubidium-79[2]	D, all compounds	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
37	Rubidium-81m[2]	D, all compounds	2E+5	3E+5	1E-4	5E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rubidium-88[2]	D, all compounds	2E+4	6E+4	3E-5	9E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
37	Rubidium-89[2]	D, all compounds	4E+4	1E+5	6E-5	2E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
			St wall (6E+4)	-	-	-	9E-4	9E-3
38	Strontium-80[2]	D, all soluble compounds except SrTiO	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and SrTi0	-	1E+4	5E-6	2E-8	-	-
38	Strontium-81[2]	D, see ^{80}Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{80}Sr	2E+4	8E+4	3E-5	1E-7	-	-
38	Strontium-82	D, see ^{80}Sr	3E+2	4E+2	2E-7	6E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		Y, see ^{80}Sr	2E+2	9E+1	4E-8	1E-10	-	-
38	Strontium-83	D, see ^{80}Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{80}Sr	2E+3	4E+3	1E-6	5E-9	-	-
38	Strontium-85m[2]	D, see ^{80}Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see ^{80}Sr	-	8E+5	4E-4	1E-6	-	-
38	Strontium-85	D, see ^{80}Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see ^{80}Sr	-	2E+3	6E-7	2E-9	-	-
38	Strontium-87m	D, see ^{80}Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{80}Sr	4E+4	2E+5	6E-5	2E-7	-	-
38	Strontium-89	D, see ^{80}Sr	6E+2	8E+2	4E-7	1E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see ^{80}Sr	5E+2	1E+2	6E-8	2E-10	-	-
38	Strontium-90	D, see ^{80}Sr	3E+1	2E+1	8E-9	-	-	-
			Bone surf (4E+1)	Bone surf (2E+1)	-	3E-11	5E-7	5E-6
		Y, see ^{80}Sr	-	4E+0	2E-9	6E-12	-	-
38	Strontium-91	D, see ^{80}Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see ^{80}Sr	-	4E+3	1E-6	5E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
38	Strontium-92	D, see ^{80}Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{80}Sr	-	7E+3	3E-6	9E-9	-	-
39	Yttrium-86m[2]	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	-	5E+4	2E-5	8E-8	-	-
39	Yttrium-86	W, see ^{86m}Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{86m}Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-87	W, see ^{86m}Y	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see ^{86m}Y	-	3E+3	1E-6	5E-9	-	-
39	Yttrium-88	W, see ^{86m}Y	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see ^{86m}Y	-	2E+2	1E-7	3E-10	-	-
39	Yttrium-90m	W, see ^{86m}Y	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see ^{86m}Y	-	1E+4	5E-6	2E-8	-	-
39	Yttrium-90	W, see ^{86m}Y	4E+2	7E+2	3E-7	9E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see ^{86m}Y	-	6E+2	3E-7	9E-10	-	-
39	Yttrium-91m[2]	W, see ^{86m}Y	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see ^{86m}Y	-	2E+5	7E-5	2E-7	-	-
39	Yttrium-91	W, see ^{86m}Y	5E+2	2E+2	7E-8	2E-10	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		Y, see ^{86m}Y	-	1E+2	5E-8	2E-10	-	-
39	Yttrium-92	W, see ^{86m}Y	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{86m}Y	-	8E+3	3E-6	1E-8	-	-
39	Yttrium-93	W, see ^{86m}Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{86m}Y	-	2E+3	1E-6	3E-9	-	-
39	Yttrium-94[2]	W, see ^{86m}Y	2E+4	8E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, see ^{86m}Y	-	8E+4	3E-5	1E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
39	Yttrium-95[2]	W, see ^{86m}Y	4E+4	2E+5	6E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{86m}Y	-	1E+5	6E-5	2E-7	-	-
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, oxides, hydroxides, halides, and nitrates	-	3E+3	1E-6	4E-9	-	-
		Y, carbide	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-88	D, see ^{86}Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
		W, see ^{86}Zr	-	5E+2	2E-7	7E-10	-	-
		Y, see ^{86}Zr	-	3E+2	1E-7	4E-10	-	-
40	Zirconium-89	D, see ^{86}Zr	2E+3	4E+3	1E-6	5E-9	2E-5	
			2E-4					
		W, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
		Y, see ^{86}Zr	-	2E+3	1E-6	3E-9	-	-
40	Zirconium-93	D, see ^{86}Zr	1E+3	6E+0	3E-9	-	-	-
			Bone surf (3E+3)	Bone surf (2E+1)	-	2E-11	4E-5	
			4E-4					
		W, see ^{86}Zr	-	2E+1	1E-8	-	-	-
			-	Bone surf (6E+1)	-	9E-11	-	-
		Y, see ^{86}Zr	-	6E+1	2E-8	-	-	-
			-	Bone surf (7E+1)	-	9E-11	-	-
40	Zirconium-95	D, see ^{86}Zr	1E+3	1E+2	5E-8	-	2E-5	
			2E-4					
			-	Bone surf (3E+2)	-	4E-10	-	-
		W, see ^{86}Zr	-	4E+2	2E-7	5E-10	-	-
		Y, see ^{86}Zr	-	3E+2	1E-7	4E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
40	Zirconium-97	D, see ^{86}Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
		W, see ^{86}Zr	-	1E+3	6E-7	2E-9	-	-
		Y, see ^{86}Zr	-	1E+3	5E-7	2E-9	-	-
41	Niobium-88[2]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides and hydroxides	-	2E+5	9E-5	3E-7	-	-
41	Niobium-89[2] (66 min)	W, see ^{88}Nb	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see ^{88}Nb	-	4E+4	2E-5	5E-8	-	-
41	Niobium-89 (122 min)	W, see ^{88}Nb	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{88}Nb	-	2E+4	6E-6	2E-8	-	-
41	Niobium-90	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-
41	Niobium-93m	W, see ^{88}Nb	9E+3	2E+3	8E-7	3E-9	--	
			LLI wall (1E+4)	-	-	-	2E-4	2E-3
		Y, see ^{88}Nb	-	2E+2	7E-8	2E-10	--	
41	Niobium-94	W, see ^{88}Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
		Y, see ^{88}Nb	-	2E+1	6E-9	2E-11	-	-
41	Niobium-95m	W, see ^{88}Nb	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{88}Nb	-	2E+3	9E-7	3E-9	-	-
41	Niobium-95	W, see ^{88}Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		Y, see ^{88}Nb	-	1E+3	5E-7	2E-9	-	-
41	Niobium-96	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{88}Nb	-	2E+3	1E-6	3E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
41	Niobium-97[2]	W, see ^{88}Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{88}Nb	-	7E+4	3E-5	1E-7	-	-
41	Niobium-98[2]	W, see ^{88}Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see ^{88}Nb	-	5E+4	2E-5	7E-8	-	-
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, oxides, hydroxides, and MoS	2E+3	5E+3	2E-6	6E-9	-	-
42	Molybdenum-93m	D, see ^{90}Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
		Y, see ^{90}Mo	4E+3	1E+4	6E-6	2E-8	-	-
42	Molybdenum-93	D, see ^{90}Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		Y, see ^{90}Mo	2E+4	2E+2	8E-8	2E-10	-	-
42	Molybdenum-99	D, see ^{90}Mo	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{90}Mo	1E+3	1E+3	6E-7	2E-9	-	-
42	Molybdenum-101[2]	D, see ^{90}Mo	4E+4	1E+5	6E-5	2E-7	--	
			St wall (5E+4)	-	-	-	7E-4	7E-3
		Y, see ^{90}Mo	-	1E+5	6E-5	2E-7	-	-
43	Technetium-93m[2]	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	-	3E+5	1E-4	4E-7	-	-
43	Technetium-93	D, see ^{93m}Tc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see ^{93m}Tc	-	1E+5	4E-5	1E-7	-	-
43	Technetium-94m[2]	D, see ^{93m}Tc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{93m}Tc	-	6E+4	2E-5	8E-8	-	-
43	Technetium-94	D, see ^{93m}Tc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	-	2E+4	1E-5	3E-8	--	

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
43	Technetium-95m	D, see ^{93m}Tc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see ^{93m}Tc	-	2E+3	8E-7	3E-9	-	-
43	Technetium-95	D, see ^{93m}Tc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	-	2E+4	8E-6	3E-8	-	-
43	Technetium-96m[2]	D, see ^{93m}Tc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-96	D, see ^{93m}Tc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{93m}Tc	-	2E+3	9E-7	3E-9	-	-
43	Technetium-97m	D, see ^{93m}Tc	5E+3	7E+3	3E-6	-	6E-5	6E-4
			St wall -	(7E+3)	-	1E-8	-	-
		W, see ^{93m}Tc	-	1E+3	5E-7	2E-9	-	-
43	Technetium-97	D, see ^{93m}Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see ^{93m}Tc	-	6E+3	2E-6	8E-9	-	-
43	Technetium-98	D, see ^{93m}Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{93m}Tc	-	3E+2	1E-7	4E-10	-	-
43	Technetium-99m	D, see ^{93m}Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{93m}Tc	-	2E+5	1E-4	3E-7	-	-
43	Technetium-99	D, see ^{93m}Tc	4E+3	5E+3	2E-6	-	6E-5	6E-4
			St wall -	(6E+3)	-	8E-9	-	-
		W, see ^{93m}Tc	-	7E+2	3E-7	9E-10	-	-
43	Technetium-101[2]	D, see ^{93m}Tc	9E+4	3E+5	1E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, see ^{93m}Tc	-	4E+5	2E-4	5E-7	-	-
43	Technetium-104[2]	D, see ^{93m}Tc	2E+4	7E+4	3E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see ^{93m}Tc	-	9E+4	4E-5	1E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
44	Ruthenium-94[2]	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, halides	-	6E+4	3E-5	9E-8	-	-
		Y, oxides and hydroxides	-	6E+4	2E-5	8E-8	-	-
44	Ruthenium-97	D, see ^{94}Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
		Y, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-103	D, see ^{94}Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see ^{94}Ru	-	1E+3	4E-7	1E-9	-	-
		Y, see ^{94}Ru	-	6E+2	3E-7	9E-10	-	-
44	Ruthenium-105	D, see ^{94}Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{94}Ru	-	1E+4	6E-6	2E-8	-	-
		Y, see ^{94}Ru	-	1E+4	5E-6	2E-8	-	-
44	Ruthenium-106	D, see ^{94}Ru	2E+2	9E+1	4E-8	1E-10	-	-
			LLI wall (2E+2)	-	-	-	3E-6	3E-5
		W, see ^{94}Ru	-	5E+1	2E-8	8E-11	-	-
		Y, see ^{94}Ru	-	1E+1	5E-9	2E-11	-	-
45	Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		W, halides	-	8E+4	3E-5	1E-7	-	-
		Y, oxides and hydroxides	-	7E+4	3E-5	9E-8	-	-
45	Rhodium-99	D, see ^{99m}Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{99m}Rh	-	2E+3	9E-7	3E-9	-	-
		Y, see ^{99m}Rh	-	2E+3	8E-7	3E-9	-	-
45	Rhodium-100	D, see ^{99m}Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{99m}Rh	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{99m}Rh	-	4E+3	2E-6	5E-9	-	-
45	Rhodium-101m	D, see ^{99m}Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{99m}Rh	-	8E+3	4E-6	1E-8	-	-
		Y, see ^{99m}Rh	-	8E+3	3E-6	1E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
45	Rhodium-101	D, see ^{99m}Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{99m}Rh	-	8E+2	3E-7	1E-9	-	-
		Y, see ^{99m}Rh	-	2E+2	6E-8	2E-10	-	-
45	Rhodium-102m	D, see ^{99m}Rh	1E+3	5E+2	2E-7	7E-10	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		W, see ^{99m}Rh	-	4E+2	2E-7	5E-10	-	-
		Y, see ^{99m}Rh	-	1E+2	5E-8	2E-10	-	-
45	Rhodium-102	D, see ^{99m}Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see ^{99m}Rh	-	2E+2	7E-8	2E-10	-	-
		Y, see ^{99m}Rh	-	6E+1	2E-8	8E-11	-	-
45	Rhodium-103m[2]	D, see ^{99m}Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
		Y, see ^{99m}Rh	-	1E+6	5E-4	2E-6	-	-
45	Rhodium-105	D, see ^{99m}Rh	4E+3	1E+4	5E-6	2E-8	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see ^{99m}Rh	-	6E+3	3E-6	9E-9	-	-
		Y, see ^{99m}Rh	-	6E+3	2E-6	8E-9	-	-
45	Rhodium-106m	D, see ^{99m}Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{99m}Rh	-	4E+4	2E-5	5E-8	-	-
		Y, see ^{99m}Rh	-	4E+4	1E-5	5E-8	-	-
45	Rhodium-107[2]	D, see ^{99m}Rh	7E+4	2E+5	1E-4	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{99m}Rh	-	3E+5	1E-4	4E-7	-	-
		Y, see ^{99m}Rh	-	3E+5	1E-4	3E-7	-	-
46	Palladium-100	D, all compounds except those given for W and Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	-	1E+3	5E-7	2E-9	-	-
		Y, oxides and hydroxides	-	1E+3	6E-7	2E-9	-	-
46	Palladium-101	D, see ^{100}Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{100}Pd	-	3E+4	1E-5	5E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
		Y, see ^{100}Pd	-	3E+4	1E-5	4E-8	-	-
46	Palladium-103	D, see ^{100}Pd	6E+3	6E+3	3E-6	9E-9	-	-
			LLI wall (7E+3)	-	-	-	1E-4	1E-3
		W, see ^{100}Pd	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{100}Pd	-	4E+3	1E-6	5E-9	-	-
46	Palladium-107	D, see ^{100}Pd	3E+4 LLI wall	2E+4 Kidneys	9E-6	-	-	-
47	Silver-111	D, see ^{102}Ag	9E+2	2E+3	6E-7	-	-	-
			LLI wall (1E+3)	Liver (2E+3)	-	2E-9	2E-5	2E-4
		W, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
		Y, see ^{102}Ag	-	9E+2	4E-7	1E-9	-	-
47	Silver-112	D, see ^{102}Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{102}Ag	-	1E+4	4E-6	1E-8	-	-
		Y, see ^{102}Ag	-	9E+3	4E-6	1E-8	-	-
47	Silver-115[2]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		W, see ^{102}Ag	-	9E+4	4E-5	1E-7	-	-
		Y, see ^{102}Ag	-	8E+4	3E-5	1E-7	-	-
48	Cadmium-104[2]	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, sulfides, halides, and nitrates	-	1E+5	5E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
48	Cadmium-107	D, see ^{104}Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{104}Cd	-	6E+4	2E-5	8E-8	-	-
		Y, see ^{104}Cd	-	5E+4	2E-5	7E-8	-	-
48	Cadmium-109	D, see ^{104}Cd	3E+2	4E+1	1E-8	-	-	-
			Kidneys (4E+2)	Kidneys (5E+1)	-	7E-11	6E-6	6E-5

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
		W, see ^{104}Cd	-	1E+2 Kidneys	5E-8	-	-	-
			-	(1E+2)	-	2E-10	-	-
		Y, see ^{104}Cd	-	1E+2	5E-8	2E-10	-	-
48	Cadmium-113m	D, see ^{104}Cd	2E+1 Kidneys	2E+0 Kidneys	1E-9	-	-	-
			(4E+1)	(4E+0)	-	5E-12	5E-7	5E-6
		W, see ^{104}Cd	-	8E+0 Kidneys	4E-9	-	-	-
			-	(1E+1)	-	2E-11	-	-
		Y, see ^{104}Cd	-	1E+1	5E-9	2E-11	-	-
48	Cadmium-113	D, see ^{104}Cd	2E+1 Kidneys	2E+0 Kidneys	9E-10	-	-	-
			(3E+1)	(3E+0)	-	5E-12	4E-7	4E-6
		W, see ^{104}Cd	-	8E+0 Kidneys	3E-9	-	-	-
			-	(1E+1)	-	2E-11	-	-
		Y, see ^{104}Cd	-	1E+1	6E-9	2E-11	-	-
48	Cadmium-115m	D, see ^{104}Cd	3E+2	5E+1 Kidneys	2E-8	-	4E-6	4E-5
			-	(8E+1)	-	1E-10	-	-
		W, see ^{104}Cd	-	1E+2	5E-8	2E-10	-	-
		Y, see ^{104}Cd	-	1E+2	6E-8	2E-10	-	-
48	Cadmium-115	D, see ^{104}Cd	9E+2 LLI wall	1E+3	6E-7	2E-9	-	-
			(1E+3)	-	-	-	1E-5	1E-4
		W, see ^{104}Cd	-	1E+3	5E-7	2E-9	-	-
		Y, see ^{104}Cd	-	1E+3	6E-7	2E-9	-	-
48	Cadmium-117m	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see ^{104}Cd	-	1E+4	6E-6	2E-8	-	-
48	Cadmium-117	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	-	2E+4	7E-6	2E-8	-	-
		Y, see ^{104}Cd	-	1E+4	6E-6	2E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values: Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values: Inhalation Col. 2 ALI (µCi)	Table I Occupational Values: Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration: Col. 1 Air (µCi/ml)	Table II Effluent Concentration: Col. 2 Water (µCi/ml)	Table III Releases to Sewers: Monthly Average Concentration (µCi/ml)
49	Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	-	6E+4	3E-5	9E-8	-	-
49	Indium-110[2] (69.1 min)	D, see ^{109}In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	-	6E+4	2E-5	8E-8	--	
49	Indium-110 (4.9 h)	D, see ^{109}In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		W, see ^{109}In	-	2E+4	8E-6	3E-8	-	-
49	Indium-111	D, see ^{109}In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
		W, see ^{109}In	-	6E+3	3E-6	9E-9	-	-
49	Indium-112[2]	D, see ^{109}In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
		W, see ^{109}In	-	7E+5	3E-4	1E-6	-	-
49	Indium-113m[2]	D, see ^{109}In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		W, see ^{109}In	-	2E+5	8E-5	3E-7	-	-
49	Indium-114m	D, see ^{109}In	3E+2	6E+1	3E-8	9E-11	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		W, see ^{109}In	-	1E+2	4E-8	1E-10	-	-
49	Indium-115m	D, see ^{109}In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	-	5E+4	2E-5	7E-8	-	-
49	Indium-115	D, see ^{109}In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
		W, see ^{109}In	-	5E+0	2E-9	8E-12	-	-
49	Indium-116m[2]	D, see ^{109}In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{109}In	-	1E+5	5E-5	2E-7	-	-
49	Indium-117m[2]	D, see ^{109}In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{109}In	-	4E+4	2E-5	6E-8	-	-
49	Indium-117[2]	D, see ^{109}In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see ^{109}In	-	2E+5	9E-5	3E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
49	Indium-119m[2]	D, see ^{109}In	4E+4	1E+5	5E-5	2E-7	-	-
			St wall (5E+4)	-	-	-	7E-4	7E-3
		W, see ^{109}In	-	1E+5	6E-5	2E-7	-	-
50	Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	-	1E+4	5E-6	2E-8	-	-
50	Tin-111[2]	D, see ^{110}Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
		W, see ^{110}Sn	-	3E+5	1E-4	4E-7	-	-
50	Tin-113	D, see ^{110}Sn	2E+3	1E+3	5E-7	2E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-117m	D, see ^{110}Sn	2E+3	1E+3	5E-7	-	-	-
			LLI wall (2E+3)	Bone surf (2E+3)	-	3E-9	3E-5	3E-4
		W, see ^{110}Sn	-	1E+3	6E-7	2E-9	-	-
50	Tin-119m	D, see ^{110}Sn	3E+3	2E+3	1E-6	3E-9	-	-
			LLI wall (4E+3)	-	-	-	6E-5	6E-4
		W, see ^{110}Sn	-	1E+3	4E-7	1E-9	-	-
50	Tin-121m	D, see ^{110}Sn	3E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (4E+3)	-	-	-	5E-5	5E-4
		W, see ^{110}Sn	-	5E+2	2E-7	8E-10	-	-
50	Tin-121	D, see ^{110}Sn	6E+3	2E+4	6E-6	2E-8	-	-
			LLI wall (6E+3)	-	-	-	8E-5	8E-4
		W, see ^{110}Sn	-	1E+4	5E-6	2E-8	-	-
50	Tin-123m[2]	D, see ^{110}Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
		W, see ^{110}Sn	-	1E+5	6E-5	2E-7	-	-
50	Tin-123	D, see ^{110}Sn	5E+2	6E+2	3E-7	9E-10	-	-
			LLI wall (6E+2)	-	-	-	9E-6	9E-5
		W, see ^{110}Sn	-	2E+2	7E-8	2E-10	-	-
50	Tin-125	D, see ^{110}Sn	4E+2	9E+2	4E-7	1E-9	-	-
			LLI wall (5E+2)	-	-	-	6E-6	6E-5
		W, see ^{110}Sn	-	4E+2	1E-7	5E-10	-	-
50	Tin-126	D, see ^{110}Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
		W, see ^{110}Sn	-	7E+1	3E-8	9E-11	-	-
50	Tin-127	D, see ^{110}Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		W, see ^{110}Sn	-	2E+4	8E-6	3E-8	-	-
50	Tin-128[2]	D, see ^{110}Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{110}Sn	-	4E+4	1E-5	5E-8	-	-
51	Antimony-115[2]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	-	3E+5	1E-4	4E-7	-	-
51	Antimony-116m[2]	D, see ^{115}Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{115}Sb	-	1E+5	6E-5	2E-7	-	-
51	Antimony-116[2]	D, see ^{115}Sb	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{115}Sb	-	3E+5	1E-4	5E-7	-	-
51	Antimony-117	D, see ^{115}Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see ^{115}Sb	-	3E+5	1E-4	4E-7	-	-
51	Antimony-118m	D, see ^{115}Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see ^{115}Sb	5E+3	2E+4	9E-6	3E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
51	Antimony-119	D, see ^{115}Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{115}Sb	2E+4	3E+4	1E-5	4E-8	-	-
51	Antimony-120[2] (16 min)	D, see ^{115}Sb	1E+5	4E+5	2E-4	6E-7	-	-
			St wall (2E+5)	-	-	-	2E-3	2E-2
		W, see ^{115}Sb	-	5E+5	2E-4	7E-7	-	-
51	Antimony-120 (5.76 d)	D, see ^{115}Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see ^{115}Sb	9E+2	1E+3	5E-7	2E-9	-	-
51	A ntimony-122	D, see ^{115}Sb	8E+2	2E+3	1E-6	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see ^{115}Sb	7E+2	1E+3	4E-7	2E-9	-	-
51	Antimony-124m[2]	D, see ^{115}Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see ^{115}Sb	2E+5	6E+5	2E-4	8E-7	-	-
51	Antimony-124	D, see ^{115}Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	2E+2	1E-7	3E-10	-	-
51	Antimony-125	D, see ^{115}Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
		W, see ^{115}Sb	-	5E+2	2E-7	7E-10	-	-
51	Antimony-126m[2]	D, see ^{115}Sb	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (7E+4)	-	-	-	9E-4	9E-3
		W, see ^{115}Sb	-	2E+5	8E-5	3E-7	-	-
51	Antimony-126	D, see ^{115}Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	5E+2	2E-7	7E-10	-	-
51	Antimony-127	D, see ^{115}Sb	8E+2	2E+3	9E-7	3E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
		W, see ^{115}Sb	7E+2	9E+2	4E-7	1E-9	-	-
51	Antimony-128[2] (10.4 min)	D, see ^{115}Sb	8E+4	4E+5	2E-4	5E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see ^{115}Sb	-	4E+5	2E-4	6E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
51	Antimony-128 (9.01 h)	D, see ^{115}Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see ^{115}Sb	-	3E+3	1E-6	5E-9	-	-
51	Antimony-129	D, see ^{115}Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see ^{115}Sb	-	9E+3	4E-6	1E-8	-	-
51	Antimony-130[2]	D, see ^{115}Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{115}Sb	-	8E+4	3E-5	1E-7	-	-
51	Antimony-131[2]	D, see ^{115}Sb	1E+4	2E+4	1E-5	-	-	-
			Thyroid (2E+4)	Thyroid (4E+4)	-	6E-8	2E-4	2E-3
		W, see ^{115}Sb	-	2E+4	1E-5		-	-
				Thyroid				
			-	(4E+4)	-	6E-8	-	-
52	Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, oxides, hydroxides, and nitrates	-	3E+4	1E-5	4E-8	-	-
52	Tellurium-121m	D, see ^{116}Te	5E+2	2E+2	8E-8	-	-	-
			Bone surf (7E+2)	Bone surf (4E+2)	-	5E-10	1E-5	1E-4
		W, see ^{116}Te	-	4E+2	2E-7	6E-10	-	-
52	Tellurium-121	D, see ^{116}Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{116}Te	-	3E+3	1E-6	4E-9	-	-
52	Tellurium-123m	D, see ^{116}Te	6E+2	2E+2	9E-8	-	-	-
			Bone surf (1E+3)	Bone surf (5E+2)	-	8E-10	1E-5	1E-4
		W, see ^{116}Te	-	5E+2	2E-7	8E-10	-	-
52	Tellurium-123	D, see ^{116}Te	5E+2	2E+2	8E-8	-	-	-
			Bone surf (1E+3)	Bone surf (5E+2)	-	7E-10	2E-5	2E-4
		W, see ^{116}Te	-	4E+2	2E-7	-	-	-
				Bone surf				
			-	(1E+3)	-	2E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
52	Tellurium-125m	D, see ^{116}Te	1E+3 Bone surf	4E+2 Bone surf	2E-7	-	-	-
			(1E+3)	(1E+3)	-	1E-9	2E-5	2E-4
		W, see ^{116}Te	-	7E+2	3E-7	1E-9	-	-
52	Tellurium-127m	D, see ^{116}Te	6E+2	3E+2	1E-7	-	9E-6	9E-5
			-	Bone surf (4E+2)	-	6E-10	-	-
		W, see ^{116}Te	-	3E+2	1E-7	4E-10	-	-
52	Tellurium-127	D, see ^{116}Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{116}Te	-	2E+4	7E-6	2E-8	-	-
52	Tellurium-129m	D, see ^{116}Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see ^{116}Te	-	2E+2	1E-7	3E-10	-	-
52	Tellurium-129[2]	D, see ^{116}Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{116}Te	-	7E+4	3E-5	1E-7	-	-
52	Tellurium-131m	D, see ^{116}Te	3E+2 Thyroid	4E+2 Thyroid	2E-7	-	-	-
			(6E+2)	(1E+3)	-	2E-9	8E-6	8E-5
		W, see ^{116}Te	-	4E+2 Thyroid	2E-7	-	-	-
			-	(9E+2)	-	1E-9	-	-
52	Tellurium-131[2]	D, see ^{116}Te	3E+3 Thyroid	5E+3 Thyroid	2E-6	-	-	-
			(6E+3)	(1E+4)	-	2E-8	8E-5	8E-4
		W, see ^{116}Te	-	5E+3 Thyroid	2E-6	-	-	-
			-	(1E+4)	-	2E-8	-	-
52	Tellurium-132	D, see ^{116}Te	2E+2 Thyroid	2E+2 Thyroid	9E-8	-	-	-
			(7E+2)	(8E+2)	-	1E-9	9E-6	9E-5
		W, see ^{116}Te	-	2E+2 Thyroid	9E-8	-	-	-
			-	(6E+2)	-	9E-10	-	-
52	Tellurium-133m[2]	D, see ^{116}Te	3E+3 Thyroid	5E+3 Thyroid	2E-6	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
			(6E+3)	(1E+4)	-	2E-8	9E-5	9E-4
		W, see ^{116}Te	-	5E+3 Thyroid	2E-6	-	-	-
			-	(1E+4)	-	2E-8	-	-
52	Tellurium-133[2]	D, see ^{116}Te	1E+4 Thyroid	2E+4 Thyroid	9E-6	-	-	-
			(3E+4)	(6E+4)	-	8E-8	4E-4	4E-3
		W, see ^{116}Te	-	2E+4 Thyroid	9E-6	-	-	-
			-	(6E+4)	-	8E-8	-	-
52	Tellurium-134[2]	D, see ^{116}Te	2E+4 Thyroid	2E+4 Thyroid	1E-5	-	-	-
			(2E+4)	(5E+4)	-	7E-8	3E-4	3E-3
		W, see ^{116}Te	-	2E+4 Thyroid	1E-5	-	-	-
			-	(5E+4)	-	7E-8	-	-
53	Iodine-120m[2]	D, all compounds	1E+4 Thyroid	2E+4	9E-6	3E-8	-	-
			(1E+4)	-	-	-	2E-4	2E-3
53	Iodine-120[2]	D, all compounds	4E+3 Thyroid	9E+3 Thyroid	4E-6	-	-	-
			(8E+3)	(1E+4)	-	2E-8	1E-4	1E-3
53	Iodine-121	D, all compounds	1E+4 Thyroid	2E+4 Thyroid	8E-6	-	-	-
			(3E+4)	(5E+4)	-	7E-8	4E-4	4E-3
53	Iodine-123	D, all compounds	3E+3 Thyroid	6E+3 Thyroid	3E-6	-	-	-
			(1E+4)	(2E+4)	-	2E-8	1E-4	1E-3
53	Iodine-124	D, all compounds	5E+1 Thyroid	8E+1 Thyroid	3E-8	-	-	-
			(2E+2)	(3E+2)	-	4E-10	2E-6	2E-5
53	Iodine-125	D, all compounds	4E+1 Thyroid	6E+1 Thyroid	3E-8	-	-	-
			(1E+2)	(2E+2)	-	3E-10	2E-6	2E-5

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
53	Iodine-126	D, all compounds	2E+1 Thyroid (7E+1)	4E+1 Thyroid (1E+2)	1E-8 -	- 2E-10	- 1E-6	- 1E-5
53	Iodine-128[2]	D, all compounds	4E+4 St wall (6E+4)	1E+5 -	5E-5 -	2E-7 -	- 8E-4	- 8E-3
53	Iodine-129	D, all compounds	5E+0 Thyroid (2E+1)	9E+0 Thyroid (3E+1)	4E-9 -	- 4E-11	- 2E-7	- 2E-6
53	Iodine-130	D, all compounds	4E+2 Thyroid (1E+3)	7E+2 Thyroid (2E+3)	3E-7 -	- 3E-9	- 2E-5	- 2E-4
53	Iodine-131	D, all compounds	3E+1 Thyroid (9E+1)	5E+1 Thyroid (2E+2)	2E-8 -	- 2E-10	- 1E-6	- 1E-5
53	Iodine-132m[2]	D, all compounds	4E+3 Thyroid (1E+4)	8E+3 Thyroid (2E+4)	4E-6 -	- 3E-8	- 1E-4	- 1E-3
53	Iodine-132	D, all compounds	4E+3 Thyroid (9E+3)	8E+3 Thyroid (1E+4)	3E-6 -	- 2E-8	- 1E-4	- 1E-3
53	Iodine-133	D, all compounds	1E+2 Thyroid (5E+2)	3E+2 Thyroid (9E+2)	1E-7 -	- 1E-9	- 7E-6	- 7E-5
53	Iodine-134[2]	D, all compounds	2E+4 Thyroid (3E+4)	5E+4 -	2E-5 -	6E-8 -	- 4E-4	- 4E-3
53	Iodine-135	D, all compounds	8E+2 Thyroid (3E+3)	2E+3 Thyroid (4E+3)	7E-7 -	- 6E-9	- 3E-5	- 3E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
54	Xenon-120[2]	Submersion[1]	-	-	1E-5	4E-8	-	-
54	Xenon-121[2]	Submersion[1]	-	-	2E-6	1E-8	-	-
54	Xenon-122	Submersion[1]	-	-	7E-5	3E-7	-	-
54	Xenon-123	Submersion[1]	-	-	6E-6	3E-8	-	-
54	Xenon-125	Submersion[1]	-	-	2E-5	7E-8	-	-
54	Xenon-127	Submersion[1]	-	-	1E-5	6E-8	-	-
54	Xenon-129m	Submersion[1]	-	-	2E-4	9E-7	-	-
54	Xenon-131m	Submersion[1]	-	-	4E-4	2E-6	-	-
54	Xenon-133m	Submersion[1]	-	-	1E-4	6E-7	-	-
54	Xenon-133	Submersion[1]	-	-	1E-4	5E-7	-	-
54	Xenon-135m[2]	Submersion[1]	-	-	9E-6	4E-8	-	-
54	Xenon-135	Submersion[1]	-	-	1E-5	7E-8	-	-
54	Xenon-138[2]	Submersion[1]	-	-	4E-6	2E-8	-	-
55	Cesium-125[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
55	Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cesium-130[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
55	Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
55	Cesium-134m	D, all compounds	1E+5	1E+5	6E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
55	Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55	Cesium-135m[2]	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55	Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cesium-138[2]	D, all compounds	2E+4	6E+4	2E-5	8E-8	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
56	Barium-126[2]	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Barium-131m[2]	D, all compounds	4E+5	1E+6	6E-4	2E-6	-	-
			St wall (5E+5)	-	-	-	7E-3	7E-2
56	Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56	Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
56	Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Barium-139[2]	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
56	Barium-141[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56	Barium-142[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	Lanthanum-131[2]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	-	2E+5	7E-5	2E-7	-	-
57	Lanthanum-132	D, see ^{131}La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-135	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-
57	Lanthanum-137	D, see ^{131}La	1E+4	6E+1	3E-8	-	2E-4	2E-3
			-	Liver (7E+1)	-	1E-10	-	-
		W, see ^{131}La	-	3E+2	1E-7	-	-	-
			-	Liver (3E+2)	-	4E-10	-	-
57	Lanthanum-138	D, see ^{131}La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see ^{131}La	-	1E+1	6E-9	2E-11	-	-
57	Lanthanum-140	D, see ^{131}La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{131}La	-	1E+3	5E-7	2E-9	-	-
57	Lanthanum-141	D, see ^{131}La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see ^{131}La	-	1E+4	5E-6	2E-8	-	-
57	Lanthanum-142[2]	D, see ^{131}La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{131}La	-	3E+4	1E-5	5E-8	-	-
57	Lanthanum-143[2]	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	-	-
			St wall (4E+4)	-	-	-	5E-4	5E-3
		W, see ^{131}La	-	9E+4	4E-5	1E-7	-	-
58	Cerium-134	W, all compounds except those given for Y	5E+2 LLI wall	7E+2	3E-7	1E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
			(6E+2)	-	-	-	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	-	7E+2	3E-7	9E-10	-	-
58	Cerium-135	W, see ^{134}Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see ^{134}Ce	-	4E+3	1E-6	5E-9	-	-
58	Cerium-137m	W, see ^{134}Ce	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{134}Ce	-	4E+3	2E-6	5E-9	-	-
58	Cerium-137	W, see ^{134}Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see ^{134}Ce	-	1E+5	5E-5	2E-7	-	-
58	Cerium-139	W, see ^{134}Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see ^{134}Ce	-	7E+2	3E-7	9E-10	-	-
58	Cerium-141	W, see ^{134}Ce	2E+3	7E+2	3E-7	1E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
		Y, see ^{134}Ce	-	6E+2	2E-7	8E-10	-	-
58	Cerium-143	W, see ^{134}Ce	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{134}Ce	-	2E+3	7E-7	2E-9	-	-
58	Cerium-144	W, see ^{134}Ce	2E+2	3E+1	1E-8	4E-11	-	-
			LLI wall (3E+2)	-	-	-	3E-6	3E-5
		Y, see ^{134}Ce	-	1E+1	6E-9	2E-11	-	-
59	Praseodymium-136[2]	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	9E-5	3E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
59	Praseodymium-137[2]	W, see ^{136}Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see ^{136}Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-138m	W, see ^{136}Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see ^{136}Pr	-	4E+4	2E-5	6E-8	-	-
59	Praseodymium-139	W, see ^{136}Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{136}Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-142m[2]	W, see ^{136}Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
		Y, see ^{136}Pr	-	1E+5	6E-5	2E-7	-	-
59	Praseodymium-142	W, see ^{136}Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		Y, see ^{136}Pr	-	2E+3	8E-7	3E-9	-	-
59	Praseodymium-143	W, see ^{136}Pr	9E+2	8E+2	3E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{136}Pr	-	7E+2	3E-7	9E-10	-	-
59	Praseodymium-144[2]	W, see ^{136}Pr	3E+4	1E+5	5E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		Y, see ^{136}Pr	-	1E+5	5E-5	2E-7	-	-
59	Praseodymium-145	W, see ^{136}Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{136}Pr	-	8E+3	3E-6	1E-8	-	-
59	Praseodymium-147[2]	W, see ^{136}Pr	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
		Y, see ^{136}Pr	-	2E+5	8E-5	3E-7	-	-
60	Neodymium-136[2]	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	5E+4	2E-5	8E-8	-	-
60	Neodymium-138	W, see ^{136}Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see ^{136}Nd	-	5E+3	2E-6	7E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
60	Neodymium-139m	W, see ^{136}Nd	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		Y, see ^{136}Nd	-	1E+4	6E-6	2E-8	-	-
60	Neodymium-139[2]	W, see ^{136}Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see ^{136}Nd	-	3E+5	1E-4	4E-7	-	-
60	Neodymium-141	W, see ^{136}Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see ^{136}Nd	-	6E+5	3E-4	9E-7	-	-
60	Neodymium-147	W, see ^{136}Nd	1E+3	9E+2	4E-7	1E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{136}Nd	-	8E+2	4E-7	1E-9	-	-
60	Neodymium-149[2]	W, see ^{136}Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see ^{136}Nd	-	2E+4	1E-5	3E-8	-	-
60	Neodymium-151[2]	W, see ^{136}Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see ^{136}Nd	-	2E+5	8E-5	3E-7	-	-
61	Promethium-141[2]	W, all compounds except those given for Y	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
		Y, oxides, hydroxides, carbides, and fluorides	-	2E+5	7E-5	2E-7	-	-
61	Promethium-143	W, see ^{141}Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see ^{141}Pm	-	7E+2	3E-7	1E-9	-	-
61	Promethium-144	W, see ^{141}Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see ^{141}Pm	-	1E+2	5E-8	2E-10	-	-
61	Promethium-145	W, see ^{141}Pm	1E+4	2E+2	7E-8	-	1E-4	1E-3
			-	Bone surf (2E+2)	-	3E-10	-	-
		Y, see ^{141}Pm	-	2E+2	8E-8	3E-10	-	-
61	Promethium-146	W, see ^{141}Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see ^{141}Pm	-	4E+1	2E-8	6E-11	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
61	Promethium-147	W, see ^{141}Pm	4E+3	1E+2	5E-8	-	-	-
			LLI wall (5E+3)	Bone surf (2E+2)	-	3E-10	7E-5	7E-4
		Y, see ^{141}Pm	-	1E+2	6E-8	2E-10	-	-
61	Promethium-148m	W, see ^{141}Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see ^{141}Pm	-	3E+2	1E-7	5E-10	-	-
61	Promethium-148	W, see ^{141}Pm	4E+2	5E+2	2E-7	8E-10	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
		Y, see ^{141}Pm	-	5E+2	2E-7	7E-10	-	-
61	Promethium-149	W, see ^{141}Pm	1E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{141}Pm	-	2E+3	8E-7	2E-9	-	-
61	Promethium-150	W, see ^{141}Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{141}Pm	-	2E+4	7E-6	2E-8	-	-
61	Promethium-151	W, see ^{141}Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{141}Pm	-	3E+3	1E-6	4E-9	-	-
62	Samarium-141m[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141[2]	W, all compounds	5E+4	2E+5	8E-5	2E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
62	Samarium-142[2]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1	4E2	1E-11	-	-	-
			Bone surf (3E+1)	Bone surf (6E-2)	-	9E-14	3E-7	3E-6
62	Samarium-147	W, all compounds	2E+1	4E2	2E-11	-	-	-
			Bone surf (3E+1)	Bone surf (7E-2)	-	1E-13	4E-7	4E-6

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
62	Samarium-151	W, all compounds	1E+4	1E+2	4E-8	-	-	-
			LLI wall (1E+4)	Bone surf (2E+2)	-	2E-10	2E-4	2E-3
62	Samarium-153	W, all compounds	2E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
62	Samarium-155[2]	W, all compounds	6E+4	2E+5	9E-5	3E-7	-	-
			St wall (8E+4)	-	-	-	1E-3	1E-2
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (1E+2)	-	2E-10	-	-
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158[2]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145[2]	D, all compounds except those given for W	5E+4 St wall (5E+4)	2E+5 -	6E-5 -	2E-7 -	- 6E-4	- 6E-3
		W, oxides, hydroxides, and fluorides	-	2E+5	7E-5	2E-7	-	-
64	Gadolinium-146	D, see ^{145}Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see ^{145}Gd	-	3E+2	1E-7	4E-10	-	-
64	Gadolinium-147	D, see ^{145}Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{145}Gd	-	4E+3	1E-6	5E-9	-	-
64	Gadolinium-148	D, see ^{145}Gd	1E+1 Bone surf (2E+1)	8E+3 Bone surf (2E+2)	3E-12 -	- 2E-14	- 3E-7	- 3E-6
		W, see ^{145}Gd	- -	3E-2 Bone surf (6E-2)	1E-11 -	- 8E-14	- -	- -
64	Gadolinium-149	D, see ^{145}Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
		W, see ^{145}Gd	-	2E+3	1E-6	3E-9	-	-
64	Gadolinium-151	D, see ^{145}Gd	6E+3 -	4E+2 Bone surf (6E+2)	2E-7 -	- 9E-10	9E-5 -	9E-4 -
		W, see ^{145}Gd	-	1E+3	5E-7	2E-9	-	-
64	Gadolinium-152	D, see ^{145}Gd	2E+1 Bone surf (3E+1)	1E-2 Bone surf (2E-2)	4E-12 -	- 3E-14	- 4E-7	- 4E-6
		W, see ^{145}Gd	- -	4E-2 Bone surf (8E-2)	2E-11 -	- 1E-13	- -	- -
64	Gadolinium-153	D, see ^{145}Gd	5E+3	1E+2 Bone surf	6E-8	-	6E-5	6E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
			-	(2E+2)	-	3E-10	-	-
		W, see ^{145}Gd	-	6E+2	2E-7	8E-10	-	-
64	Gadolinium-159	D, see ^{145}Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{145}Gd	-	6E+3	2E-6	8E-9	-	-
65	Terbium-147[2]	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4
65	Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65	Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3
65	Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
65	Terbium-157	W, all compounds	5E+4 LLI wall (5E+4)	3E+2 Bone surf (6E+2)	1E-7 -	- 8E-10	- 7E-4	- 7E-3
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3 LLI wall (2E+3)	2E+3 -	7E-7 -	2E-9 -	- 3E-5	- 3E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
66	Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66	Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66	Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66	Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66	Dysprosium-166	W, all compounds	6E+2	7E+2	3E-7	1E-9	-	-
			LLI wall (8E+2)	-	-	-	1E-5	1E-4
67	Holmium-155[2]	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67	Holmium-157[2]	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Holmium-159[2]	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m[2]	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162[2]	W, all compounds	5E+5	2E+6	1E-3	3E-6	-	-
			St wall (8E+5)	-	-	-	1E-2	1E-1
67	Holmium-164m[2]	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-164[2]	W, all compounds	2E+5	6E+5	3E-4	9E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	-	-
			LLI wall (9E+2)	-	-	-	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	-	-
			LLI wall (4E+3)	- -	-	5E-5	5E-4	
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	-	-
			LLI wall (E+3)	- -	-	2E-5	2E-4	
69	Thulium-162[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (7E+4)	- -	-	1E-3	1E-2	
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	-	-
			LLI wall (2E+3)	- -	-	3E-5	3E-4	
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	-	-
			LLI wall (1E+3)	- -	-	1E-5	1E-4	
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	-	-	-
			LLI wall (1E+4)	Bone surf (6E+2)	-	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (8E+2)	- -	-	1E-5	1E-4	
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Thulium-175[2]	W, all compounds	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (9E+4)	- -	-	1E-3	1E-2	
70	Ytterbium-162[2]	W, all compounds except						

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
		those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
		Y, oxides, hydroxides, and fluorides	-	3E+5	1E-4	4E-7	-	-
70	Ytterbium-166	W, see ^{162}Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		Y, see ^{162}Yb	-	2E+3	8E-7	3E-9	-	-
70	Ytterbium-167[2]	W, see ^{162}Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
		Y, see ^{162}Yb	-	7E+5	3E-4	1E-6	-	-
70	Ytterbium-169	W, see ^{162}Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
		Y, see ^{162}Yb	-	7E+2	3E-7	1E-9	-	-
70	Ytterbium-175	W, see ^{162}Yb	3E+3	4E+3	1E-6	5E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		Y, see ^{162}Yb	-	3E+3	1E-6	5E-9	-	-
70	Ytterbium-177[2]	W, see ^{162}Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
		Y, see ^{162}Yb	-	5E+4	2E-5	6E-8	-	-
70	Ytterbium-178[2]	W, see ^{162}Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		Y, see ^{162}Yb	-	4E+4	2E-5	5E-8	-	-
71	Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		Y, oxides, hydroxides, and fluorides	-	4E+3	2E-6	6E-9	-	-
71	Lutetium-170	W, see ^{169}Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
		Y, see ^{169}Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-171	W, see ^{169}Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
		Y, see ^{169}Lu	-	2E+3	8E-7	3E-9	-	-
71	Lutetium-172	W, see ^{169}Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
		Y, see ^{169}Lu	-	1E+3	5E-7	2E-9	-	-
71	Lutetium-173	W, see ^{169}Lu	5E+3	3E+2	1E-7	-	7E-5	7E-4
			-	Bone surf (5E+2)	-	6E-10	-	-
		Y, see ^{169}Lu	-	3E+2	1E-7	4E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
71	Lutetium-174m	W, see ^{169}Lu	2E+3	2E+2	1E-7	-	-	-
			LLI wall	Bone surf				
			(3E+3)	(3E+2)	-	5E-10	4E-5	4E-4
		Y, see ^{169}Lu	-	2E+2	9E-8	3E-10	-	-
71	Lutetium-174	W, see ^{169}Lu	5E+3	1E+2	5E-8	-	7E-5	7E-4
				Bone surf				
			-	(2E+2)	-	3E-10	-	-
		Y, see ^{169}Lu	-	2E+2	6E-8	2E-10	-	-
71	Lutetium-176m	W, see ^{169}Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see ^{169}Lu	-	2E+4	9E-6	3E-8	-	-
71	Lutetium-176	W, see ^{169}Lu	7E+2	5E+0	2E-9	-	1E-5	1E-4
				Bone surf				
			-	(1E+1)	-	2E-11	-	-
		Y, see ^{169}Lu	-	8E+0	3E-9	1E-11	-	-
71	Lutetium-177m	W, see ^{169}Lu	7E+2	1E+2	5E-8	-	1E-5	1E-4
				Bone surf				
			-	(1E+2)	-	2E-10	-	-
		Y, see ^{169}Lu	-	8E+1	3E-8	1E-10	-	-
71	Lutetium-177	W, see ^{169}Lu	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall					
			(3E+3)	-	-	-	4E-5	4E-4
		Y, see ^{169}Lu	-	2E+3	9E-7	3E-9	-	-
71	Lutetium-178m[2]	W, see ^{169}Lu	5E+4	2E+5	8E-5	3E-7	-	-
			St. wall					
			(6E+4)	-	-	-	8E-4	8E-3
		Y, see ^{169}Lu	-	2E+5	7E-5	2E-7	-	-
71	Lutetium-178[2]	W, see ^{169}Lu	4E+4	1E+5	5E-5	2E-7	-	-
			St wall					
			(4E+4)	-	-	-	6E-4	6E-3
		Y, see ^{169}Lu	-	1E+5	5E-5	2E-7	-	-
71	Lutetium-179	W, see ^{169}Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{169}Lu	-	2E+4	6E-6	3E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Ingestion ALI (µCi)	Table I Occupational Values Col. 3 Ingestion DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
72	Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides, carbides, and nitrates	-	5E+3	2E-6	6E-9	-	-
72	Hafnium-172	D, see ^{170}Hf	1E+3	9E+0	4E-9	-	2E-5	2E-4
			-	Bone surf (2E+1)	-	3E-11	-	-
		W, see ^{170}Hf	-	4E+1	2E-8	-	-	-
			-	Bone surf (6E+1)	-	8E-11	-	-
72	Hafnium-173	D, see ^{170}Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{170}Hf	-	1E+4	5E-6	2E-8	-	-
72	Hafnium-175	D, see ^{170}Hf	3E+3	9E+2	4E-7	-	4E-5	4E-4
			-	Bone surf (1E+3)	-	1E-9	-	-
		W, see ^{170}Hf	-	1E+3	5E-7	2E-9	-	-
72	Hafnium-177m[2]	D, see ^{170}Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{170}Hf	-	9E+4	4E-5	1E-7	-	-
72	Hafnium-178m	D, see ^{170}Hf	3E+2	1E+0	5E-10	-	3E-6	3E-5
			-	Bone surf (2E+0)	-	3E-12	-	-
		W, see ^{170}Hf	-	5E+0	2E-9	-	-	-
			-	Bone surf (9E+0)	-	1E-11	-	-
72	Hafnium-179m	D, see ^{170}Hf	1E+3	3E+2	1E-7	-	1E-5	1E-4
			-	Bone surf (6E+2)	-	8E-10	-	-
		W, see ^{170}Hf	-	6E+2	3E-7	8E-10	-	-
72	Hafnium-180m	D, see ^{170}Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{170}Hf	-	3E+4	1E-5	4E-8	-	-
72	Hafnium-181	D, see ^{170}Hf	1E+3	2E+2	7E-8	-	2E-5	2E-4
			-	Bone surf (4E+2)	-	6E-10	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
		W, see ^{170}Hf	-	4E+2	2E-7	6E-10	-	-
72	Hafnium-182m[2]	D, see ^{170}Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see ^{170}Hf	-	1E+5	6E-5	2E-7	-	-
72	Hafnium-182	D, see ^{170}Hf	2E+2 Bone surf (4E+2)	8E-1 Bone surf (2E+0)	3E-10 -	- 2E-12	- 5E-6	- 5E-5
		W, see ^{170}Hf	- -	3E+0 Bone surf (7E+0)	1E-9 -	- 1E-11	- -	- -
72	Hafnium-183[2]	D, see ^{170}Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{170}Hf	-	6E+4	2E-5	8E-8	-	-
72	Hafnium-184	D, see ^{170}Hf	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{170}Hf	-	6E+3	3E-6	9E-9	-	-
73	Tantalum-172[2]	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
		Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	-	1E+5	4E-5	1E-7	-	-
73	Tantalum-173	W, see ^{172}Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{172}Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-174[2]	W, see ^{172}Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	-	9E+4	4E-5	1E-7	-	-
73	Tantalum-175	W, see ^{172}Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see ^{172}Ta	-	1E+4	6E-6	2E-8	-	-
73	Tantalum-176	W, see ^{172}Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see ^{172}Ta	-	1E+4	5E-6	2E-8	-	-
73	Tantalum-177	W, see ^{172}Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see ^{172}Ta	-	2E+4	7E-6	2E-8	-	-
73	Tantalum-178	W, see ^{172}Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
		Y, see ^{172}Ta	-	7E+4	3E-5	1E-7	-	-
73	Tantalum-179	W, see ^{172}Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see ^{172}Ta	-	9E+2	4E-7	1E-9	-	-
73	Tantalum-180m	W, see ^{172}Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{172}Ta	-	6E+4	2E-5	8E-8	-	-
73	Tantalum-180	W, see ^{172}Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see ^{172}Ta	-	2E+1	1E-8	3E-11	-	-
73	Tantalum-182m[2]	W, see ^{172}Ta	2E+5	5E+5	2E-4	8E-7	-	-
			St wall (2E+5)	-	-	-	3E-3	3E-2
		Y, see ^{172}Ta	-	4E+5	2E-4	6E-7	-	-
73	Tantalum-182	W, see ^{172}Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see ^{172}Ta	-	1E+2	6E-8	2E-10	-	-
73	Tantalum-183	W, see ^{172}Ta	9E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (1E+3)	-	-	-	2E-5	2E-4
		Y, see ^{172}Ta	-	1E+3	4E-7	1E-9	-	-
73	Tantalum-184	W, see ^{172}Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
		Y, see ^{172}Ta	-	5E+3	2E-6	7E-9	-	-
73	Tantalum-185[2]	W, see ^{172}Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	-	6E+4	3E-5	9E-8	-	-
73	Tantalum-186[2]	W, see ^{172}Ta	5E+4	2E+5	1E-4	3E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
		Y, see ^{172}Ta	-	2E+5	9E-5	3E-7	-	-
74	Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74	Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
74	Tungsten-179[2]	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74	Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74	Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
74	Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74	Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	-	-
			LLI wall (5E+2)	-	-	-	7E-6	7E-5
75	Rhenium-177[2]	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	2E-3	2E-2
		W, oxides, hydroxides, and nitrates	-	4E+5	1E-4	5E-7	-	-
75	Rhenium-178[2]	D, see ^{177}Re	7E+4	3E+5	1E-4	4E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		W, see ^{177}Re	-	3E+5	1E-4	4E-7	-	-
75	Rhenium-181	D, see ^{177}Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see ^{177}Re	-	9E+3	4E-6	1E-8	-	-
75	Rhenium-182 (12.7 h)	D, see ^{177}Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
		W, see ^{177}Re	-	2E+4	6E-6	2E-8	-	-
75	Rhenium-182 (64.0 h)	D, see ^{177}Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, see ^{177}Re	-	2E+3	9E-7	3E-9	-	-
75	Rhenium-184m	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	-	4E+2	2E-7	6E-10	-	-
75	Rhenium-184	D, see ^{177}Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{177}Re	-	1E+3	6E-7	2E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
75	Rhenium-186m	D, see ^{177}Re	1E+3	2E+3	7E-7	-	-	-
		St wall	(2E+3)	(2E+3)	-	3E-9	2E-5	2E-4
		W, see ^{177}Re	-	2E+2	6E-8	2E-10	-	-
75	Rhenium-186	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	-	2E+3	7E-7	2E-9	-	-
75	Rhenium-187	D, see ^{177}Re	6E+5	8E+5	4E-4	-	8E-3	8E-2
		St wall	-	(9E+5)	-	1E-6	-	-
		W, see ^{177}Re	-	1E+5	4E-5	1E-7	-	-
75	Rhenium-188m[2]	D, see ^{177}Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{177}Re	-	1E+5	6E-5	2E-7	-	-
75	Rhenium-188	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		W, see ^{177}Re	-	3E+3	1E-6	4E-9	-	-
75	Rhenium-189	D, see ^{177}Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
		W, see ^{177}Re	-	4E+3	2E-6	6E-9	-	-
76	Osmium-180[2]	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
		W, halides and nitrates	-	5E+5	2E-4	7E-7	-	-
		Y, oxides and hydroxides	-	5E+5	2E-4	6E-7	-	-
76	Osmium-181[2]	D, see ^{180}Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{180}Os	-	5E+4	2E-5	6E-8	-	-
		Y, see ^{180}Os	-	4E+4	2E-5	6E-8	-	-
76	Osmium-182	D, see ^{180}Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
		W, see ^{180}Os	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{180}Os	-	4E+3	2E-6	6E-9	-	-
76	Osmium-185	D, see ^{180}Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{180}Os	-	8E+2	3E-7	1E-9	-	-
		Y, see ^{180}Os	-	8E+2	3E-7	1E-9	-	-
76	Osmium-189m	D, see ^{180}Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, see ^{180}Os	-	2E+5	9E-5	3E-7	-	-
		Y, see ^{180}Os	-	2E+5	7E-5	2E-7	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
76	Osmium-191m	D, see ^{180}Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{180}Os	-	2E+4	8E-6	3E-8	-	-
		Y, see ^{180}Os	-	2E+4	7E-6	2E-8	-	-
76	Osmium-191	D, see ^{180}Os	2E+3	2E+3	9E-7	3E-9	-	-
			LLI wall (3E+3)	-	-	-	3E-5	3E-4
		W, see ^{180}Os	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{180}Os	-	1E+3	6E-7	2E-9	-	-
76	Osmium-193	D, see ^{180}Os	2E+3	5E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	2E-5	2E-4
		W, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
		Y, see ^{180}Os	-	3E+3	1E-6	4E-9	-	-
76	Osmium-194	D, see ^{180}Os	4E+2	4E+1	2E-8	6E-11	-	-
			LLI wall (6E+2)	-	-	-	8E-6	8E-5
		W, see ^{180}Os	-	6E+1	2E-8	8E-11	-	-
		Y, see ^{180}Os	-	8E+0	3E-9	1E-11	-	-
77	Iridium-182[2]	D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	-	-
			St wall (4E+4)	-	-	-	6E-4	6E-3
		W, halides, nitrates, and metallic iridium	-	2E+5	6E-5	2E-7	-	-
		Y, oxides and hydroxides	-	1E+5	5E-5	2E-7	-	-
77	Iridium-184	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	5E-8	-	-
		Y, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-185	D, see ^{182}Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{182}Ir	-	1E+4	5E-6	2E-8	-	-
		Y, see ^{182}Ir	-	1E+4	4E-6	1E-8	-	-
77	Iridium-186	D, see ^{182}Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{182}Ir	-	6E+3	3E-6	9E-9	-	-
		Y, see ^{182}Ir	-	6E+3	2E-6	8E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
77	Iridium-187	D, see ^{182}Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
77	Iridium-188	D, see ^{182}Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{182}Ir	-	4E+3	1E-6	5E-9	-	-
		Y, see ^{182}Ir	-	3E+3	1E-6	5E-9	-	-
77	Iridium-189	D, see ^{182}Ir	5E+3	5E+3	2E-6	7E-9	-	-
			LLI wall (5E+3)	-	-	-	7E-5	7E-4
		W, see ^{182}Ir	-	4E+3	2E-6	5E-9	-	-
		Y, see ^{182}Ir	-	4E+3	1E-6	5E-9	-	-
77	Iridium-190m[2]	D, see ^{182}Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see ^{182}Ir	-	2E+5	9E-5	3E-7	-	-
		Y, see ^{182}Ir	-	2E+5	8E-5	3E-7	-	-
77	Iridium-190	D, see ^{182}Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
		W, see ^{182}Ir	-	1E+3	4E-7	1E-9	-	-
		Y, see ^{182}Ir	-	9E+2	4E-7	1E-9	-	-
77	Iridium-192m	D, see ^{182}Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
		W, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
		Y, see ^{182}Ir	-	2E+1	6E-9	2E-11	-	-
77	Iridium-192	D, see ^{182}Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		W, see ^{182}Ir	-	4E+2	2E-7	6E-10	-	-
		Y, see ^{182}Ir	-	2E+2	9E-8	3E-10	-	-
77	Iridium-194m	D, see ^{182}Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
		W, see ^{182}Ir	-	2E+2	7E-8	2E-10	-	-
		Y, see ^{182}Ir	-	1E+2	4E-8	1E-10	-	-
77	Iridium-194	D, see ^{182}Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{182}Ir	-	2E+3	9E-7	3E-9	-	-
		Y, see ^{182}Ir	-	2E+3	8E-7	3E-9	-	-
77	Iridium-195m	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	-	3E+4	1E-5	4E-8	-	-
		Y, see ^{182}Ir	-	2E+4	9E-6	3E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
77	Iridium-195	D, see ^{182}Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{182}Ir	-	5E+4	2E-5	7E-8	-	-
		Y, see ^{182}Ir	-	4E+4	2E-5	6E-8	-	-
78	Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78	Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78	Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78	Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78	Platinum-193m	D, all compounds	3E+3	6E+3	3E-6	8E-9	-	-
			LLI wall (3E+4)	-	-	-	4E-5	4E-4
78	Platinum-193	D, all compounds	4E+4	2E+4	1E-5	3E-8	-	-
			LLI wall (5E+4)	-	-	-	6E-4	6E-3
78	Platinum-195m	D, all compounds	2E+3	4E+3	2E-6	6E-9	-	-
			LLI wall (2E+3)	-	-	-	3E-5	3E-4
78	Platinum-197m[2]	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78	Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78	Platinum-199[2]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78	Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	-	2E+4	9E-6	3E-8	-	-
		Y, oxides and hydroxides	-	2E+4	8E-6	3E-8	-	-
79	Gold-194	D, see ^{193}Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193}Au	-	5E+3	2E-6	8E-9	-	-
		Y, see ^{193}Au	-	5E+3	2E-6	7E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
79	Gold-195	D, see ^{193}Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{193}Au	-	1E+3	6E-7	2E-9	-	-
		Y, see ^{193}Au	-	4E+2	2E-7	6E-10	-	-
79	Gold-198m	D, see ^{193}Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
		Y, see ^{193}Au	-	1E+3	5E-7	2E-9	-	-
79	Gold-198	D, see ^{193}Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	-	2E+3	8E-7	3E-9	-	-
		Y, see ^{193}Au	-	2E+3	7E-7	2E-9	-	-
79	Gold-199	D, see ^{193}Au	3E+3	9E+3	4E-6	1E-8	-	-
			LLI wall (3E+3)	-	-	-	4E-5	4E-4
		W, see ^{193}Au	-	4E+3	2E-6	6E-9	-	-
		Y, see ^{193}Au	-	4E+3	2E-6	5E-9	-	-
79	Gold-200m	D, see ^{193}Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	-	3E+3	1E-6	4E-9	-	-
		Y, see ^{193}Au	-	2E+4	1E-6	3E-9	-	-
79	Gold-200[2]	D, see ^{193}Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{193}Au	-	8E+4	3E-5	1E-7	-	-
		Y, see ^{193}Au	-	7E+4	3E-5	1E-7	-	-
79	Gold-201[2]	D, see ^{193}Au	7E+4	2E+5	9E-5	3E-7	-	-
			St wall (9E+4)	-	-	-	1E-3	1E-2
		W, see ^{193}Au	-	2E+5	1E-4	3E-7	-	-
		Y, see ^{193}Au	-	2E+5	9E-5	3E-7	-	-
80	Mercury-193m	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, oxides, hydroxides, halides, nitrates, and sulfides	-	8E+3	3E-6	1E-8	-	-
80	Mercury-193	Vapor	-	3E+4	1E-5	4E-8	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
		Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		D, see ^{193m}Hg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{193m}Hg	-	4E+4	2E-5	6E-8	-	-
80	Mercury-194	Vapor	-	3E+1	1E-8	4E-11	-	-
		Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
		D, see ^{193m}Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
		W, see ^{193m}Hg	-	1E+2	5E-8	2E-10	-	-
80	Mercury-195m	Vapor	-	4E+3	2E-6	6E-9	-	-
		Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
		D, see ^{193m}Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
		W, see ^{193m}Hg	-	4E+3	2E-6	5E-9	-	-
80	Mercury-195	Vapor	-	3E+4	1E-5	4E-8	-	-
		Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		D, see ^{193m}Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{193m}Hg	-	3E+4	1E-5	5E-8	-	-
80	Mercury-197m	Vapor	-	5E+3	2E-6	7E-9	-	-
		Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		D, see ^{193m}Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193m}Hg	-	5E+3	2E-6	7E-9	-	-
80	Mercury-197	Vapor	-	8E+3	4E-6	1E-8	-	-
		Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
		D, see ^{193m}Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{193m}Hg	-	9E+3	4E-6	1E-8	-	-
80	Mercury-199m[2]	Vapor	-	8E+4	3E-5	1E-7	-	-
		Organic D	6E+4	2E+5	7E-5	2E-7	-	-
			St wall (1E+5)	-	-	-	1E-3	1E-2
		D, see ^{193m}Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
		W, see ^{193m}Hg	-	2E+5	7E-5	2E-7	-	-
80	Mercury-203	Vapor	-	8E+2	4E-7	1E-9	-	-
		Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
		D, see ^{193m}Hg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		W, see ^{193m}Hg	-	1E+3	5E-7	2E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
81	Thallium-194m[2]	D, all compounds	5E+4	2E+5	6E-5	2E-7	-	-
			St wall (7E+4)	-	-	-	1E-3	1E-2
81	Thallium-194[2]	D, all compounds	3E+5	6E+5	2E-4	8E-7	-	-
			St wall (3E+5)	-	-	-	4E-3	4E-2
81	Thallium-195[2]	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81	Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Thallium-198m[2]	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81	Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81	Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81	Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81	Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81	Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
81	Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82	Lead-195m[2]	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82	Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Lead-199[2]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82	Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
82	Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E1 Bone surf (1E+0)	2E1 Bone surf (4E-1)	1E-10 -	- 6E-13	- 1E-8	- 1E-7
82	Lead-211[2]	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1 Bone surf (1E+2)	3E+1 -	1E-8 -	5E-11 -	- 2E-6	- 2E-5
82	Lead-214[2]	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83	Bismuth-200[2]	D, nitrates W, all other compounds	3E+4 -	8E+4 1E+5	4E-5 4E-5	1E-7 1E-7	4E-4 -	4E-3 -
83	Bismuth-201[2]	D, see ^{200}Bi W, see ^{200}Bi	1E+4 -	3E+4 4E+4	1E-5 2E-5	4E-8 5E-8	2E-4 -	2E-3 -
83	Bismuth-202[2]	D, see ^{200}Bi W, see ^{200}Bi	1E+4 -	4E+4 8E+4	2E-5 3E-5	6E-8 1E-7	2E-4 -	2E-3 -
83	Bismuth-203	D, see ^{200}Bi W, see ^{200}Bi	2E+3 -	7E+3 6E+3	3E-6 3E-6	9E-9 9E-9	3E-5 -	3E-4 -
83	Bismuth-205	D, see ^{200}Bi W, see ^{200}Bi	1E+3 -	3E+3 1E+3	1E-6 5E-7	3E-9 2E-9	2E-5 -	2E-4 -
83	Bismuth-206	D, see ^{200}Bi W, see ^{200}Bi	6E+2 -	1E+3 9E+2	6E-7 4E-7	2E-9 1E-9	9E-6 -	9E-5 -
83	Bismuth-207	D, see ^{200}Bi W, see ^{200}Bi	1E+3 -	2E+3 4E+2	7E-7 1E-7	2E-9 5E-10	1E-5 -	1E-4 -
83	Bismuth-210m	D, see ^{200}Bi W, see ^{200}Bi	4E+1 Kidneys (6E+1) -	5E+0 Kidneys (6E+0) 7E-1	2E-9 - 3E-10	- 9E-12 9E-13	- 8E-7 -	- 8E-6 -

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
83	Bismuth-210	D, see ^{200}Bi	8E+2	2E+2	1E-7	-	1E-5	1E-4
		-	-	Kidneys (4E+2)	-	5E-10	-	-
		W, see ^{200}Bi	-	3E+1	1E-8	4E-11	-	-
83	Bismuth-212[2]	D, see ^{200}Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
		W, see ^{200}Bi	-	3E+2	1E-7	4E-10	-	-
83	Bismuth-213[2]	D, see ^{200}Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
		W, see ^{200}Bi	-	4E+2	1E-7	5E-10	-	-
83	Bismuth-214[2]	D, see ^{200}Bi	2E+4 St wall (2E+4)	8E+2	3E-7	1E-9	-	-
			-	-	-	-	3E-4	3E-3
		W, see ^{200}Bi	-	9E-2	4E-7	1E-9	-	-
84	Polonium-203[2]	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, oxides, hydroxides, and nitrates	-	9E+4	4E-5	1E-7	-	-
84	Polonium-205[2]	D, see ^{203}Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see ^{203}Po	-	7E+4	3E-5	1E-7	-	-
84	Polonium-207	D, see ^{203}Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{203}Po	-	3E+4	1E-5	4E-8	-	-
84	Polonium-210	D, see ^{203}Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see ^{203}Po	-	6E-1	3E-10	9E-13	-	-
85	Astatine-207[2]	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
		W	-	2E+3	9E-7	3E-9	-	-
85	Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
		W	-	5E+1	2E-8	8E-11	-	-
86	Radon-220	With daughters removed	-	2E+4	7E-6	2E-8	-	-
		With daughters present	-	2E+1 (or 12 working level months)	9E-9	3E-11 (or 1.0 working level)	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
86	Radon-222	With daughters removed	-	1E+4	4E-6	1E-8	-	-
		With daughters present	-	1E+2 (or 4 working level months)	3E-8	1E-10 (or 0.33 working level)	-	-
87	Francium-222[2]	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Francium-223[2]	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0 Bone surf (9E+0)	7E-1	3E-10	9E-13	-	-
				-	-	-	1E-7	1E-6
88	Radium-224	W, all compounds	8E+0 Bone surf (2E+1)	2E+0	7E-10	2E-12	-	-
				-	-	-	2E-7	2E-6
88	Radium-225	W, all compounds	8E+0 Bone surf (2E+1)	7E-1	3E-10	9E-13	-	-
				-	-	-	2E-7	2E-6
88	Radium-226	W, all compounds	2E+0 Bone surf (5E+0)	6E-1	3E-10	9E-13	-	-
				-	-	-	6E-8	6E-7
88	Radium-227[2]	W, all compounds	2E+4 Bone surf (2E+4)	1E+4 Bone surf (2E+4)	6E-6	-	-	-
					-	3E-8	3E-4	3E-3
88	Radium-228	W, all compounds	2E+0 Bone surf (4E+0)	1E+0	5E-10	2E-12	-	-
				-	-	-	6E-8	6E-7
89	Actinium-224	D, all compounds except those given for W and Y	2E+3 LLI wall (2E+3)	3E+1 Bone surf (4E+1)	1E-8	-	-	-
					-	5E-11	3E-5	3E-4
		W, halides and nitrates	-	5E+1	2E-8	7E-11	-	-
		Y, oxides and hydroxides	-	5E+1	2E-8	6E-11	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
89	Actinium-225	D, see ^{224}Ac	5E+1	3E-1	1E-10	-	-	-
			LLI wall (5E+1)	Bone surf (5E-1)	-	7E-13	7E-7	7E-6
		W, see ^{224}Ac	-	6E-1	3E-10	9E-13	-	-
		Y, see ^{224}Ac	-	6E-1	3E-10	9E-13	-	-
89	Actinium-226	D, see ^{224}Ac	1E+2	3E+0	1E-9	-	-	-
			LLI wall (1E+2)	Bone surf (4E+0)	-	5E-12	2E-6	2E-5
		W, see ^{224}Ac	-	5E+0	2E-9	7E-12	-	-
		Y, see ^{224}Ac	-	5E+0	2E-9	6E-12	-	-
89	Actinium-227	D, see ^{224}Ac	2E-1	4E-4	2E-13	-	-	-
			Bone surf (4E-1)	Bone surf (8E-4)	-	1E-15	5E-9	5E-8
		W, see ^{224}Ac	-	2E-3	7E-13	-	-	-
			-	Bone surf (3E-3)	-	4E-15	-	-
		Y, see ^{224}Ac	-	4E-3	2E-12	6E-15	-	-
89	Actinium-228	D, see ^{224}Ac	2E+3	9E+0	4E-9	-	3E-5	3E-4
			-	Bone surf (2E+1)	-	2E-11	-	-
		W, see ^{224}Ac	-	4E+1	2E-8	-	-	-
			-	Bone surf (6E+1)	-	8E-11	-	-
		Y, see ^{224}Ac	-	4E+1	2E-8	6E-11	-	-
90	Thorium-226[2]	W, all compounds except those given for Y	5E+3	2E+2	6E-8	2E-10	-	-
			St wall (5E+3)	-	-	-	7E-5	7E-4
		Y, oxides and hydroxides	-	1E+2	6E-8	2E-10	-	-
90	Thorium-227	W, see ^{226}Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
		Y, see ^{226}Th	-	3E-1	1E-10	5E-13	-	-
90	Thorium-228	W, see ^{226}Th	6E+0	1E-2	4E-12	-	-	-
			Bone surf (1E+1)	Bone surf (2E-2)	-	3E-14	2E-7	2E-6
		Y, see ^{226}Th	-	2E-2	7E-12	2E-14	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
90	Thorium-229	W, see ^{226}Th	6E-1	9E-4	4E-13	-	-	-
			Bone surf (1E+0)	Bone surf (2E-3)	-	3E-15	2E-8	2E-7
		Y, see ^{226}Th	-	2E-3	1E-12	-	-	-
				Bone surf				
			-	(3E-3)	-	4E-15	-	-
90	Thorium-230	W, see ^{226}Th	4E+0	6E-3	3E-12	-	-	-
			Bone surf (9E+0)	Bone surf (2E-2)	-	2E-14	1E-7	1E-6
		Y, see ^{226}Th	-	2E-2	6E-12	-	-	-
				Bone surf				
			-	(2E-2)	-	3E-14	-	-
90	Thorium-231	W, see ^{226}Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		Y, see ^{226}Th	-	6E+3	3E-6	9E-9	-	-
90	Thorium-232	W, see ^{226}Th	7E-1	1E-3	5E-13	-	-	-
			Bone surf (2E+0)	Bone surf (3E-3)	-	4E-15	3E-8	3E-7
		Y, see ^{226}Th	-	3E-3	1E-12	-	-	-
				Bone surf				
			-	(4E-3)	-	6E-15	-	-
90	Thorium-234	W, see ^{226}Th	3E+2	2E+2	8E-8	3E-10	-	-
			LLI wall (4E+2)	-	-	-	5E-6	5E-5
		Y, see ^{226}Th	-	2E+2	6E-8	2E-10	-	-
91	Protactinium-227[2]	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	-	1E+2	4E-8	1E-10	-	-
91	Protactinium-228	W, see ^{227}Pa	1E+3	1E+1	5E-9	-	2E-5	2E-4
				Bone surf				
			-	(2E+1)	-	3E-11	-	-
		Y, see ^{227}Pa	-	1E+1	5E-9	2E-11	-	-
91	Protactinium-230	W, see ^{227}Pa	6E+2	5E+0	2E-9	7E-12	-	-
			Bone surf (9E+2)	-	-	-	1E-5	1E-4

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
		Y, see ^{227}Pa	-	4E+0	1E-9	5E-12	-	-
91	Protactinium-231	W, see ^{227}Pa	2E-1 Bone surf (5E-1)	2E-3 Bone surf (4E-3)	6E-13 -	- 6E-15	- 6E-9	- 6E-8
		Y, see ^{227}Pa	- -	4E-3 Bone surf (6E-3)	2E-12 -	- 8E-15	- -	- -
91	Protactinium-232	W, see ^{227}Pa	1E+3 -	2E+1 Bone surf (6E+1)	9E-9 -	- 8E-11	2E-5 -	2E-4 -
		Y, see ^{227}Pa	- -	6E+1 Bone surf (7E+1)	2E-8 -	- 1E-10	- -	- -
91	Protactinium-233	W, see ^{227}Pa	1E+3 LLI wall (2E+3)	7E+2 -	3E-7 -	1E-9 -	- 2E-5	- 2E-4
		Y, see ^{227}Pa	-	6E+2	2E-7	8E-10	-	-
91	Protactinium-234	W, see ^{227}Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{227}Pa	-	7E+3	3E-6	9E-9	-	-
92	Uranium-230	D, UF, UOF, UO(NO)	4E+0 Bone surf (6E+0)	4E-1 Bone surf (6E-1)	2E-10 -	- 8E-13	- 8E-8	- 8E-7
		W, UO, UF, UCl	-	4E-1	1E-10	5E-13	-	-
		Y, UO, UO	-	3E-1	1E-10	4E-13	-	-
92	Uranium-231	D, see ^{230}U	5E+3 LLI wall (4E+3)	8E+3 -	3E-6 -	1E-8 -	- 6E-5	- 6E-4
		W, see ^{230}U	-	6E+3	2E-6	8E-9	-	-
		Y, see ^{230}U	-	5E+3	2E-6	6E-9	-	-
92	Uranium-232	D, see ^{230}U	2E+0 Bone surf (4E+0)	2E-1 Bone surf (4E-1)	9E-11 -	- 6E-13	- 6E-8	- 6E-7
		W, see ^{230}U	-	4E-1	2E-10	5E-13	-	-
		Y, see ^{230}U	-	8E-3	3E-12	1E-14	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
92	Uranium-233	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 -	- 3E-12	- 3E-7	- 3E-6
		W, see ^{230}U	-	7E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-234[3]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 -	- 3E-12	- 3E-7	- 3E-6
		W, see ^{230}U	-	7E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	5E-14	-	-
92	Uranium-235[3]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 -	- 3E-12	- 3E-7	- 3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-236	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 -	- 3E-12	- 3E-7	- 3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-237	D, see ^{230}U	2E+3 LLI wall (2E+3)	3E+3 -	1E-6 -	4E-9 -	- 3E-5	- 3E-4
		W, see ^{230}U	-	2E+3	7E-7	2E-9	-	-
		Y, see ^{230}U	-	2E+3	6E-7	2E-9	-	-
92	Uranium-238[3]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 -	- 3E-12	- 3E-7	- 3E-6
		W, see ^{230}U	-	8E-1	3E-10	1E-12	-	-
		Y, see ^{230}U	-	4E-2	2E-11	6E-14	-	-
92	Uranium-239[2]	D, see ^{230}U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		W, see ^{230}U	-	2E+5	7E-5	2E-7	-	-
		Y, see ^{230}U	-	2E+5	6E-5	2E-7	-	-
92	Uranium-240	D, see ^{230}U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{230}U	-	3E+3	1E-6	4E-9	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
		Y, see ^{230}U	-	2E+3	1E-6	3E-9	-	-
92	Uranium-natural[3]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 -	- 3E-12	- 3E-7	- 3E-6
		W, see ^{230}U	-	8E-1	3E-10	9E-13	-	-
		Y, see ^{230}U	-	5E-2	2E-11	9E-14	-	-
93	Neptunium-232[2]	W, all compounds	1E+5 -	2E+3 Bone surf (5E+2)	7E-7 -	- 6E-9	2E-3 -	2E-2 -
93	Neptunium-233[2]	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93	Neptunium-235	W, all compounds	2E+4 LLI wall (2E+4)	8E+2 Bone surf (1E+3)	3E-7 -	- 2E-9	- 3E-4	- 3E-3
93	Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0 Bone surf (6E+0)	2E-2 Bone surf (5E-2)	9E-12 -	- 8E-14	- 9E-8	- 9E-7
93	Neptunium-236 (22.5 h)	W, all compounds	3E+3 Bone surf (4E+3)	3E+1 Bone surf (7E+1)	1E-8 -	- 1E-10	- 5E-5	- 5E-4
93	Neptunium-237	W, all compounds	5E-1 Bone surf (1E+0)	4E-3 Bone surf (1E-2)	2E-12 -	- 1E-14	- 2E-8	- 2E-7
93	Neptunium-238	W, all compounds	1E+3 -	6E+1 Bone surf (2E+2)	3E-8 -	- 2E-10	2E-5 -	2E-4 -
93	Neptunium-239	W, all compounds	2E+3 LLI wall (2E+3)	2E+3 -	9E-7 -	3E-9 -	- 2E-5	- 2E-4
93	Neptunium-240[2]	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
94	Plutonium-234	W, all compounds except PuO	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO	-	2E+2	8E-8	3E-10	-	-
94	Plutonium-235[2]	W, see ^{234}Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see ^{234}Pu	-	3E+6	1E-3	3E-6	-	-
94	Plutonium-236	W, see ^{234}Pu	2E+0 Bone surf (4E+0)	2E-2 Bone surf (4E-2)	8E-12 -	- 5E-14	- 6E-8	- 6E-7
		Y, see ^{234}Pu	-	4E-2	2E-11	6E-14	-	-
94	Plutonium-237	W, see ^{234}Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see ^{234}Pu	-	3E+3	1E-6	4E-9	-	-
94	Plutonium-238	W, see ^{234}Pu	9E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	-	2E-2	8E-12	2E-14	-	-
94	Plutonium-239	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-240	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	- -	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-241	W, see ^{234}Pu	4E+1 Bone surf (7E+1)	3E-1 Bone surf (6E-1)	1E-10 -	- 8E-13	- 1E-6	- 1E-5
		Y, see ^{234}Pu	- -	8E-1 Bone surf (1E+0)	3E-10 -	- 1E-12	- -	- -

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Inhalation Col. 2 ALI (µCi)	Table I Occupational Values Inhalation Col. 3 DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
94	Plutonium-242	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	-	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-243	W, see ^{234}Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
		Y, see ^{234}Pu	-	4E+4	2E-5	5E-8	-	-
94	Plutonium-244	W, see ^{234}Pu	8E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
		Y, see ^{234}Pu	-	2E-2 Bone surf (2E-2)	7E-12 -	- 2E-14	- -	- -
94	Plutonium-245	W, see ^{234}Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see ^{234}Pu	-	4E+3	2E-6	6E-9	-	-
94	Plutonium-246	W, see ^{234}Pu	4E+2 LLI wall (4E+2)	3E+2 -	1E-7 -	4E-10 -	- 6E-6	- 6E-5
		Y, see ^{234}Pu	-	3E+2	1E-7	4E-10	-	-
95	Americium-237[2]	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Americium-238[2]	W, all compounds	4E+4	3E+3 Bone surf (6E+3)	1E-6 -	- 9E-9	5E-4 -	5E-3 -
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Americium-241	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 -	- 2E-14	- 2E-8	- 2E-7
95	Americium-242m	W, all compounds	8E-1 Bone surf	6E-3 Bone surf	3E-12	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
			(1E+0)	(1E-2)	-	2E-14	2E-8	2E-7
95	Americium-242	W, all compounds	4E+3	8E+1	4E-8	-	5E-5	5E-4
			-	Bone surf (9E+1)	-	1E-10	-	-
95	Americium-243	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
95	Americium-244m[2]	W, all compounds	6E+4	4E+3	2E-6	-	-	-
			St wall (8E+4)	Bone surf (7E+3)	-	1E-8	1E-3	1E-2
95	Americium-244	W, all compounds	3E+3	2E+2	8E-8	-	4E-5	4E-4
			-	Bone surf (3E+2)	-	4E-10	-	-
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m[2]	W, all compounds	5E+4	2E+5	8E-5	3E-7	-	-
			St wall (6E+4)	-	-	-	8E-4	8E-3
95	Americium-246[2]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1	6E-1	2E-10	-	-	-
			Bone surf (8E+1)	Bone surf (6E-1)	-	9E-13	1E-6	1E-5
96	Curium-241	W, all compounds	1E+3	3E+1	1E-8	-	2E-5	2E-4
			-	Bone surf (4E+1)	-	5E-11	-	-
96	Curium-242	W, all compounds	3E+1	3E-1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	4E-13	7E-7	7E-6
96	Curium-243	W, all compounds	1E+0	9E-3	4E-12	-	-	-

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
			Bone surf (2E+0)	Bone surf (2E-2)	-	2E-14	3E-8	3E-7
96	Curium-244	W, all compounds	1E+0	1E-2	5E-12	-	-	-
			Bone surf (3E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
96	Curium-245	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-246	W, all compounds	7E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-247	W, all compounds	8E-1	6E-3	3E-12	-	-	-
			Bone surf (1E+0)	Bone surf (1E-2)	-	2E-14	2E-8	2E-7
96	Curium-248	W, all compounds	2E-1	2E-3	7E-13	-	-	-
			Bone surf (4E-1)	Bone surf (3E-3)	-	4E-15	5E-9	5E-8
96	Curium-249[2]	W, all compounds	5E+4	2E+4	7E-6	-	7E-4	7E-3
			-	Bone surf (3E+4)	-	4E-8	-	-
96	Curium-250	W, all compounds	4E-2	3E-4	1E-13	-	-	-
			Bone surf (6E-2)	Bone surf (5E-4)	-	8E-16	9E-10	9E-9
97	Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Berkelium-247	W, all compounds	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
97	Berkelium-249	W, all compounds	2E+2	2E+0	7E-10	-	-	-
			Bone surf	Bone surf				

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentration		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
			(5E+2)	(4E+0)	-	5E-12	6E-6	6E-5
97	Berkelium-250	W, all compounds	9E+3	3E+2	1E-7	-	1E-4	1E-3
			-	Bone surf (7E+2)	-	1E-9	-	-
98	Californium-244[2]	W, all compounds except those given for Y	3E+4	6E+2	2E-7	8E-10	-	-
			St wall (3E+4)	-	-	-	4E-4	4E-3
		Y, oxides and hydroxides	-	6E+2	2E-7	8E-10	-	-
98	Californium-246	W, see ^{244}Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see ^{244}Cf	-	9E+0	4E-9	1E-11	-	-
98	Californium-248	W, see ^{244}Cf	8E+0	6E-2	3E-11	-	-	-
			Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
		Y, see ^{244}Cf	-	1E-1	4E-11	1E-13	-	-
98	Californium-249	W, see ^{244}Cf	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	-	1E-2	4E-12	-	-	-
			-	Bone surf (1E-2)	-	2E-14	-	-
98	Californium-250	W, see ^{244}Cf	1E+0	9E-3	4E-12	-	-	-
			Bone surf (2E+0)	Bone surf (2E-2)	-	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	-	3E-2	1E-11	4E-14	-	-
98	Californium-251	W, see ^{244}Cf	5E-1	4E-3	2E-12	-	-	-
			Bone surf (1E+0)	Bone surf (9E-3)	-	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	-	1E-2	4E-12	-	-	-
			-	Bone surf (1E-2)	-	2E-14	-	-
98	Californium-252	W, see ^{244}Cf	2E+0	2E-2	8E-12	-	-	-
			Bone surf	Bone surf				

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
			(5E+0)	(4E-2)	-	5E-14	7E-8	7E-7
		Y, see ^{244}Cf	-	3E-2	1E-11	5E-14	-	-
98	Californium-253	W, see ^{244}Cf	2E+2	2E+0	8E-10	3E-12	-	-
			Bone surf (4E+2)	-	-	-	5E-6	5E-5
		Y, see ^{244}Cf	-	2E+0	7E-10	2E-12	-	-
98	Californium-254	W, see ^{244}Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	-	2E-2	7E-12	2E-14	-	-
99	Einsteinium-250	W, all compounds	4E+4	5E+2	2E-7	-	6E-4	6E-3
			-	Bone surf (1E+3)	-	2E-9	-	-
99	Einsteinium-251	W, all compounds	7E+3	9E+2	4E-7	-	1E-4	1E-3
			-	Bone surf (1E+3)	-	2E-9	-	-
99	Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99	Einsteinium-254m	W, all compounds	3E+2	1E+1	4E-9	1E-11	-	-
			LLI wall (3E+2)	-	-	-	4E-6	4E-5
99	Einsteinium-254	W, all compounds	8E+0	7E-2	3E-11	-	-	-
			Bone surf (2E+1)	Bone surf (1E-1)	-	2E-13	2E-7	2E-6
100	Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1	2E-1	7E-11	-	-	-
			Bone surf (4E+1)	Bone surf (2E-1)	-	3E-13	5E-7	5E-6

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
101	Mendelevium-257	W, all compounds	7E+3	8E+1	4E-8	-	1E-4	1E-3
			-	Bone surf (9E+1)	-	1E-10	-	-
101	Mendelevium-258	W, all compounds	3E+1	2E-1	1E-10	-	-	-
			Bone surf (5E+1)	Bone surf (3E-1)	-	5E-13	6E-7	6E-6
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours Submersion [1]			–	2E+2	1E-7	1E-9	--
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours		-	2E-1	1E-10	1E-12	1E-8	1E-7
-	Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known		-	4E-4	2E-13	1E-15	2E-9	2E-8

FOOTNOTES:

[1] "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[2] These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 µCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation

measuring instruments that measure external exposure to demonstrate compliance with the limits. (See §20.1203.)

[3]For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see §20.1201(e)). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) µCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

SA = 3.6E-7 curies/gram U U-depleted

SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment)2] E-6 , enrichment > 0.72

where enrichment is the percentage by weight of U-235, expressed as percent.

NOTE:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
	If it is known that Ac-227-D and Cm-250-W are not present		-	7E-4	3E-13	-	-	-
	If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present		-	7E-3	3E-12	-	-	-
	If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present		-	7E-2	3E-11	-	-	-
	If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present		-	7E-1	3E-10	-	-	-
	If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present		-	7E+0	3E-9	-	-	-
	If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W are not present		-	-	-		1E-14	- -
	If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y,							

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalaltion ALI (µCi)	Table I Occupational Values Col. 3 Inhalaltion DAC (µCi/ml)	Table II Effluent Concentration Col. 1 Air (µCi/ml)	Table II Effluent Concentration Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present			-	-	-	1E-13	-	-
If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present				-	-	1E-12	-	
If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present			-	-	-	-	1E-6	1E-5

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 µm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 µCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 µCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix B to 420-3-26-.03 for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Example: If radionuclides "A," "B," and "C" are present in concentrations C_A, C_B, and C_C, and if the applicable DACs are DAC_A, DAC_B, and DAC_C, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

Author:
Statutory Authority:
History:

420-3-26-.03-AC **Appendix C - Quantities[1] of Licensed Material Requiring Labeling.**

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Hydrogen-3	1,000	Chromium-48	1,000
Beryllium-7	1,000	Chromium-49	1,000
Beryllium-10	1	Chromium-51	1,000
Carbon-1	11,000	Manganese-5	11,000
Carbon-1	41,000	Manganese-52m	1,000
Fluorine-18	1,000	Manganese-52	100
Sodium-22	10	Manganese-53	1,000
Sodium-24	100	Manganese-54	100
Magnesium-28	100	Manganese-56	1,000
Aluminum-26	10	Iron-52	100
Silicon-31	1,000	Iron-55	100
Silicon-32	1	Iron-59	10
Phosphorus-32	10	Iron-60	1
Phosphorus-33	100	Cobalt-55	100
Sulfur-35	100	Cobalt-56	10
Chlorine-36	10	Cobalt-57	100
Chlorine-38	1,000	Cobalt-58m	1,000
Chlorine-39	1,000	Cobalt-58	100
Argon-39	1,000	Cobalt-60m	1,000
Argon-41	1,000	Cobalt-60	1
Potassium-40	100	Cobalt-61	1,000
Potassium-42	1,000	Cobalt-62	1,000
Potassium-43	1,000	Nickel-56	100
Potassium-44	1,000	Nickel-57	100
Potassium-45	1,000	Nickel-59	100
Calcium-41	100	Nickel-63	100
Calcium-45	100	Nickel-65	1,000
Calcium-47	100	Nickel-66	10
Scandium-43	1,000	Copper-60	1,000
Scandium-44m	100	Copper-61	1,000
Scandium-44	100	Copper-64	1,000
Scandium-46	10	Copper-67	1,000
Scandium-47	100	Zinc-62	100
Scandium-48	100	Zinc-63	1,000
Scandium-49	1,000	Zinc-65	10
Titanium-44	1	Zinc-69m	100
Titanium-45	1,000	Zinc-69	1,000
Vanadium-47	1,000	Zinc-71m	1,000
Vanadium-48	100	Zinc-72	100
Vanadium-49	1,000	Gallium-65	1,000
Gallium-66	100	Krypton-81	1,000
Gallium-67	1,000	Krypton-83m	1,000
Gallium-68	1,000	Krypton-85m	1,000
Gallium-70	1,000	Krypton-85	1,000

*To convert µCi to kBq, multiply the µCi value by 37.

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*

Gallium-72	100	Krypton-87	1,000
Gallium-73	1,000	Krypton-88	1,000
Germanium-66	1,000	Rubidium-79	1,000
Germanium-67	1,000	Rubidium-81m	1,000
Germanium-68	10	Rubidium-81	1,000
Germanium-69	1,000	Rubidium-82	1,000
Germanium-71	1,000	Rubidium-83	100
Germanium-75	1,000	Rubidium-84	100
Germanium-77	1,000	Rubidium-86	100
Germanium-78	1,000	Rubidium-87	100
Arsenic-69	1,000	Rubidium-88	1,000
Arsenic-70	1,000	Rubidium-89	1,000
Arsenic-71	100	Strontium-80	100
Arsenic-72	100	Strontium-81	1,000
Arsenic-73	100	Strontium-83	100
Arsenic-74	100	Strontium-85m	1,000
Arsenic-76	100	Strontium-85	100
Arsenic-77	100	Strontium-87m	1,000
Arsenic-78	1,000	Strontium-89	10
Selenium-70	1,000	Strontium-90	0.1
Selenium-73m	1,000	Strontium-91	100
Selenium-73	100	Strontium-91	100
Selenium-75	100	Yttrium-86m	1,000
Selenium-79	100	Yttrium-86	100
Selenium-81m	1,000	Yttrium-87	100
Selenium-81	1,000	Yttrium-88	10
Selenium-83	1,000	Yttrium-90m	1,000
Bromine-74m	1,000	Yttrium-90	10
Bromine-74	1,000	Yttrium-91m	1,000
Bromine-75	1,000	Yttrium-91	10
Bromine-76	100	Yttrium-92	100
Bromine-77	1,000	Yttrium-93	100
Bromine-80m	1,000	Yttrium-94	1,000
Bromine-80	1,000	Yttrium-95	1,000
Bromine-82	100	Zirconium-86	100
Bromine-83	1,000	Zirconium-88	10
Bromine-84	1,000	Zirconium-89	100
Krypton-74	1,000	Zirconium-93	1
Krypton-76	1,000	Zirconium-95	10
Krypton-77	1,000	Zirconium-97	100
Krypton-79	1,000		
Niobium-88	1,000	Palladium-10	1,000
Niobium-89m (66 min)	1,000	Palladium-10	100
		Palladium-10	10
Niobium-89 (122 min)	1,000	Palladium-10	100
		Silver-10	1,000
Niobium-90	100	Silver-10	1,000
Niobium-93m	10	Silver-10	1,000
Niobium-94	1	Silver-10	1,000

*To convert µCi to kBq, multiply the µCi value by 37.

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Niobium-95m	100	Silver-105	100
Niobium-95	100	Silver-106m	100
Niobium-96	100	Silver-106	1,000
Niobium-97	1,000	Silver-108m	1
Niobium-98	1,000	Silver-110m	10
Molybdenum-90	100	Silver-111	100
Molybdenum-93m	100	Silver-112	100
Molybdenum-93	10	Silver-115	1,000
Molybdenum-99	100	Cadmium-104	1,000
Molybdenum-101	1,000	Cadmium-107	1,000
Technetium-93m	1,000	Cadmium-109	1
Technetium-93	1,000	Cadmium-113m	0.1
Technetium-94m	1,000	Cadmium-113	100
Technetium-94	1,000	Cadmium-115m	10
Technetium-96m	1,000	Cadmium-115	100
Technetium-96	100	Cadmium-117m	1,000
Technetium-97m	100	Cadmium-117	1,000
Technetium-97	1,000	Indium-109	1,000
Technetium-98	10	Indium-1	10
Technetium-99m	1,000	(69.1m)	1,000
Technetium-99	100	Indium-110	1,000
Technetium-101	1,000	(4.9h)	
Technetium-104	1,000	Indium-111	100
Ruthenium-94	1,000	Indium-112	1,000
Ruthenium-97	1,000	Indium-113m	1,000
Ruthenium-103	100	Indium-114m	10
Ruthenium-105	1,000	Indium-115m	1,000
Ruthenium-106	1	Indium-115	100
Rhodium-99m	1,000	Indium-116m	1,000
Rhodium-99	100	Indium-117m	1,000
Rhodium-100	100	Indium-117	1,000
Rhodium-101m	1,000	Indium-119m	1,000
Rhodium-101	10	Tin-110	100
Rhodium-102m	10	Tin-111	1,000
Rhodium-102	10	Tin-113	100
Rhodium-103m	1,000	Tin-117m	100
Rhodium-105	100	Tin-119m	100
Rhodium-106m	1,000	Tin-121m	100
Rhodium-107	1,000	Tin-121	1,000
Palladium-100	100		
Tin-123m	1,000	Tellurium-133	1,000
Tin-123	10	Tellurium-134	1,000
Tin-125	10	Iodine-120m	1,000
Tin-126	10	Iodine-120	100
Tin-127	1,000	Iodine-121	1,000
Tin-128	1,000	Iodine-123	100
Antimony-115	1,000	Iodine-124	10
Antimony-116m	1,000	Iodine-125	1

*To convert µCi to kBq, multiply the µCi value by 37.

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Antimony-116	1,000	Iodine-126	1
Antimony-117	1,000	Iodine-128	1,000
Antimony-118m	1,000	Iodine-129	1
Antimony-119	1,000	Iodine-130	10
Antimony-120	1,000	Iodine-131	1
		Iodine-132m	100
Antimony-120	100	Iodine-132	100
		Iodine-133	10
Antimony-122	100	Iodine-134	1,000
Antimony-124m	1,000	Iodine-135	100
Antimony-124	10	Xenon-120	1,000
Antimony-125	100	Xenon-121	1,000
Antimony-126m	1,000	Xenon-122	1,000
Antimony-126	100	Xenon-123	1,000
Antimony-127	100	Xenon-125	1,000
Antimony-128 (10.4m)	1,000	Xenon-127	1,000
		Xenon-129m	1,000
Antimony-128 (9.01h)	100	Xenon-131m	1,000
		Xenon-133m	1,000
Antimony-129	100	Xenon-133	1,000
Antimony-130	1,000	Xenon-135m	1,000
Antimony-131	1,000	Xenon-135	1,000
Tellurium-116	1,000	Xenon-138	1,000
Tellurium-121m	10	Cesium-125	1,000
Tellurium-121	100	Cesium-127	1,000
Tellurium-123m	10	Cesium-129	1,000
Tellurium-122	100	Cesium-130	1,000
Tellurium-125m	10	Cesium-131	1,000
Tellurium-127m	10	Cesium-132	100
Tellurium-127	1,000	Cesium-134m	1,000
Tellurium-129m	10	Cesium-134	10
Tellurium-129	1,000	Cesium-135m	1,000
Tellurium-131m	10	Cesium-135	100
Tellurium-131	100	Cesium-136	10
Tellurium-132	10	Cesium-137	10
Tellurium-133m	100	Cesium-138	1,000
Barium-126	1,000	Promethium-141	1,000
Barium-128	100	Promethium-143	100
Barium-131m	1,000	Promethium-14	10
Barium-131	100	Promethium-141	10
Barium-133m	100	Promethium-141	1
Barium-133	100	Promethium-141	10
Barium-135m	100	Promethium-141	10
Barium-139	1,000	Promethium-141	10
Barium-140	100	Promethium-141	100
Barium-141	1,000	Promethium-141	1,000
Barium-142	1,000	Promethium-141	100
Lanthanum-131	1,000	Samarium-141m	1,000

*To convert µCi to kBq, multiply the µCi value by 37.

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Lanthanum-13	100	Samarium-141	1,000
Lanthanum-13	1,000	Samarium-142	1,000
Lanthanum-13	10	Samarium-145	100
Lanthanum-13	100	Samarium-146	1
Lanthanum-13	100	Samarium-147	100
Lanthanum-13	100	Samarium-151	10
Lanthanum-13	1,000	Samarium-153	100
Lanthanum-13	1,000	Samarium-155	1,000
Cerium-134	100	Samarium-156	1,000
Cerium-135	100	Europium-145	100
Cerium-137m	100	Europium-146	100
Cerium-137	1,000	Europium-147	100
Cerium-139	100	Europium-148	10
Cerium-141	100	Europium-149	100
Cerium-143	100	Europium-150	100
Cerium-144	1	(12.62h)	
Praseodymium-136	1,000	Europium-150	1
Praseodymium-137	1,000	(34.2y)	
Praseodymium-138m	1,000	Europium-152m	100
Praseodymium-139	1,000	Europium-152	1
Praseodymium-142m	1,000	Europium-154	1
Praseodymium-142	100	Europium-155	10
Praseodymium-143	100	Europium-156	100
Praseodymium-144	1,000	Europium-157	100
Praseodymium-145	100	Europium-158	1,000
Praseodymium-147	1,000	Gadolinium-145	1,000
Neodymium-136	1,000	Gadolinium-146	10
Neodymium-138	100	Gadolinium-147	100
Neodymium-139m	1,000	Gadolinium-148	0.001
Neodymium-139	1,000	Gadolinium-149	100
Neodymium-141	1,000	Gadolinium-151	10
Neodymium-147	100	Gadolinium-152	100
Neodymium-149	1,000	Gadolinium-153	10
Neodymium-151	1,000	Gadolinium-159	100
Terbium-147	1,000	Ytterbium-162	1,000
Terbium-149	100	Ytterbium-166	100
Terbium-150	1,000	Ytterbium-167	1,000
Terbium-151	100	Ytterbium-169	100
Terbium-153	1,000	Ytterbium-175	100
Terbium-154	100	Ytterbium-177	1,000
Terbium-155	1,000	Ytterbium-178	1,000
Terbium-156m	1,000	Lutetium-169	100
		Lutetium-170	100
Terbium-156m	1,000	Lutetium-171	100
		Lutetium-172	100
Terbium-156	100	Lutetium-173	10
Terbium-157	10	Lutetium-174m	10

*To convert µCi to kBq, multiply the µCi value by 37.

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Terbium-157	1	Lutetium-174	10
Terbium-160	10	Lutetium-176m	1,000
Terbium-161	100	Lutetium-176	100
Dysprosium-155	1,000	Lutetium-177m	10
Dysprosium-157	1,000	Lutetium-177	100
Dysprosium-159	100	Lutetium-178m	1,000
Dysprosium-165	1,000	Lutetium-178	1,000
Dysprosium-166	100	Lutetium-179	1,000
Holmium-155	1,000	Hafnium-170	100
Holmium-157	1,000	Hafnium-172	1
Holmium-159	1,000	Hafnium-173	1,000
Holmium-161	1,000	Hafnium-175	100
Holmium-162m	1,000	Hafnium-177m	1,000
Holmium-162	1,000	Hafnium-178m	0.1
Holmium-164m	1,000	Hafnium-179m	10
Holmium-164	1,000	Hafnium-180m	1,000
Holmium-166m	1	Hafnium-181	10
Holmium-166	100	Hafnium-182m	1,000
Holmium-167	1,000	Hafnium-182	0.1
Erbium-161	1,000	Hafnium-183	1,000
Erbium-165	1,000	Hafnium-184	100
Erbium-169	100	Tantalum-172	1,000
Erbium-171	100	Tantalum-173	1,000
Erbium-172	100	Tantalum-174	1,000
Thulium-162	1,000	Tantalum-175	1,000
Thulium-166	100	Tantalum-176	100
Thulium-167	100	Tantalum-177	1,000
Thulium-170	10	Tantalum-178	1,000
Thulium-171	10	Tantalum-179	100
Thulium-172	100	Tantalum-180m	1,000
Thulium-173	100	Tantalum-180	100
Thulium-175	1,000	Tantalum-182m	1,000
Tantalum-182	10	Iridium-188	100
Tantalum-183	100	Iridium-189	100
Tantalum-184	100	Iridium-190m	1,000
Tantalum-185	1,000	Iridium-190	100
Tantalum-186	1,000	Iridium-192m	10
Tungsten-176	1,000	(1.4m)	
Tungsten-177	1,000	Iridium-192	1
Tungsten-178	1,000	(73.8d)	
Tungsten-179	1,000	Iridium-194m	10
Tungsten-181	1,000	Iridium-194	100
Tungsten-185	100	Iridium-195m	1,000
Tungsten-187	100	Iridium-195	1,000
Tungsten-188	10	Platinum-186	1,000
Rhenium-177	1,000	Platinum-188	100
Rhenium-178	1,000	Platinum-189	1,000
Rhenium-181	1,000	Platinum-191	100

*To convert µCi to kBq, multiply the µCi value by 37.

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Rhenium-182 (12.7h)	1,000	Platinum-193m	100
		Platinum-193	1,000
Rhenium-182 (64.0h)	100	Platinum-195m	100
		Platinum-197m	1,000
Rhenium-184m	10	Platinum-197	100
Rhenium-184	100	Platinum-199	1,000
Rhenium-186m	10	Platinum-200	100
Rhenium-186	100	Gold-193	1,000
Rhenium-187	1,000	Gold-194	100
Rhenium-188m	1,000	Gold-195	10
Rhenium-188	100	Gold-198m	100
Rhenium-189	100	Gold-198	100
Osmium-180	1,000	Gold-199	100
Osmium-181	1,000	Gold-200m	100
Osmium-182	100	Gold-200	1,000
Osmium-185	100	Gold-201	1,000
Osmium-189m	1,000	Mercury-193m	100
Osmium-191m	1,000	Mercury-193	1,000
Osmium-191	100	Mercury-194	1
Osmium-193	100	Mercury-195m	100
Osmium-194	1	Mercury-195	1,000
Iridium-182	1,000	Mercury-197m	100
Iridium-184	1,000	Mercury-197	1,000
Iridium-185	1,000	Mercury-199m	1,000
Iridium-186	100	Mercury-203	100
Iridium-187	1,000		
Thallium-194m	1,000	Francium-223	100
Thallium-194	1,000	Radium-223	0.1
Thallium-195	1,000	Radium-224	0.1
Thallium-197	1,000	Radium-225	0.1
Thallium-198m	1,000	Radium-226	0.1
Thallium-198	1,000	Radium-227	1,000
Thallium-199	1,000	Radium-228	0.1
Thallium-201	1,000	Actinium-224	1
Thallium-200	1,000	Actinium-225	0.01
Thallium-202	100	Actinium-226	0.1
Thallium-204	100	Actinium-227	0.001
Lead-195m	1,000	Actinium-228	1
Lead-198	1,000	Thorium-226	10
Lead-199	1,000	Thorium-227	0.01
Lead-200	100	Thorium-228	0.001
Lead-201	1,000	Thorium-229	0.001
Lead-202m	1,000	Thorium-230	0.001
Lead-202	10	Thorium-231	100
Lead-203	1,000	Thorium-232	100
Lead-205	100	Thorium-234	10
Lead-209	1,000	Thorium-natural	100
Lead-210	0.01	Protactinium-227	10

*To convert µCi to kBq, multiply the µCi value by 37.

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Lead-211	100	Protactinium-228	1
Lead-212	1	Protactinium-230	0.1
Lead-214	100	Protactinium-231	0.001
Bismuth-200	1,000	Protactinium-232	1
Bismuth-201	1,000	Protactinium-233	100
Bismuth-202	1,000	Protactinium-234	100
Bismuth-203	100	Uranium-230	0.01
Bismuth-205	100	Uranium-231	100
Bismuth-206	100	Uranium-232	0.001
Bismuth-207	10	Uranium-233	0.001
Bismuth-210m	0.1	Uranium-234	0.001
Bismuth-210	1	Uranium-235	0.001
Bismuth-212	10	Uranium-236	0.001
Bismuth-213	10	Uranium-237	100
Bismuth-214	100	Uranium-238	100
Polonium-203	1,000	Uranium-239	1,000
Polonium-205	1,000	Uranium-240	100
Polonium-207	1,000	Uranium-natural	100
Polonium-210	0.1	Neptunium-232	100
Astatine-207	100	Neptunium-233	1,000
Astatine-210	10	Neptunium-234	100
Radon-220	1	Neptunium-235	100
Radon-222	1	Neptunium-236 (1.15E+5)	0.001
Francium-222	100		
Neptunium-236 (22.5h)	1	Curium-242	0.01
		Curium-243	0.001
Neptunium-237	0.001	Curium-244	0.001
Neptunium-238	10	Curium-245	0.001
Neptunium-239	100	Curium-246	0.001
Neptunium-240	1,000	Curium-247	0.001
Plutonium-234	10	Curium-248	0.001
Plutonium-235	1,000	Curium-249	1,000
Plutonium-236	0.001	Berkelium-245	100
Plutonium-237	100	Berkelium-246	100
Plutonium-238	0.001	Berkelium-247	0.001
Plutonium-239	0.001	Berkelium-249	0.1
Plutonium-240	0.001	Berkelium-250	10
Plutonium-241	0.01	Californium-244	100
Plutonium-242	0.001	Californium-246	1
Plutonium-243	1,000	Californium-247	0.01
Plutonium-244	0.001	Californium-249	0.001
Plutonium-245	100	Californium-250	0.001
Americium-237	1,000	Californium-251	0.001
Americium-238	100	Californium-252	0.001
Americium-239	1,000	Californium-253	0.1
Americium-240	100	Californium-254	0.001
Americium-241	0.001	Einsteinium-250	100

*To convert µCi to kBq, multiply the µCi value by 37.

Radionuclide	Quantity (µCi)*	Radionuclide	Quantity (µCi)*
Americium-242m	0.001	Einsteinium-251	100
Americium-242	10	Einsteinium-253	0.1
Americium-243	0.001	Einsteinium-254m	1
Americium-244m	100	Einsteinium-254	0.01
Americium-244	10	Fermium-252	1
Americium-245	1,000	Fermium-253	1
Americium-246m	1,000	Fermium-254	10
Americium-246	1,000	Fermium-255	1
Curium-238	100	Fermium-257	0.01
Curium-240	0.1	Mendelevium-257	10
Curium-241	1	Mendelevium-258	0.01

*To convert µCi to kBq, multiply the µCi value by 37.

NOTE: For purposes of 420-3-26-.03(28)(e), 420-3-26-.03(31)(a), and 420-3-26-.03(51)(a) where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

[1] The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix B to this Rule, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 mCi). Values of 3.7 MBq (100 µCi) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 37 MBq (1,000 µCi), to take into account their low specific activity.

*To convert µCi to kBq, multiply the µCi value by 37.

Author:
Statutory Authority:
History:

420-3-26-.03-AD **Appendix D - Nationally Tracked Source Thresholds.**

The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

Author:
Statutory Authority:
History:

420-3-26-.03-AE **Appendix E - Classification and Characteristics of Low-Level Radioactive Waste.**

I. Classification of Radioactive Waste for Land Disposal

(a) Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

(b) Classes of waste.

(1) Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in Section II.(a). If Class A waste also meets the stability requirements set forth in Section II.(b), it is not necessary to segregate the waste for disposal.

(2) Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in Section II.

(3) Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in Section II.

(c) Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table I, classification shall be determined as follows:

(1) If the concentration does not exceed 0.1 times the value in Table I, the waste is Class A.

(2) If the concentration exceeds 0.1 times the value in Table I, but does not exceed the value in Table I, the waste is Class C.

(3) If the concentration exceeds the value in Table I, the waste is not generally acceptable for land disposal.

(4) For wastes containing mixtures of radionuclides listed in Table I, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE I

Radionuclide	Concentration	
	curie/cubic meter[a]	nanocurie/ gram[b]
C-14	8	
C-14 in activated metal	80	
Ni-59 in activated metal	220	
Nb-94 in activated metal	0.2	
Tc-99		3
I-129		0.08
Alpha emitting transuranic radionuclides with half- life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

[a]To convert the µCi/m3 values to gigabecquerel (GBq) per cubic meter, multiply the µCi/m3 value by 37.

[b]To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by 37.

(d) Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table I, classification shall be determined based on the concentrations shown in Table II. However, as specified in Section I.(f), if radioactive waste does not contain any nuclides listed in either Table I or II, it is Class A.

(1) If the concentration does not exceed the value in Column 1, the waste is Class A.

(2) If the concentration exceeds the value in Column 1 but does not exceed the value in Column 2, the waste is Class B.

(3) If the concentration exceeds the value in Column 2 but does not exceed the value in Column 3, the waste is Class C.

(4) If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

5) For wastes containing mixtures of the radionuclides listed in Table II, the total concentration shall be determined by the sum of fractions rule described in Section I.(g).

TABLE II

Radionuclide	Concentration, curie/cubic meter*		
	Column 1	Column 2	Column 3
Total of all radio-nuclides with less than 5-year half-life	700	*	*
H-3	40	*	*
Co-60	700	*	*
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

*AGENCY NOTE: To convert the µCi/m3 value to gigabecquerel (GBq) per cubic meter, multiply the µCi/m3 value by 37.There are no limits established for these radionuclides in Class B or C wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be Class B unless the concentrations of other radionuclides in Table II determine the waste to be Class C independent of these radionuclides.

(e) Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in Table I and some of which are listed in Table II, classification shall be determined as follows:

(1) If the concentration of a radionuclide listed in Table I is less than 0.1 times the value listed in Table I, the class shall be that determined by the concentration of radionuclides listed in Table II.

(2) If the concentration of a radionuclide listed in Table I exceeds 0.1 times the value listed in Table I, but does not exceed the value in Table I, the waste shall be Class C, provided the concentration of radionuclides listed in Table II does not exceed the value shown in Column 3 of Table II.

(f) Classification of wastes with radionuclides other than those listed in Tables I and II. If the waste does not contain any radionuclides listed in either Table I or II, it is Class A.

(g) The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate

limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of 1.85 TBq/m3 (50 µCi/m3) and Cs-137 in a concentration of 814 GBq/m3 (22 µCi/m3). Since the concentrations both exceed the values in Column 1, Table II, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33., for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83.Since the sum is less than 1.0, the waste is Class B.

(h) Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

II. Radioactive Waste Characteristics

(a) The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

(1) Wastes shall be packaged in conformance with the conditions of the license issued to the site operator to which the waste will be shipped. Where the conditions of the site license are more restrictive than the provisions of this Rule, the site license conditions shall govern.

(2) Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

(3) Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

(4) Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume.

(5) Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

(6) Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with Section II.(a)(8).

(7) Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.

(8) Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at 20øC. Total activity shall not exceed 3.7 TBq (100 µCi) per container.

(9) Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

(b) The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

(1) Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

(2) Notwithstanding the provisions in Section II.(a)(3) and (4), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed 1% of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

(3) Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

III. Labeling. Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with Section I.

Author:
Statutory Authority:
History:

420-3-26-.03-AF **Appendix F - Quantities for use with Decommissioning.**

Material	**Microcurie***
Americium-241	0.01
Antimony-122	100
Antimony-124	10
Antimony-125	10
Arsenic-73	100
Arsenic-74	10
Arsenic-76	10
Arsenic-77	100
Barium-131	10
Barium-133	10
Barium-140	10
Bismuth-210	1
Bromine-82	10
Cadmium-109	10
Cadmium-115m	10
Cadmium-115	100
Calcium-45	10
Calcium-47	10
Carbon-14	100
Cerium-141	100
Cerium-143	100
Cerium-144	1
Cerium-131	1,000
Cerium-134m	100
Cerium-134	1
Cerium-135	10
Cerium-136	10
Cerium-137	10
Chlorine-36	10
Chlorine-38	10
Chromium-51	1,000
Cobalt-58m	10
Cobalt-58	10
Cobalt-60	1
Copper-64	100
Dysprosium-165	10
Dysprosium-166	100
Erbium-169	100
Erbium-171	100
Europium-152 (9.2 h)	100
Europium-152 (13 yr)	1
Europium-154	1
Europium-155	10
*To convert µCi to kBq, multiply the µCi value by 37.	
**Based on alpha disintegration rate of Th-232, Th-230 and their daughter products	
***Based on alpha disintegration rate of U-238, U-234, and U-235.	

Material	Microcurie*
Florine-18	1,000
Gadolinium-153	10
Gadolinium-159	100
Gallium-72	10
Germanium-71	100
Gold-198	100
Gold-199	100
Hafnium-181	10
Holmium-166	100
Hydrogen-3	1,000
Indium-113m	100
Indium-114m	10
Indium-115m	100
Indium-115	10
Iodine-125	1
Iodine-126	1
Iodine-129	0.1
Iodine-131	1
Iodine-132	10
Iodine-133	1
Iodine-134	10
Iodine-135	10
Iridium-192	10
Iridium-194	100
Iron-55	100
Iron-59	10
Krypton-85	100
Krypton-87	10
Lanthanum-140	10
Lutetium-177	100
Manganese-52	10
Manganese-54	10
Manganese-56	10
Mercury-197m	100
Mercury-197	100
Mercury-203	10
Molybdenum-99	100
Neodymium-147	100
Neodymium-149	100
Nickel-59	100
Nickel-63	10
Nickel-65	100
Niobium-93m	10
Niobium-95	10
Niobium-97	10
*To convert µCi to kBq, multiply the µCi value by 37.	
**Based on alpha disintegration rate of Th-232, Th-230 and their daughter products	
***Based on alpha disintegration rate of U-238, U-234, and U-235.	

Material	Microcurie*
Osmium-185	10
Osmium-191m	100
Osmium-191	100
Osmium-193	100
Palladium-103	100
Palladium-109	100
Phosphorus-32	10
Platinum-191	100
Platinum-193m	100
Platinum-193	100
Platinum-197m	100
Platinum-197	100
Plutonium-239	0.01
Polonium-210	0.1
Potassium-42	10
Praseodymium-142	100
Praseodymium-143	100
Promethium-147	10
Promethium-149	10
Radium-226	0.01
Rhenium-186	100
Rhenium-188	100
Rhodium-103m	100
Rhodium-105	100
Rubidium-86	10
Rubidium-87	10
Ruthenium-97	100
Ruthenium-103	10
Ruthenium-105	10
Ruthenium-106	1
Samarium-151	10
Samarium-153	100
Scandium-46	10
Scandium-47	100
Scandium-48	10
Selenium-75	10
Silicon-31	100
Silver-105	10
Silver-110m	1
Silver-111	100
Sodium-22	1
Sodium-24	10
Strontium-85	10
Strontium-89	1
Strontium-90	0.1
*To convert µCi to kBq, multiply the µCi value by 37.	
**Based on alpha disintegration rate of Th-232, Th-230 and their daughter products	
***Based on alpha disintegration rate of U-238, U-234, and U-235.	

Material	Microcurie*
Strontium-91	10
Strontium-92	10
Sulfur -35	100
Tantalum-182	10
Technetium-96	10
Technetium-96	100
Technetium-96	100
Technetium-96	100
Technetium-96	10
Tellurium-125m	10
Tellurium-127m	10
Tellurium-127	100
Tellurium-129m	10
Tellurium-129	100
Tellurium-131m	10
Tellurium-132	10
Terbium-160	10
Thallium-200	100
Thallium-201	100
Thallium-202	100
Thallium-204	10
Thorium (natural)**	100
Thulium-170	10
Thulium-171	10
Tin-113	10
Tin-125	10
Tungsten-181	10
Tungsten-185	10
Tungsten-187	100
Uranium (natural**)	100
Uranium-233	0.01
Uranium-233	0.01
Uranium-233	0.01
Vanadium-48	10
Xenon-131m	1,000
Xenon-133	100
Xenon-135	100
Ytterbium-175	100
Yttrium-90	10
Yttrium-91	10
Yttrium-92	100
Yttrium-93	100
Zinc-65	10
Zinc-69m	100
Zinc-69	1,000
*To convert µCi to kBq, multiply the µCi value by 37.	
**Based on alpha disintegration rate of Th-232, Th-230 and their daughter products	
***Based on alpha disintegration rate of U-238, U-234, and U-235.	

Material	**Microcurie***
Zirconium-93	10
Zirconium-93	10
Zirconium-93	10
Any alpha emitting radio- nuclide not listed above or mixtures of alpha emitters unknown composition	0.01
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1
*To convert µCi to kBq, multiply the µCi value by 37.	
**Based on alpha disintegration rate of Th-232, Th-230 and their daughter products	
***Based on alpha disintegration rate of U-238, U-234, and U-235.	

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed "1" -- that is, unity.]

Author:

Statutory Authority:

History:

420-3-26-.03-AG **Appendix G - Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests.**

I. Manifest. A waste generator, collector, or processor who transports, or offers for transportation, low-level radioactive waste intended for ultimate disposal at a licensed low-level radioactive waste land disposal facility must prepare a Manifest (OMB Control Numbers 3150-0164, -0165, and -0166) reflecting information requested on applicable NRC Form 540 (Uniform Low-Level Radioactive Waste Manifest (Shipping Paper)) and 541 (Uniform Low-Level Radioactive Waste Manifest (Container and Waste Description)) and, if necessary, of an applicable NRC Form 542 (Uniform Low-Level Radioactive Waste Manifest (Manifest Index and Regional Compact Tabulation)). NRC Forms 540 and 540A must be completed and must physically accompany the pertinent low-level waste shipment. Upon agreement between shipper and consignee, NRC Forms 541 and 541A and 542 and 542A may be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete records on the respective forms. Licensees are not required by NRC to comply with the manifesting requirements of this part when they ship:

(a) LLW for processing and expect its return (i.e., for storage under their license) prior to disposal at a licensed land disposal facility.

(b) LLW that is being returned to the licensee who is the "waste generator" or “generator," as defined in this part; or

(c) Radioactively contaminated material to a "waste processor" that becomes the processor's "residual waste."

For guidance in completing these forms, refer to the instructions that accompany the forms. Copies of manifests required by this appendix may be legible carbon copies, photocopies, or computer printouts that reproduce the data in the format of the uniform manifest.

NRC Forms 540, 540A, 541, 541A, 542 and 542A, and the accompanying instructions, in hard copy, may be obtained from the information and Records Management Branch, Office of

nformation Resources Management, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555., telephone (301) 415-7232.

This appendix includes information requirements of the Department of Transportation, as codified in 49 CFR Part 172.

Information on hazardous, medical, or other waste, required to meet Environmental Protection Agency regulations, as codified in 40 CFR Parts 259, 261 or elsewhere, is not addressed in this

section, and must be provided on the required EPA forms. However, the required EPA forms must accompany the Uniform Low-Level Radioactive Waste Manifest required by this chapter.

As used in this appendix, the following definitions apply:

Chelating agent has the same meaning as that given in 10 CFR Part 61.2.

Chemical description means a description of the principal chemical characteristics of a low-level radioactive waste.

Computer-readable medium means that the regulatory agency's computer can transfer the information from the medium into its memory.

Consignee means the designated receiver of the shipment of low-level radioactive waste.

Decontamination facility means a facility operating under a Commission, Agency, or Agreement State license whose principal purpose is decontamination of equipment or materials to accomplish recycle, reuse, or other waste management objectives, and, for purposes of this part, is not considered to be a consignee for LLW shipments.

Disposal container means a container principally used to confine low-level radioactive waste during disposal operations at a land disposal facility (also see "high integrity container"). Note that for some shipments, the disposal container may be the transport package.

EPA identification number means the number received by a transporter following application to the Administrator of EPA as required by 40 CFR Part 263.

Generator means a licensee operating under a Commission, Agency, or Agreement State license who (1) is a waste generator as defined in his part, or (2) is the licensee to whom waste can be attributed within the context of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (e.g., waste generated as a result of decontamination or recycle activities).

High integrity container (HIC) means a container commonly designed to meet the structural stability requirements of 10 CFR Part 61.56, and to meet Department of Transportation requirements for a Type A package.

Land disposal facility has the same meaning as that given in 10 CFR Part 61.2.

NRC Forms 540, 540A, 541, 541A, 542, and 542A are official NRC Forms referenced in this appendix. Licensees need not use

originals of these NRC Forms as long as any substitute forms are equivalent to the original documentation in respect to content, clarity, size, and location of information. Upon agreement between the shipper and consignee, NRC Forms 541 (and 541A) and NRC Forms 542 (and 542A) may be completed, transmitted, and stored in electronic media. The electronic media must have the capability for producing legible, accurate, and complete records in the format of the uniform manifest.

Package means the assembly of components necessary to ensure compliance with the package requirements of DOT regulations, together with its radioactive contents, as presented for transport.

Physical description means the items called for on NRC Form 541 to describe a low-level radioactive waste.

Residual waste means low-level radioactive waste resulting from processing or decontamination activities that cannot be easily separated into distinct batches attributable to specific waste generators. This waste is attributable to the processor or decontamination facility, as applicable.

Shipper means the licensed entity (i.e., the waste generator, waste collector, or waste processor) who offers low-level radioactive waste for transportation, typically consigning this type of waste to a licensed waste collector, waste processor, or land disposal facility operator.

Shipping paper means NRC Form 540 and, if required, NRC Form 540A which includes the information required by DOT in 49 CFR part 172.

Source material has the same meaning as that given in 10 CFR Part 40.4.

Special nuclear material has the same meaning as that given in 10 CFR Part 70.4.

Uniform Low-Level Radioactive Waste Manifest or uniform manifest means the combination of NRC Forms 540, 541, and, if necessary, 542, and their respective continuation sheets as needed, or equivalent.

Waste collector means an entity, operating under a Commission, Agency, or Agreement State license, whose principal purpose is to collect and consolidate waste generated by others, and to transfer this waste, without processing or repackaging the collected waste, to another licensed waste collector, licensed waste processor, or licensed land disposal facility.

Waste description means the physical, chemical and radiological description of a low-level radioactive waste as called for on NRC Form 541.

Waste generator means an entity, operating under a Commission, Agency, or Agreement State license, who (1) possesses any material or component that contains radioactivity or is radioactively contaminated for which the licensee foresees no further use, and (2) transfers this material or component to a licensed land disposal facility or to a licensed waste collector or processor for handling or treatment prior to disposal. A licensee performing processing or decontamination services may be a "waste generator" if the transfer of low-level radioactive waste from its facility is defined as "residual waste."

Waste processor means an entity, operating under a Commission, Agency, or Agreement State license, whose principal purpose is to process, repackage, or otherwise treat low-level radioactive material or waste generated by others prior to eventual transfer of waste to a licensed low-level radioactive waste land disposal facility.

Waste type means a waste within a disposal container having a unique physical description (i.e., a specific waste descriptor code or description; or a waste sorbed on or solidified in a specifically defined media).

Information Requirements

A. General Information

The shipper of the radioactive waste, shall provide the following information on the uniform manifest:

1. The name, facility address, and telephone number of the licensee shipping the waste;

2. An explicit declaration indicating whether the shipper is acting as a waste generator, collector, processor, or a combination of these identifiers for purposes of the manifested shipment; and

3. The name, address, and telephone number, or the name and EPA identification number for the carrier transporting the waste.

B. Shipment Information

The shipper of the radioactive waste shall provide the following information regarding the waste shipment on the uniform manifest:

1. The date of the waste shipment;

2. The total number of packages/disposal containers;

3. The total disposal volume and disposal weight in the shipment;

4. The total radionuclide activity in the shipment;

5. The activity of each of the radionuclides H-3, C-14, Tc-99, and I-129 contained in the shipment; and

6. The total masses of U-233, U-235, and plutonium in special nuclear material, and the total mass of uranium and thorium in source material.

C. Disposal Container and Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding the waste and each disposal container of waste in the shipment:

1. An alphabetic or numeric identification that uniquely identifies each disposal container in the shipment;

2. A physical description of the disposal container, including the manufacturer and model of any high integrity container;

3. The volume displaced by the disposal container;

4. The gross weight of the disposal container, including the waste;

5. For waste consigned to a disposal facility, the maximum radiation level at the surface of each disposal container;

6. A physical and chemical description of the waste;

7. The total weight percentage of chelating agent for any waste containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

8. The approximate volume of waste within a container;

9. The sorbing or solidification media, if any, and the identity of the solidification media vendor and brand name;

10. The identities and activities of individual radionuclides contained in each container, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material. For discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides associated with or contained on these waste types within a disposal container shall be reported;

11. The total radioactivity within each container; and

12. For wastes consigned to a disposal facility, the classification of the waste pursuant to 10 CFR Part 61.55.Waste

not meeting the structural stability requirements of 10 CFR Part 61.56(b) must be identified.

D. Uncontainerized Waste Information

The shipper of the radioactive waste shall provide the following information on the uniform manifest regarding a waste shipment delivered without a disposal container:

1. The approximate volume and weight of the waste;

2. A physical and chemical description of the waste;

3. The total weight percentage of chelating agent if the chelating agent exceeds 0.1% by weight, plus the identity of the principal chelating agent;

4. For waste consigned to a disposal facility, the classification of the waste pursuant to 10 CFR Part 61.55.Waste not meeting the structural stability requirements of 10 CFR Part 61.56(b) must be identified;

5. The identities and activities of individual radionuclides contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material; and

6. For wastes consigned to a disposal facility, the maximum radiation levels at the surface of the waste.

E. Multi-Generator Disposal Container Information

This section applies to disposal containers enclosing mixtures of waste originating from different generators. (Note: The origin of the LLW resulting from a processor's activities may be attributable to one or more "generators" (including "waste generators") as defined in this part). It also applies to mixtures of wastes shipped in an uncontainerized form, for which portions of the mixture within the shipment originate from different generators.

1. For homogeneous mixtures of waste, such as incinerator ash, provide the waste description applicable to the mixture and the volume of the waste attributed to each generator.

2. For heterogeneous mixtures of waste, such as the combined products from a large compactor, identify each generator contributing waste to the disposal container, and, for discrete waste types (i.e., activated materials, contaminated equipment, mechanical filters, sealed source/devices, and wastes in solidification/stabilization media), the identities and activities of individual radionuclides contained on these waste types within the disposal container. For each generator, provide the following:

(a) The volume of waste within the disposal container;

(b) A physical and chemical description of the waste, including the solidification agent, if any;

(c) The total weight percentage of chelating agents for any disposal container containing more than 0.1% chelating agent by weight, plus the identity of the principal chelating agent;

(d) The sorbing or solidification media, if nay, and the identity of the solidification media vendor and brand name if the media is claimed to meet stability requirements in 10 CFR 61.56(b); and

(e) Radionuclide identities and activities contained in the waste, the masses of U-233, U-235, and plutonium in special nuclear material, and the masses of uranium and thorium in source material if contained in the waste.

II. Certification. An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation, the Commission, and the Agency. A collector in signing the certification is certifying that nothing has been done to the collected waste which would invalidate the waste generator's certification.

III. Control and Tracking

A. Any licensee who transfers radioactive waste to a land disposal facility or a licensed waste collector shall comply with the requirements in paragraphs A.1 through 9 of this section. Any licensee who transfers waste to a licensed waste processor for waste treatment or repackaging shall comply with the requirements of paragraphs A.4 through 9 of this section. A licensee shall:

1. Prepare all wastes so that the waste is classified according to 10 CFR Part 61.55 and meets the waste characteristics requirements in 10 CFR Part 61.56;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste to identify whether it is Class A waste, Class B waste, Class C waste, or greater than Class C waste. In accordance with 10 CFR Part 61.55;

3. Conduct a quality assurance program to assure compliance with 10 CFR Parts 61.55 and 61.56 (the program must include management evaluation of audits);

4. Prepare the NRC Uniform Low-Level Radioactive Waste Manifest as required by this appendix;

5. Forward a copy or electronically transfer the Uniform Low-Level radioactive Waste Manifest to the intended consignee so that either (i) receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

6. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph A.5 of this section;

7. Receive acknowledgment of the receipt of this shipment in the form of a signed copy of NRC Form 540;

8. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 10 CFR Parts 30, 40, and 70; and

9. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix.

B. Any waste collector licensee who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the shipper within one week of receipt by returning a signed copy of NRC Form 540;

2. Prepare a new manifest to reflect consolidated shipments that meet the requirements of this appendix. The waste collector shall ensure that, for each container of waste in the shipment, the manifest identifies the generator of that container of waste;

3. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either: (i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

4. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph B.3 of this section;

5. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

6. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer or licensed material as required by 10 CFR Parts 30, 40, and 70;

7. For any shipments or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

8. Notify the shipper and the Administrator of the nearest Commission Regional Office when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

C. Any licensed waste processor who treats or repackages waste shall:

1. Acknowledge receipt of the waste form the shipper within one week of receipt by returning a signed copy of NRC Form 540;

2. Prepare a new manifest that meets the requirements of this appendix. Preparation of the new manifest reflects that the processor is responsible for meeting these requirements. For each container of waste in the shipment, the manifest shall identify the waste generators, the preprocessed waste volume, and the other information as required in paragraph 1.E. of this appendix;

3. Prepare all wastes so that the waste is classified according to 10 CFR Part 61.55;

4. Label each package of waste to identify whether it is Class A waste, Class B waste, or Class C waste, in accordance with 10 CFR Parts 61.55 and 61.57;

5. Conduct a quality assurance program to assure compliance with 10 CFR Parts 61.55 and 61.56 (the program shall include management; evaluation of audits);

6. Forward a copy or electronically transfer the Uniform Low-Level Radioactive Waste Manifest to the intended consignee so that either;

(i) Receipt of the manifest precedes the LLW shipment or (ii) the manifest is delivered to the consignee with the waste at the time the waste is transferred to the consignee. Using both (i) and (ii) is also acceptable;

7. Include NRC Form 540 (and NRC Form 540A, if required) with the shipment regardless of the option chosen in paragraph C.6 of this section;

8. Receive acknowledgment of the receipt of the shipment in the form of a signed copy of NRC Form 540;

9. Retain a copy of or electronically store the Uniform Low-Level Radioactive Waste Manifest and documentation of acknowledgment of receipt as the record of transfer of licensed material as required by 10 CFR Parts 30, 40, and 70;

10. For any shipment or any part of a shipment for which acknowledgment of receipt has not been received within the times set forth in this appendix, conduct an investigation in accordance with paragraph E of this appendix; and

11. Notify the shipper and the Administrator of the nearest Commission Regional Office when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

D. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one week of receipt by returning, as a minimum, a signed copy of NRC Form 540 to the shipper. The shipper to be notified is the licensee who last possessed the waste and transferred the waste to the operator. If any discrepancy exists between materials listed on the Uniform Low-Level Radioactive Waste Manifest and materials received, copies or electronic transfer of the affected forms must be returned indicating the discrepancy;

2. Maintain copies of all completed manifests and electronically store the information required by 10 CFR 61.80(1) until the commission terminates the license; and

3. Notify the shipper and the Administrator of the nearest commission Regional Office when any shipment, or part of a shipment, has not arrived within 60 days after receipt of an advance manifest, unless notified by the shipper that the shipment has been canceled.

E. Any shipment or part of a shipment for which acknowledgment is not received within the times set forth in this section must:

1. Be investigated by the shipper if shipper has not received notification receipt within 20 days after transfer;

2. Be traced and reported. The investigation shall include tracing the shipment and filing a report with the nearest Commission Regional Office. Each licensee who conducts a trace investigation shall file a written report with the appropriate NRC Regional Office within 2 weeks of completion of the investigation.

Author:

Statutory Authority:

History:

420-3-26-.04 Radiation Safety Requirements For Industrial Radiographic Operations.

(1) Purpose. This Rule prescribes requirements for the issuance of licenses or registrations for the industrial use of sources of radiation and radiation safety requirements for persons using these sources of radiation in industrial radiography.

(2) Scope. The provisions and requirements of this Rule are in addition to, and not in substitution for, other requirements of the Rules of State Board of Health, Chapter 420-3-26 Radiation Control, Alabama Administrative Code. In particular, the general requirements and provisions of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, 420-3-26-.05, and 420-3-26-.10 apply to applicants, licensees and registrants subject to this Rule. Rule 420-3-26-.02 applies to licensing and transportation of radioactive material and 420-3-26-.05 applies to the registration of radiation machines. Except for sections which are applicable only to sealed radioactive sources, radiation machines and sealed radioactive sources are both covered by this Rule. This rule does not apply to medical uses of sources of radiation.

(3) Definitions. As used in this Rule, the following definitions apply:

(a) "Annual refresher safety training" means a review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review shall include, as a minimum, any results of internal inspections, new procedures or equipment, new or revised rules, and accidents or errors that have been observed. The review shall also provide opportunities for employees to ask safety questions.

(b) "ANSI" means the American National Standards Institute.

(c) "Associated equipment" means equipment that is used in conjunction with a radiographic exposure device to make radiographic exposures that drives, guides, or comes in contact with the source.[19]

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[19] e.g., guide tube, control tube, control (drive) cable, removable source stop,

(d) "Cabinet radiography" means industrial radiography conducted in an enclosure or cabinet so shielded that every location on the exterior meets the dose limits for individual members of the public as specified in 420-3-26-.03(14).

(e) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure, hereinafter termed a cabinet, that is independent of existing architectural structures except the floor. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. This definition includes x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment that may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

(f) "Camera" see "Radiographic exposure device".

(g) "Certifiable cabinet x-ray system" means an existing uncertified x-ray system that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

(h) "Certified cabinet x-ray system" means an x-ray system that has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

(i) "Certifying entity" means an independent certifying organization meeting the requirements in Appendix A of this Rule or a state regulatory program meeting the requirements in Appendix A, Parts II and III of this Rule.

(j) "Collimator" means a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

(k) "Control cable" means the cable that is connected to the source assembly and used to drive the source to and from the exposure location.

(l) "Control drive mechanism" means a device that enables the source assembly to be moved into and out of the exposure device.

(m) "Control tube" means a protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

(n) "Drive cable" see "Control cable".

(o) "Exposure head" means a device that locates the gamma radiography sealed source in the selected working position.

(p) "Field station" means a facility at which sources of radiation may be stored or used and from which equipment is dispatched.

(q) "Guide tube" means a flexible or rigid tube, or "J" tube, for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

(r) "Hands-on experience" means experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records and radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, shall not be counted toward the 2000 hours of hands-on experience required for a radiation safety officer in 420-3-26-.04(15) or the hands-on experience for a radiographer as required by 420-3-26-.04(16)(a).

(s) "Independent certifying organization" means an independent organization that meets all of the criteria of Appendix A of this Rule.

(t) "Industrial radiography" means an examination of the structure of materials by the nondestructive method of utilizing ionizing radiation to make radiographic images.

(u) "Lay-barge radiography" means industrial radiography performed on any water vessel used for laying pipe.

(v) "Offshore platform radiography" means industrial radiography conducted from a platform over a body of water.

(w) "Permanent radiographic installation" means an enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

(x) "Pigtail" see "Source assembly".

(y) "Pill" see "Sealed source".

(z) "Practical examination" means a demonstration through application of the safety rules and principles in industrial radiography including use of all procedures and equipment to be used by radiographic personnel.

(aa) "Projection sheath" see "Guide tube".

(bb) "Projector" see "Radiographic exposure device".

(cc) “Radiation machine” means any device capable of producing radiation except, those devices with radioactive material as the only source of radiation.

(dd) “Radiation monitor badge” means an individual personnel dosimeter used to measure the radiation dose to the individual’s whole body and is processed and evaluated by a dosimetry processor meeting the requirements of 420-3-26-.03(17)(c)1 and 2.

(ee) "Radiation safety officer for industrial radiography" means an individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of 420-3-26-.04(15).

(ff) "Radiographer" means any individual who performs or who, in attendance at the site where the sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with requirements of Agency rules and the conditions of the license or registration.

(gg) "Radiographer certification" means written approval received from a certifying entity stating that an individual has satisfactorily met the radiation safety, testing, and experience criteria in 420-3-26-.04(16).

(hh) "Radiographer's assistant" means any individual who under the direct supervision of a radiographer, uses radiographic exposure devices, sources of radiation, related handling tools, or radiation survey instruments in industrial radiography.

(ii) "Radiographic exposure device" means any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

(jj) "Radiographic operations" means all activities performed with a radiographic exposure device, or with a radiation machine. Activities include using, transporting except by common or contract carriers, or storing at a temporary job site, performing surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine is not considered a radiographic operation.

(kk) "Radiography" see "Industrial radiography."

(ll) "S-tube" means a tube through which the radioactive source travels when inside a radiographic exposure device.

(mm) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(nn) "Shielded position" means the location within the radiographic exposure device, source changer, or storage container

that, by manufacturer's design, is the proper location for storage of the sealed source.

(oo) "Source assembly" means an assembly that consists of the sealed source and a connector that attaches the source to the control cable. The source assembly may include a ballstop to secure the source in the shielded position.

(pp) "Source changer" means a device designed and used for replacement of sealed sources in radiographic exposure devices. They may also be used for transporting and storing sealed sources.

(qq) "Source stop" see "Exposure head."

(rr) "Storage area" means any location, facility, or vehicle that is used to store and secure a radiographic exposure device, a radiation machine, or a storage container when it is not being used for radiographic operations. Storage areas must be capable of being locked or have a physical barrier to prevent accidental exposure, tampering, or unauthorized removal of the device, machine, or container.

(ss) "Storage container" means a device in which sealed sources or radiation machines are secured and stored.

(tt) "Temporary jobsite" means a location where radiographic operations are performed and where sources of radiation may be stored other than the location(s) of use authorized on the license or registration.

(uu) "Underwater radiography" means radiographic operations performed when the radiographic exposure device or radiation machine and/or related equipment are beneath the surface of the water.

(4) Exemptions for Cabinet X-Ray Systems. Uses of certified and certifiable cabinet x-ray systems are exempt from the requirements of this Rule except for the following:

(a) For certified and certifiable cabinet x-ray systems, including those designed to allow admittance of individuals:

1. No registrant shall permit any individual to operate a cabinet x-ray system until the individual has received a copy of and instruction in the operating procedures for the unit. Records that demonstrate compliance with this subparagraph shall be maintained for Agency inspection until disposal is authorized by the Agency.

2. Tests for proper operation of interlocks must be conducted and recorded at intervals not to exceed six months. Records of these tests shall be maintained for Agency inspection until disposal is authorized by the Agency.

3. The registrant shall perform an evaluation of the radiation dose limits to determine compliance with 420-3-26-.03(14) (a), (b), and (c) of these rules, and 21 CFR 1020.40, Cabinet X-Ray Systems, at intervals not to exceed one year. Records of these evaluations shall be maintained for Agency inspection for two years after the evaluation.

(b) Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40, Cabinet X-Ray Systems and no modification shall be made to the system unless prior Agency approval has been granted.

(5) Performance Requirements for Industrial Radiography Equipment. Equipment used in industrial radiographic operations must meet the following minimum criteria:

(a) Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in ANSI N432-1980 "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981);

(b) In addition to the requirements specified in 420-3-26-.04(5) (a), the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources;

1. The licensee shall ensure that each radiographic exposure device has attached to it a durable, legible, clearly visible label bearing the:

(i) Chemical symbol and mass number of the radionuclide in the device;

(ii) Activity and the date on which this activity was last measured;

(iii) Model or product code and serial number of the sealed source;

(iv) Name of the manufacturer of the sealed source; and

(v) Licensee's name, address, and telephone number.

2. Radiographic exposure devices intended for use as Type B packages must meet the applicable transportation requirements of 420-3-26-.02 (21), 420-3-26-.02(23), and 420-3-26-.04(24).

3. Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited, unless approved by the Agency or other approval body.

(c) In addition to the requirements specified in 420-3-26-.04(5) (a) and (b), the following requirements apply to radiographic

exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operations or to source changers;

1. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

2. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. This securing system may only be released by means of a deliberate operation on the exposure device.

3. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand or other foreign matter.

4. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words:

"DANGER -- RADIOACTIVE."

The label may not interfere with the safe operation of the exposure device or associated equipment.

5. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use, and be able to withstand a kinking resistance test that closely approximates the kinking forces that are likely to be encountered during use.

6. Guide tubes must be used when moving the source out of the device.

7. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiography operations.

8. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432-1980.

9. Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

(d) All radiographic exposure devices and associated equipment in use after January 10, 1996, must comply with the requirements of this section; and

(e) As an exception to rule 420-3-26-.04(5)(a), equipment used in industrial radiographic operations need not comply with §8.9.2(c) of the Endurance Test in ANSI N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can reasonably exert on the lever or crankshaft of the drive mechanism.

(6) Limits on External Radiation Levels From Storage Containers and Source Changers. The maximum exposure rate limits for storage containers and source changers are 2 millisieverts (200 mrem) per hour at any exterior surface, and 0.1 millisieverts (10 mrem) per hour at 1 meter from any exterior surface with the sealed source in the shielded position.

(7) Locking of Sources of Radiation, Storage Containers and Source Changers.

(a) Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The exposure device and/or its container must be kept locked, with the key removed if it is a keyed lock, at all times when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as stated in 420-3-26-.04(21). In addition, during radiographic operations the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

(b) Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. Storage containers and source changers must be kept locked, with the key removed if it is a keyed lock, at all times when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

(c) The control panel of each radiation machine shall be equipped with a lock that will prevent the unauthorized use of an x-ray system or the accidental production of radiation. The radiation machine shall be kept locked and the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer’s assistant.

(8) Radiation Survey Instruments.

(a) The licensee or registrant shall keep a sufficient number of calibrated and operable radiation survey instruments at each location where sources of radiation are present to make the

radiation surveys required by this Rule and by Rule 420-3-26-.03 of these rules. Instrumentation required by this section must be capable of measuring a range from 0.02 millisieverts (2 mrem) per hour through 0.01 sievert (1 rem) per hour.

(b) The licensee or registrant shall have each radiation survey instrument required under 420-3-26-.04(8)(a) calibrated:

1. At energies appropriate for use and at intervals not to exceed 6 months or after instrument servicing, except for battery changes;

2. For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and

3. So that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

(c) The licensee or registrant shall maintain records of the results of the instrument calibrations in accordance with 420-3-26-.04(25).

(9) Leak Testing and Replacement of Sealed Sources.

(a) The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed by persons authorized to do so by the Agency, the Nuclear Regulatory Commission, or another Agreement State.

(b) The opening, repair, or modification of any sealed source must be performed by persons specifically authorized to do so by the Agency, the Nuclear Regulatory Commission, or another Agreement State.

(c) Testing and recordkeeping requirements.

1. Each licensee who uses a sealed source shall have the source tested for leakage at intervals not to exceed 6 months. The leak testing of the source must be performed using a method approved by the Agency, the Nuclear Regulatory Commission, or by another Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 185 becquerel (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis.

2. The licensee shall maintain records of the leak tests in accordance with 420-3-26-.04(26).

3. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within 6 months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing, but must be tested and the test results received before use or transfer to another person if the interval of storage exceeds 6 months.

(d) Any test conducted pursuant to 420-3-26-.04(9)(b) and (c) that reveals the presence of 185 becquerel (0.005 microcuries) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall have it decontaminated and repaired or disposed of in accordance with Agency rules. A report must be filed with the Agency within 5 days of any test with results that exceed the threshold in this paragraph, describing the equipment involved, the test results, and the corrective action taken.

(e) Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed 12 months. The analysis must be capable of detecting the presence of 185 becquerel (0.005 microcuries) of radioactive material on the test sample and must be performed by a person specifically authorized by the Agency, the Nuclear Regulatory Commission, or another Agreement State to perform the analysis. Should such testing reveal the presence of DU contamination, the exposure device must be removed from use until an evaluation of the wear of the S-tube has been made. Should the evaluation reveal that the S-tube is worn through, the device may not be used again. DU shielded devices do not have to be tested for DU contamination while not in use and in storage. Before using or transferring such a device, however, the device must be tested for DU contamination, if the interval of storage exceeds 12 months. A record of the DU leak-test must be made in accordance with 420-3-26-.04(26).

(10) Physical Inventory.

(a) Each licensee or registrant shall conduct a physical inventory at intervals not to exceed 3 months to account for all sources of radiation, and for devices containing depleted uranium received and possessed under the license or registration.

(b) The licensee or registrant shall maintain records of the physical inventory in accordance with 420-3-26-.04(27).

(11) Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) The licensee or registrant shall perform visual and operability checks on survey meters, radiation machines, radiographic exposure devices, transport and storage containers, associated equipment and source changers before each day's use, or work shift, to ensure that:

1. The equipment is in good working condition;

2. The sources are adequately shielded; and

3. Required labeling is present.

(b) Survey instrument operability must be performed using check sources or other appropriate means.

(c) If equipment problems are found, the equipment must be removed from service until repaired.

(d) Each licensee or registrant shall have written procedures for and perform inspection and routine maintenance of radiation machines, radiographic exposure devices, source changers, associated equipment, transport and storage containers, and survey instruments at intervals not to exceed 3 months or before the first use thereafter to ensure the proper functioning of components important to safety. If equipment problems are found, the equipment must be removed from service until repaired.

(e) The licensee's inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the certificate of compliance or other approval.

(f) Records of equipment problems and of any maintenance performed under 420-3-26-.04(11) must be made in accordance with 420-3-26-.04(29).

(12) Permanent Radiographic Installations.

(a) Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

1. An entrance control of the type described in 420-3-26-.03(19) of these rules that causes the radiation level upon entry into the area to be reduced; or

2. Both conspicuous visible and audible warning signals to warn of the presence of radiation. The visible signal must be actuated by radiation whenever the source is exposed or the machine is energized. The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

(b) The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. The test must include a check of both the visible and audible signals. Entrance control devices that reduce the radiation level upon entry as designated in 420-3-26-.04(12)(a)1 must be tested monthly. If an entrance control device or an alarm is not operating properly, it must be immediately labeled as defective and repaired within 7 calendar days. The facility may continue to be used during this 7-day period, provided the licensee or registrant implements the continuous surveillance requirements of 420-3-26-.04(21) and uses an alarming ratemeter, unless otherwise exempted. Test records for entrance controls and audible and visual alarms must be maintained in accordance with 420-3-26-.04(30).

(13) Labeling, Storage, and Transportation.

(a) The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol conventional colors (magenta, purple or black on a yellow background) having a minimum diameter of 25 mm, and the wording:

CAUTION *

RADIOACTIVE MATERIAL

NOTIFY CIVIL AUTHORITIES [or " NAME OF COMPANY"]

* --- or "DANGER"

(b) The licensee may not transport radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with rules set out in Rule 420-3-26-.02.

(c) Radiographic exposure devices, source changers, storage containers, and radiation machines, must be physically secured to prevent tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner that will minimize danger from explosion or fire.

(d) The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(e) The licensee's or registrant's name and city or town where the main business office is located shall be prominently displayed with a durable, clearly visible label(s) on both sides of all

vehicles used to transport radioactive material or radiation machines for temporary job site use.

Radiation Safety Requirements

(14) Conducting Industrial Radiographic Operations.

(a) Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of 420-3-26-.04(16)(c). The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one qualified individual is present.

(b) All radiographic operations must be conducted in a permanent radiographic installation unless otherwise specifically authorized by the Agency.

(c) Except when physically impossible, collimators shall be used in industrial radiographic operations that use radiographic exposure devices that allow the source to be moved out of the device.

(d) A licensee or registrant may conduct lay-barge, offshore platform, or underwater radiography only if procedures have been approved by the Agency, the Nuclear Regulatory Commission, or by another Agreement State.

(15) Radiation Safety Officer. The radiation safety officer shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's or registrant’s program.

(a) The minimum qualifications, training, and experience for radiation safety officers for industrial radiography are as follows:

1. Completion of the training and testing requirements of 420-3-26-.04(16)(a);

2. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

3. Formal training in the establishment and maintenance of a radiation protection program.

(b) The Agency will consider alternatives when the radiation safety officer has appropriate training and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

(c) The specific duties and authorities of the radiation safety officer include:

1. Establishing and overseeing all operating, emergency, and ALARA procedures as required by Rule 420-3-26-.03 of these rules and reviewing them regularly to ensure that they conform to Agency rules and to the license or registration conditions;

2. Overseeing and approving the training program for radiographic personnel to ensure that appropriate and effective radiation protection practices are taught;

3. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the rules, including any corrective measures when levels of radiation exceed established limits;

4. Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly; that records are kept of the monitoring results; and that timely notifications are made as required by Rule 420-3-26-.03; and

5. Ensuring that operations are conducted safely and for implementing corrective actions including terminating operations.

(d) Licensees and registrants will have 2 years from the effective date of this rule to meet the requirements of 420-3-26-.04(15)(a) and (b).

(16) Training.

(a) The licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received at least 40 hours of training in the subjects outlined in 420-3-26-.04(16)(g), in addition to on the job training consisting of hands-on experience under the supervision of a radiographer, is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of this Rule, and has on their person a valid certification ID card issued by a certifying entity. The on the job training shall include a minimum of 320 hours of active participation in the performance of industrial radiography utilizing radioactive material and/or 160 hours of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (480 hours); or

2. The licensee or registrant may, until May 25, 2002, allow an individual who has not met the requirements of 420-3-26-.04(16)(a)1, to act as a radiographer provided the individual has

received training in an approved training course and successfully completed a written examination that was previously submitted to and approved by the Agency, the Nuclear Regulatory Commission, or another Agreement State, in addition to on the job training consisting of hands-on experience under the supervision of a radiographer. The on the job training shall include a minimum of 320 hours of active participation in the performance of industrial radiography utilizing radioactive material and/or 160 hours of active participation in the performance of industrial radiography utilizing radiation machines. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on the job training (480 hours).

(b) In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

1. Has received copies of and instruction in the requirements described in the applicable sections of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, and 420-3-26-.10, in the license or registration under which the radiographer will perform industrial radiography, and the licensee's or registrant’s operating and emergency procedures;

2. Has demonstrated an understanding of items in 420-3-26-.04(16)(b)1 by successful completion of a written or oral examination;

3. Has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices, sealed sources, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4 Has demonstrated understanding of the use of the equipment described in 420-3-26-.04(16)(b)3 by successful completion of a practical examination.

(c) The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

1. Has received copies of and instruction in the applicable sections of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, and 420-3-26-.10, in the license or registration under which the radiographer's assistant will perform industrial radiography, and the licensee's or registrant's operating and emergency procedures;

2. Has demonstrated an understanding of items in 420-3-26-.04(16)(c)1 by successful completion of a written or oral examination;

3. Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, or the licensee's radiographic exposure devices and sealed sources, in

the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

4. Has demonstrated understanding of the use of the equipment described in 420-3-26-.04(16)(c)3 by successful completion of a practical examination.

(d) The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

(e) Except as provided in 420-3-26-.04(16)(e)4, the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency rules, license or registration requirements, and operating and emergency procedures are followed. The inspection program must:

1. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

2. Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 420-3-26-.04(16)(b)3 and the radiographer's assistant must demonstrate knowledge of the training requirements of 420-3-26-.04(16)(c)3 by a practical examination before these individuals can next participate in a radiographic operation.

3. The Agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

4. In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

(f) The licensee or registrant shall maintain records of the required training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance in accordance with 420-3-26-.04(31).

(g) The licensee or registrant shall include the following subjects required in 420-3-26-.04(16)(a):

1. Fundamentals of radiation safety including:

(i) Characteristics of gamma and x-radiation;

(ii) Units of radiation dose and quantity of radioactivity;

(iii) Hazards of exposure to radiation;

(iv) Levels of radiation from sources of radiation; and

(v) Methods of controlling radiation dose (time, distance, and shielding);

2. Radiation detection instruments including:

(i) Use, operation, calibration, and limitations of radiation survey instruments;

(ii) Survey techniques; and

(iii) Use of personnel monitoring equipment;

3. Equipment to be used including:

(i) Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails);

(ii) Operation and control of radiation machines;

(iii) Storage, control, and disposal of sources of radiation; and

(iv) Inspection and maintenance of equipment.

4. The requirements of pertinent state and federal regulations; and

5. Case histories of accidents in radiography.

(h) Licensees and registrants will have until May 25, 2001, to comply with the additional training requirements specified in 420-3-26-.04(16)(a)1, 420-3-26-.04(16)(b)1 and 420-3-26-.04(16)(c)1.

(17) Operating and Emergency Procedures.

(a) Operating and emergency procedures must include, as a minimum, instructions in the following:

1. Appropriate handling and use of sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in Rule 420-3-26-.03;

2. Methods and occasions for conducting radiation surveys;

3. Methods for posting and controlling access to radiographic areas;

4. Methods and occasions for locking and securing sources of radiation;

5. Personnel monitoring and the use of personnel monitoring equipment;

6. Transporting equipment to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when required, and control of the equipment during transportation as described in Rule 420-3-26-.02;

7. The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, survey instruments, alarming ratemeters, transport containers, and storage containers;

8. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale, an electronic personal dosimeter reads greater than 2 millisieverts (200 mrem), or an alarming ratemeter alarms unexpectedly;

9. The procedure(s) for identifying and reporting defects and noncompliance, as required by 420-3-26-.04(37);

10. The procedure for notifying proper persons in the event of an accident or incident;

11. Minimizing exposure of persons in the event of an accident or incident, including a source disconnect, a transport accident, or loss of a source of radiation;

12. Source recovery procedure if licensee will perform source recoveries; and

13. Maintenance of records.

(b) The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with 420-3-26-.04(32) and (36).

(18) Supervision of Radiographer's Assistants. The radiographer's assistant shall be under the personal supervision of a radiographer when using radiographic exposure devices, radiation machines, associated equipment, or a sealed source, or while conducting radiation surveys required by 420-3-26-.04(20)(b) or (c) to determine that the sealed source has returned to the shielded position or the radiation machine is off after an exposure. The personal supervision must include:

(a) The radiographer's physical presence at the site where the sources of radiation are being used;

(b) The availability of the radiographer to give immediate assistance if required; and

(c) The radiographer's direct observation of the assistant's performance of the operations referred to in this section.

(19) Personnel Monitoring.

(a) The licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of direct reading dosimeter, an alarming ratemeter, and a radiation monitor badge. At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, or during radiographic operations using only radiation machines, the use of an alarming ratemeter is not required.

1. Pocket dosimeters must have a range from zero to 2 millisieverts (200 mrem) and must be recharged at the start of each shift. Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

2. Each radiation monitor badge must be assigned to and worn by only one individual.

3. Radiation monitor badges must be exchanged at periods not to exceed one month.

4. After replacement, each radiation monitor badge must be returned to the supplier for processing within 14 calendar days of the end of the monitoring period, or as soon as practicable. In circumstances that make it impossible to return each radiation monitor badge in 14 calendar days, such circumstances must be documented and available for review by the Agency.

(b) Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with 420-3-26-.04(33).

(c) Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed 12 months for correct response to radiation, and records must be maintained in accordance with 420-3-26-.04(33). Acceptable dosimeters must read within plus or minus 20 percent of the true radiation exposure.

(d) If an individual's pocket dosimeter is found to be off-scale, or the electronic personal dosimeter reads greater than 2 millisieverts (200 mrem), the individual's radiation monitor badge must be sent for processing within 24 hours. In addition, the individual may not resume work associated with the use of sources of radiation until a determination of the individual's radiation

exposure has been made. This determination must be made by the radiation safety officer or the radiation safety officer's designee. The results of this determination must be included in the records maintained in accordance with 420-3-26-.04(33).

(e) If a radiation monitor badge is lost or damaged, the worker shall cease work immediately until a replacement radiation monitor badge is provided and the exposure is calculated for the time period from issuance to loss or damage of the radiation monitor badge. The results of the calculated exposure and the time period for which the radiation monitor badge was lost or damaged must be included in the records maintained in accordance with 420-3-26-.04(33).

(f) Reports received from the radiation monitor badge processor must be retained in accordance with 420-3-26-.04(33).

(g) Each alarming ratemeter must:

1. Be checked to ensure that the alarm functions properly before using at the start of each shift;

2. Be set to give an alarm signal at a preset dose rate of 5 millisieverts (500 mrem) per hour; with an accuracy of plus or minus 20 percent of the true radiation dose rate;

3. Require special means to change the preset alarm function; and

4. Be calibrated at periods not to exceed 12 months for correct response to radiation. The licensee shall maintain records of alarming ratemeter calibrations in accordance with 420-3-26-.04(33).

(20) Radiation Surveys. The licensee or registrant shall:

(a) Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of 420-3-26-.04(8);

(b) Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching the device or the guide tube. The survey must determine that the sealed source has returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. Radiation machines shall be surveyed after each exposure to determine that the machine is off;

(c) Conduct a survey of the radiographic exposure device whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area as defined in 420-3-26-.04(3), to ensure that the sealed source is in its shielded position; and

(d) Maintain records in accordance with 420-3-26-.04(34).

(21) Surveillance. During each radiographic operation, the radiographer shall ensure continuous direct visual surveillance of the operation to protect against unauthorized entry into a radiation area or a high radiation area, as defined in Rule 420-3-26-.01, except at permanent radiographic installations where all entryways are locked and the requirements of 420-3-26-.04(12) are met.

(22) Posting. All areas in which industrial radiography is being performed must be conspicuously posted as required by rule 420-3-26-.03(28). The exceptions listed in rule 420-3-26-.03(29) do not apply to industrial radiographic operations.

Recordkeeping Requirements

(23) Records for Industrial Radiography. Each licensee or registrant shall maintain a copy of its license or registration, documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Agency, or until the Agency terminates the license or registration.

(24) Records of Receipt and Transfer of Sources of Radiation.

(a) Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, devices using DU for shielding, and radiation machines, and retain each record for 3 years after transfer or disposal.

(b) These records must include the date, the name of the individual making the record, radionuclide, number of becquerels (curies) or mass (for DU), and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

(25) Records of Radiation Survey Instruments. Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required under 420-3-26-.04(8) and retain each record for 3 years after it is made.

(26) Records of Leak Testing of Sealed Sources and Devices Containing DU. Each licensee shall maintain records of leak test results for sealed sources and for devices containing DU. The results must be stated in units of becquerels (microcuries). The licensee shall retain each record for 3 years after it is made or until the source in storage is removed whichever is greater.

(27) Records of Physical Inventory.

(a) Each licensee or registrant shall maintain records of the physical inventory of all sources of radiation, including devices containing depleted uranium, as required by 420-3-26-.04(10), and retain each record for 3 years.

(b) The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of becquerels (curies) or mass (for DU) in each device, location of sources of radiation and/or devices, and manufacturer, model, and serial number of each source of radiation and/or device, as appropriate.

(28) Utilization Logs.

(a) Each licensee or registrant shall maintain utilization logs showing for each source of radiation the following information:

1. A description, including the make, model, and serial number of the radiation machine or the radiographic exposure device, transport, or storage container in which the sealed source is located;

2. The identity and signature of the radiographer to whom assigned;

3. The location and dates of use, including the dates removed and returned to storage; and

4. For permanent radiographic installations, the dates each radiation machine is energized or radiographic exposure device utilized.

(b) The licensee or registrant shall retain the logs required by 420-3-26-.04(28)(a) for 3 years.

(29) Records of Inspection and Maintenance of Radiation Machines, Radiographic Exposure Devices, Transport and Storage Containers, Associated Equipment, Source Changers, and Survey Instruments.

(a) Each licensee or registrant shall maintain records specified in 420-3-26-.04(11) of equipment problems found in daily checks and quarterly inspections of radiation machines, radiographic exposure devices, transport and storage containers, associated equipment, source changers, and survey instruments; and retain each record for 3 years after it is made.

(b) The record must include the date of check or inspection, name of inspector, equipment involved, any problems found, and what repair and/or maintenance, if any, was performed.

(30) Records of Alarm System and Entrance Control Checks at Permanent Radiographic Installations. Each licensee or registrant shall maintain records of alarm system and entrance control device tests required by 420-3-26-.04(12) and retain each record for 3 years after it is made.

(31) Records Of Training and Certification. Each licensee or registrant shall maintain the following records for 3 years following termination of employment:

(a) Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written tests, dates of oral and practical examinations, the names of individuals conducting and receiving the oral and practical examinations, and a list of items tested and the results of the oral and practical examinations; and

(b) Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked and any non-compliance observed by the radiation safety officer or designee.

(32) Copies of Operating and Emergency Procedures. Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Agency terminates the license or registration. Superseded material must be retained for 3 years after the change is made.

(33) Records of Personnel Monitoring. Each licensee or registrant shall maintain the following exposure records specified in 420-3-26-.04(19):

(a) Direct reading dosimeter readings and yearly operability checks required by 420-3-26-.04(19)(b) and (c) for 3 years after the record is made;

(b) Records of alarming ratemeter calibrations for 3 years after the record is made;

(c) Reports received from the radiation monitor badge processor until the Agency terminates the license or registration. Upon termination of the license or registration, the licensee or registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the Agency for transfer to the Agency; and

(d) Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged, radiation monitor badges until the Agency terminates the license or registration.

(34) Records of Radiation Surveys. Each licensee shall maintain a record of each exposure device survey conducted before the device

is placed in storage as specified in 420-3-26-.04(20)(c). Each record must be maintained for 3 years after it is made.

(35) Form of Records. Each record required by this Part must be legible throughout the specified retention period. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

(36) Location Of Documents and Records.

(a) Each licensee or registrant shall maintain copies of records required by this Rule and other applicable rules at the location identified by the applicant as specified in rule 420-3-26-.02(10)(g).

(b) Each licensee or registrant shall also maintain current copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite;

1. The license or registration authorizing the use of sources of radiation;

2. A copy of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, 420-3-26-.05, and 420-3-26-.10;

3. Utilization logs for each source of radiation dispatched from that location as required by 420-3-26-.04(28).

4. Records of equipment problems identified in daily checks of equipment as required by 420-3-26-.04(29)(a);

5. Records of alarm system and entrance control checks required by 420-3-26-.04(30), if applicable;

6. Records of dosimeter readings as required by 420-3-26-.04(33);

7. Operating and emergency procedures as required by 420-3-26-.04(32);

8. Evidence of the latest calibration of the radiation survey instruments in use at the site, as required by 420-3-26-.04(25);

9. Evidence of the latest calibrations of alarming ratemeters and operability checks of dosimeters as required by 420-3-26-.04(33);

10 Survey records as required by 420-3-26-.04(34) and 420-3-26-.03(42) as applicable, for the period of operation at the site;

11. The shipping papers for the transportation of radioactive materials required by Rule 420-3-26-.02(23) and (24); and

12. When operating under reciprocity pursuant to Rule 420-3-26-.02(20) or 420-3-26-.05(6), a copy of the applicable State license or registration, or Nuclear Regulatory Commission license authorizing the use of sources of radiation.

Notifications

(37) Notifications.

(a) In addition to the reporting requirements specified in Rule 420-3-26-.03, each licensee or registrant shall provide a written report to the Agency within 30 days of the occurrence of any of the following incidents involving radiographic equipment:

1. Unintentional disconnection of the source assembly from the control cable;

2. Inability to retract the source assembly to its fully shielded position and secure it in this position;

3. Failure of any component, which is critical to safe operation of the device, to properly perform its intended function; or

4. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation, or a safety interlock fails to terminate x-ray production.

(b) The licensee or registrant shall include the following information in each report submitted under 420-3-26-.04(37)(a), and in each report of overexposure submitted under Rule 420-3-26-.03(53) which involves failure of safety components of radiography equipment:

1. Description of the equipment problem;

2. Cause of each incident, if known;

3. Name of the manufacturer and model number of equipment involved in the incident;

4. Place, date, and time of the incident;

5. Actions taken to establish normal operations;

6. Corrective actions taken or planned to prevent recurrence; and

7. Names and qualifications of personnel involved in the incident.

(c) Any licensee or registrant conducting radiographic operations or storing sources of radiation at any location not listed on the license or registration for a period in excess of 90 days in a calendar year, shall notify the Agency prior to exceeding the 90 days.

Radiographer Certification

(38) Application and Examinations.

(a) Application

1. An application for taking the examination shall be on forms prescribed and furnished by the Agency.

2. A non-refundable fee of One Hundred Twenty Five Dollars ($125) shall be submitted with the application to cover certification administrative costs, such as the examination, training documentation review, and issuance of certification.

3. The application and the non-refundable fee shall be submitted to the Agency on or before the dates specified by the Agency.

4. An individual whose certification ID card has been suspended or revoked shall obtain written approval from the Agency to apply to retake the examination.

(b) Examination. The examination shall be given for the purpose of determining the qualifications of applicants.

1. A written examination shall be held at dates, times, and locations determined by the Agency. The scope of the examination and the methods of procedure, including determination of the passing score, shall be prescribed by the Agency. The examination will assess the applicant's knowledge to safely use sources of radiation and related equipment and the applicant's knowledge of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, and 420-3-26-.10.

2. The examination will be administered by the Agency or persons authorized by the Agency.

3. A candidate failing an examination may apply for re-examination in accordance with 420-3-26-.04(38)(a) and will be re-examined. A candidate shall not retake the same version of the examination.

4. The examination will be in English.

5. To take the examination, an individual shall have a picture identification card, such as a driver's license, at the time of the examination.

6. Calculators will be permitted during the examination. However, calculators or computers with preprogrammed data or formulas, including exposure calculators, will not be permitted during the examination.

7. The examination will be a "closed book" examination.

8. Any individual observed by an Agency proctor to be compromising the integrity of the examination shall be required to surrender the examination, the answer sheet, and any work paper. Such individual will not be allowed to complete the examination, will forfeit the examination fee, and will leave the examination site to avoid disturbing other examinees. Such individual must wait 90 days and must resubmit a new application and an additional non-refundable fee of One Hundred Twenty Five Dollars ($125) before taking a new examination.

9. Examination material shall be returned to the Agency at the end of the examination. No photographic or other copying of examination questions or materials shall be permitted. Disclosure by any individual of the contents of any examination prior to its administration is prohibited.

10. The names and scores of individuals taking the examination shall be a public record.

(39) Certification Identification (ID) Card.

(a) A certification ID card shall be issued to each person who successfully completes the requirements of 420-3-26-.04(16)(a)1 and the examination prescribed in 420-3-26-.04(38)(b).

1. Each person's certification ID card shall contain their photograph. The Agency will take the photograph at the time the examination is administered.

2. The certification ID card remains the property of the Agency and may be revoked or suspended.

3. Any individual who wishes to replace their certification ID card shall submit to the Agency a written request for a replacement certification ID card, stating the reason a replacement certification ID card is needed. A non-refundable fee of Twenty Dollars ($20) shall be paid to the Agency for each replacement of a certification ID card. The prescribed fee shall be submitted with the written request for a replacement certification ID card. The individual shall maintain a copy of the request in their possession while performing industrial

radiographic operations until a replacement certification ID card is received from the Agency.

(b) Each certification ID card is valid for a period of five years, unless revoked or suspended in accordance with 420-3-26-.04(39)(d). Each certification ID card expires at the end of the day, in the month and year stated on the certification ID card.

(c) Renewal of Certification ID card:

1. Applications for examination to renew a certification ID card shall be filed in accordance with 420-3-26-.04(38)(a).

2. The examination for renewal of a certification ID card shall be administered in accordance with 420-3-26-.04(38)(b).

3. A renewal certification ID card shall be issued in accordance with 420-3-26-.04(39)(a).

(d) Revocation or suspension of a certification ID card.

1. Any radiographer who violates these rules or equivalent State or Nuclear Regulatory Commission regulations, or any applicable statutory requirements may be required to show cause at a formal hearing why their certification ID card should not be revoked or suspended in accordance with 420-3-26-.04(39)(d)2.

2. When an Agency order has been issued for an industrial radiographer to cease and desist from the use of sources of radiation or the Agency revokes or suspends their certification ID card, the industrial radiographer shall surrender the certification ID card to the Agency until the order is changed or the suspension expires.

(40) Reciprocity.

(a) All reciprocal recognition of licenses and registrations by the Agency will be granted in accordance with rule 420-3-26-.02(20) and 420-3-26-.05(6).

(b) Reciprocal recognition by the Agency of an individual radiographer certification will be granted provided that:

1. The individual holds a valid certification in the appropriate category issued by a certifying entity, as defined in 420-3-26-.04(3)(i);

2. The requirements and procedures of the certifying entity issuing the certification affords the same or comparable certification standards as those afforded by 420-3-26-.04(16)(a);

3. The applicant presents the certification to the Agency prior to entry into the state; and

4. No escalated enforcement action is pending with the Nuclear Regulatory Commission or in any other state.

(c) Certified individuals who are granted reciprocity by the Agency shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of 420-3-26-.04(16)(a).

(41) Specific Requirements for Radiographic Personnel Performing Industrial Radiography.

(a) At a job site, the following shall be supplied by the licensee or registrant:

1. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

2. A current radiation monitor badge for each person performing radiographic operations;

3. An operable, calibrated direct reading dosimeter for each person performing radiographic operations ;

4. An operable, calibrated, alarming ratemeter for each person performing radiographic operations using a radiographic exposure device; and

5. The appropriate barrier ropes and signs.

(b) Each radiographer at a job site shall have on their person a valid certification ID card issued by a certifying entity.

(c) Industrial radiographic operations shall not be performed if any of the items in 420-3-26-.04(41)(a) and (b) are not available at the job site or are inoperable.

(d) During an inspection, the Agency may terminate an operation if any of the items in 420-3-26-.04(41)(a) and (b) are not available or operable, or if the required number of radiographic personnel are not present. Operations shall not be resumed until all required conditions are met.

APPENDIX A

I. Requirements for an Independent Certifying Organization. An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the field of industrial radiography;

2. Make its membership available to the general public nationwide. Membership shall not be restricted because of race, color, religion, sex, age, national origin or disability;

3. Have a certification program open to nonmembers, as well as members;

4. Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policy and decision-making review board;

6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

11. Have procedures for proctoring examinations, including qualifications for proctors. These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the Nuclear Regulatory Commission and other independent certifying organizations and/or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the Nuclear Regulatory Commission of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. Requirements for Certification Programs. All certification programs must:

1. Require applicants for certification to (a) receive training in the topics set forth in 420-3-26-.04(16)(g) or equivalent State or Nuclear Regulatory Commission regulations, and (b) satisfactorily complete a written examination covering these topics;

2. Require applicants for certification to provide documentation that demonstrates that the applicant has:

(a) received training in the topics set forth in 420-3-26-.04(16)(g) or equivalent State or Nuclear Regulatory Commission regulations;

(b) satisfactorily completed a minimum period of on-the-job training as specified in 420-3-26-.04(16)(a); and

(c) received verification by a State licensee or registrant or a Nuclear Regulatory Commission licensee that the applicant has demonstrated the capability of independently working as a radiographer.

3. Include procedures to ensure that all examination questions are protected from disclosure;

4. Include procedures for denying an application and revoking, suspending, and reinstating a certification;

5. Provide a certification period of not less than 3 years nor more than 5 years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. Requirements for Written Examinations. All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in 420-3-26-.04(16)(g) or equivalent State or Nuclear Regulatory Commission requirements;

2. Written in a multiple-choice format;

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in 420-3-26-.04(16)(g).
Author: Kirksey E. Whatley, Director, Office of Radiation Control, Alabama Department of Public Health.
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-7, 22-14-8.
History: New June 15, 1966, Revised March 18, 1970, March 17, 1971; Repromulgated August 21, 1974; Revised May 21, 1975, January 18, 1978; **Recodified** June 11, 1978; Revised November 21, 1979; Revised and Repromulgated October 21, 1981; Revised and Repromulgated effective December 31, 1983. Revised and Repromulgated effective January 31, 1990. Revised and Repromulgated Filed: April 22, 1994; effective May 26, 1994.
Amended: Filed April 20, 2000; effective May 25, 2000.

420-3-26-.05 Registration Of X-Ray Producing Machines.

General

(1) Registration Requirement.

(a) This Rule 420-3-26-.05 provides for the registration of radiation machines capable of producing x-rays of less than or equal to 1.0 meV. Every person possessing an x-ray producing machine shall register in accordance with the provisions of this rule. Except as specifically exempted in Section 420-3-26-.05(4), each person who receives, possesses, uses, or services a radiation machine shall register such machines with the Agency in accordance with the requirements of this Rule 420-3-26-.05.[20]

(b) In addition to the requirements of this Rule 420-3-26-.05, all registrants are subject to the requirements of Rules 420-3-26-.01, 420-3-26-.10, and 420-3-26-.11. Registrants using radiation machines for the performance of industrial radiography are also subject to the requirements of Rule 420-3-26-.04 and registrants using radiation machines in the healing arts are also subject to the requirements of Rule 420-3-26-.06 of these rules.

Definitions

(2) General Definitions.

(a) "Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the U.S. Nuclear Regulatory Commission and other Federal Government agencies.

(b) "Possessing an x-ray producing machine" means using, operating, storing, manufacturing, or otherwise having control of an x-ray producing machine in the State of Alabama.

(c) "Radiation producing machine" means any machine or device capable of producing radiation, but excluding devices which produce radiation only by the use of radioactive material.

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[20] See Rule 420-3-26-.08 for the registration requirements for particle accelerators

(d) "Registrant" means any person who is registering or who has registered with the Agency pursuant to this rule.

(e) "Services" means the installation, calibrating, repairing, maintaining, or performing a radiation protection survey of an x-ray producing machine or an associated x-ray component.

(3) Registration Procedure.

(a) Every person who possesses an x-ray producing machine shall register the machine with the Agency by June 1, 1965. Every person not already registered who acquires possession of an x-ray producing machine subsequent to June 1, 1965, shall register with the Agency prior to acquiring an x-ray machine.

(b) Every person possessing an x-ray producing machine shall renew such registration with the agency at such times as the Agency shall deem necessary.

(c) Registration and renewal of registration shall be made on a form furnished by the Agency (Alabama State Board of Health). The registration shall set forth all information called for by the form.

(d) Within thirty (30) days of change, the registrant shall report to the Agency of any change in the name or address of the registrant or location of the installation; receipt, sale, or disposal of any reportable source of radiation.

(e) Every registrant who permanently discontinues the use of, or permanently disposes of all his x-ray producing machines at an installation, shall notify the Agency within thirty (30) days of such action.

(f) No person, in any advertisement, shall refer to the fact that an x-ray producing machine is registered with the Agency and no person shall state or imply that any activity so registered has been approved by the Agency.

(g) Each person who commercially services an x-ray producing machine in this State, to an Agency registrant, shall apply for the registration of such services with the Agency not later than October 1, 1974, thereafter prior to furnishing or offering to furnish any such services. Such registration shall indicate the training of each individual in the subjects listed in Appendix A. Such registration is also subject to the requirements of paragraphs (b), (c), (d), (e), and (f) of this section.

(4) Exclusion from Registration. The following materials and devices do not require registration:

(a) Electrical equipment that is not primarily intended to produce radiation and that does not produce a radiation level greater than 0.5 mr/hr at any readily accessible point 5 centimeters from the surface. Such equipment shall not be exempt if it is used or handled in such a manner that any individual might receive a radiation dose exceeding the limits specified in these rules.

(b) All radioactive material.

(c) Radiation producing machines while in transit or storage incident thereto.

(5) Vendor Obligations.

(a) Any person who sells, leases, transfers, or lends x-ray producing machines in this State shall notify the Agency (Alabama State Board of Health) within thirty (30) days after the end of each calendar quarter of:

1.(i) The name and address of persons who have received these machines;

(ii) The manufacturer and model of each machine transferred;

(iii) The date of transfer of each x-ray machine.

2. Negative reports shall be furnished to the Agency (Alabama State Board of Health) within thirty (30) days after the end of each calendar quarter.

(b) No person shall sell, lease, transfer, or install x-ray equipment or the accessories used in connection with such equipment unless such accessories and equipment, when properly placed in operation and properly used, will meet the requirements of these rules. This includes responsibility for the delivery of cones or collimators, filters, adequate timers, and fluoroscopic

shutters. Further, no person shall sell, lease, deliver, install, or place in operation any x-ray equipment at any facility or for any person not registered with the Agency.

(6) Out-of-State X-ray Producing Machines. Whenever any x-ray producing machine is brought into the State for any temporary use the person proposing to bring such machine into the state shall give written notice to the Agency (Alabama State Board of Health) at least two (2) days before such machine enters the State. The notice shall include the type of x-ray producing machine; the nature, duration, and scope of use; and the exact location where the x-ray producing machine is to be used. If for a specific case the two (2) day period would impose an undue hardship on the person, he may upon application to the Agency (Alabama State Board of Health) obtain permission to proceed sooner. In addition, the out-of-state person must:

(a) Comply with all applicable rules of the Agency (Alabama State Board of Health); and

(b) Supply the Agency (Alabama State Board of Health) with such other information as the Agency (Alabama State Board of Health) may reasonably request.

(7) Plan Review.

(a) Prior to construction, the floor plans and equipment of all installations (new modification of existing installations after January 1, 1977) utilizing x-rays for diagnostic or therapeutic purposes shall be submitted to the Agency for review and approval. The required information is denoted in Appendices B and C of this Rule.

(b) The Agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(c) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 420-3-26-.03(2), 420-3-26-.03(5), and 420-3-26-.03(6).

(8) Modification, Suspension, and Termination of a Registration or Activities Registered.

(a) A registration or activity registered shall be subject to amendment, revision, or modification or such activities may be suspended or terminated by reason of amendment to the Act, or by reason of rule, regulations, and orders issued by the Agency.

(b) Any registration or activity registered may be terminated, suspended, or modified in whole, or part, for any material false

statement in the application, or because of conditions revealed by such application or statement of fact or any report, records, or inspection or other means which would warrant the Agency to refuse to grant a registration on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or the regulations, or of any rule, regulation, or order of the Agency.

(c) Except in case of willfulness or those in which the public health interest or safety requires otherwise, no registration or activity registered shall be modified, suspended, or terminated, unless prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

APPENDIX A

INSTRUCTION OF SERVICERS OF X-RAY EQUIPMENT

I. Fundamentals of radiation safety

A. Characteristics of x-radiation

B. Units of radiation dose (mrem)

C. Hazards of excessive exposure to radiation

D. Levels of radiation from sources of radiation

E. Methods of controlling radiation dose

1. Working time

2. Working distances

3. Shielding

II. Radiation detection instrumentation to be used

A. Use of radiation survey instruments

1. Operations

2. Calibration

3. Limitations

B. Survey techniques

C. Use of personnel monitoring equipment

1. Film Badges and/or Thermoluminescence Dosimeters (TLD's)

2. Pocket Dosimeters

3. Pocket Chambers

III. Operation and control of x-ray equipment

A. Effects of collimation and filtration

B. Film processing techniques

IV. The requirements of pertinent Federal and State regulations.

APPENDIX B

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the Agency to provide an evaluation, technical advice and official approval on shielding requirements for a radiation installation, the following information is needed:

1. The plans should show, as a minimum, the following:

a. The normal location of the radiation producing equipment's radiation port; the port's travel and traverse limits; general direction(s) of the radiation beam; locations of any windows; the location of the operator's booth; the location of the equipment's control console.
b. Structural composition and thickness of all walls, doors, partitions, floor, and ceiling of the rooms(s) concerned.

c. Height, floor to floor, of the room(s) concerned.

d. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest existing occupied area(s).

e. The make and model of the radiation producing equipment including the maximum energy output (for x-ray machines this is the kilovolt peak potential).

f. The type of examination(s) or treatment(s) which will be performed with the equipment (e.g., dental, orthodontal, chest, gastrointestinal, fluoroscopic, podiatry, fixed therapy, rotational therapy, etc.).

2. Information on the anticipated workload used in shielding calculations will be provided by the registrant.

3. If the services of a qualified radiation expert have been utilized, a copy of his report shall be submitted with the plans. This report must show all basic assumptions (i.e., workload, occupancy and use factors, distance, etc.) used to determine the shielding requirements.

APPENDIX C

MINIMUM DESIGN REQUIREMENTS FOR AN X-RAY MACHINE OPERATOR'S BOOTH

1. Space Requirements.

The operator shall be allotted not less than 7.5 square feet of unobstructed floor space in the booth.

(1) The minimum space as indicated above may be any geometric configuration with no dimension of less than 2 feet.

(2) The space shall be allotted excluding any encumbrance by the console, such as overhang or cables, or other similar encroachments.

(3) The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

(4) The booth walls shall be at least 7 feet high and shall be permanently fixed to the floor or other structure as may be necessary.

(5) When a door or movable panel is used as an integral part of the booth structure, it must have a permissive device which will prevent an exposure when the door or panel is not closed (this type of booth structure is not recommended).

2. Switch Placement.

The operator's switch for the radiographic machine shall be fixed within the booth and:

(1) Shall be at least 30 inches from any open edge of the booth wall which is proximal to the examining table.

(2) Shall allow the operator to use the majority of the available viewing windows.

3. Viewing System Requirements.

Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure, and

(2) The device shall be so placed that he can have full view of any occupant of the room and should be so placed that he can view any entry into the room. If any door, which allows access to the

room, cannot be seen from the booth, then that door must have a permissive device controlling the exposure which will prevent the exposure if the door is not closed.

(3) When the viewing system is a window, the following requirements also apply:

(a) It shall have a visible area of at least 1 square foot the base of which is at least 4.5 feet above the floor.

(b) The distance between the proximal edge of the window and the open edge of the booth shall not be less than 13 inches.

(c) The glass shall have the same lead equivalence as that required in the booth's wall in which it is to be mounted.

(4) When viewing system is by mirrors, the mirror(s) shall be located as to accomplish the general requirements as in (1) above.

(5) When the viewing system is by electronic means (e.g., TV, etc.):

(a) The camera shall be so located as to accomplish the general requirements in (1) above, and

(b) There shall be an alternate viewing system as a back up for electronic failure.

Author: Karl David Walter
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, and 22-14-14, also 22-2-1, 22-2-2, 22-2-5, 22-2-6.
History: New June 15, 1966. Revised March 18, 1970, March 17, 1971. Repromulgated August 21, 1974. Revised September 15, 1976. **Recodified** June 11, 1978. Revised and Repromulgated October 21, 1981. Repromulgated effective December 31, 1983. Revised effective December 31, 1986. Revised and Repromulgated effective January 31, 1990. Amended (Text only): Filed October 20, 2014; effective November 24, 2014; effective December 1, 2014.

Ed. Note: Filed September 1, 1982. Readopted with amendments filed October 24, 1983. Amended Filed January 19, 1990.

420-3-26-.06 Radiation Safety Requirements For Users Of X-Ray In Healing Arts Or Servicers Of X-Ray Equipment.

(1) Scope. Rule 420-3-26-.03 establishes standards for use of x-rays in the healing arts including but not limited to medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine or servicers of x-ray equipment. The provisions of this Rule 420-3-26-.06 are written in addition to, and not in

substitution for, other applicable provisions of these regulations. Periodic inspections will be performed of all registrants. The inspection frequency will depend upon available personnel and work load, but every x-ray unit ideally should be inspected not less than once every two years.

(2) Definitions.

(a) "Agency" means the State Board of Health.

(b) "ARCR" means the Alabama Regulations for Control of Radiation.

(c) "Aluminum Equivalent" means the thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.

(d) "Dead Man Switch" means a switch so constructed that a circuit closing contact can only be maintained by continuous pressure by the operator.

(e) "Diagnostic Tube Housing" means an x-ray tube housing so constructed that the leakage radiation with the port closed at a distance of one (1) meter in any direction from the target cannot exceed one hundred (100) milliroentgens in one (1) hour when the tube is operated at any of its specified ratings.

(f) "Filter" means material placed in the useful beam to absorb preferentially the less penetrating radiations.

(g) "Half-Value Layer (hvl)" means the thickness of absorber required to reduce a beam of radiation to one-half (1/2) its incident exposure rate.

(h) "High Radiation Area" means any area in which there exists radiation or such levels that a major portion of the body could receive in any one (1) hour a dose in excess of 100 millirems.

(i) "Inherent Filtration" means the filtration in the useful beam due to the window of the x-ray tube and any permanent tube enclosure.

(j) "Interlock" means a device for precluding access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

(k) "Kilovolts Peak (kVp)" means the crest value in kilovolts of the potential of a pulsating potential generator.

(l) "Lead Equivalent" means the thickness of lead affording the same attenuation under specified conditions as the material in question.

(m) "Leakage Radiation" means all radiation coming from within the tube housing except the useful beam.

(n) "Mobile X-Ray Unit" means a unit that is not permanently fixed to a definite location in a building or vehicle.

(o) "Personnel Monitoring Equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received (film badges, pocket dosimeters).

(p) "Primary Protective Barrier" means a barrier sufficient to attenuate the useful beam to the required degree.

(q) "Protective Apron" means a barrier of attenuating materials, used to reduce radiation exposure.

(r) "Protective Barrier" means a barrier of attenuating materials, used to reduce radiation exposure.

(s) "Protective Glove" means a glove made of attenuating materials used to reduce radiation exposure.

(t) "Radiation." The word radiation shall mean ionizing radiation, that is any electromagnetic or particulate radiation capable of producing ions directly or indirectly in its passage through matter.

(u) "Radiation Area" means any area in which there exists radiation at such levels that a major portion of the body could receive in any one (1) hour a dose in excess of 5 millirems, or in any five (5) consecutive days a dose in excess of 100 millirems.

(v) "Restricted Area" means any area to which access is controlled by the registrant for purposes of protection of individuals from exposure to radiation. "Restricted area" shall not include any areas used for residential quarters, although upon authorization by the Agency a separate room or rooms in a residential building may be set apart as a restricted area.

(w) "Scatter Radiation" means secondary radiation or radiation that, during passage through matter has been deviated in direction.

(x) "Secondary Protective Barrier" means a barrier sufficient to attenuate stray radiation to the required degree.

(y) "Shutter" means a device, generally of lead, fixed to an x-ray housing to intercept the useful beam.

(z) "Stray Radiation" means radiation not serving any useful purpose. It includes leakage and scattered radiation.

(aa) "Therapeutic Type Tube Housing" means an x-ray tube housing so constructed that the leakage radiation with the port closed at a distance of one (1) meter in any direction from the target cannot exceed one (1) roentgen in one (1) hour and at a distance of five (5) centimeters from any point of the surface of the housing accessible to the patient, cannot exceed thirty (30) roentgens in one (1) hour when the tube is operated at any of its specified ratings.

(bb) "Useful Beam" means that part of the radiation which passes through the window, aperture, cone, or other collimating device of the tube housing.

(cc) "Services" means the installation, calibrating, repairing, maintaining or performing a radiation protection survey of an x-ray producing machine or associated x-ray component.

(dd) "Healing Arts" means the practice of medicine, dentistry, osteopathy, chiropractic, podiatry, and for nonhumans, veterinary medicine.

(ee) "Portable" means x-ray equipment designed to be hand-carried.

(ff) "Stationary" means x-ray equipment which is installed in a fixed location.

(gg) "Gonad Shield" means a primary protective barrier for the testes or ovaries.

(hh) "Image Receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further electronic or chemical transformations.

(3) General Safety Provisions.

(a) The Agency may waiver compliance with the specific requirements of this Rule 420-3-26-.06 by an existing machine or installation if (1) such compliance would require replacement or substantial modification of the machine or installation and (2) the registrant demonstrates, to the Agency's satisfaction, achievement through other means of radiation protection equivalent to that required by these rules.

(b) Persons shall not be exposed to the useful beam except for healing arts purposes, each exposure of which shall be authorized by:

1. A licensed practitioner of the healing arts; or

2. A licensed physician's assistant, a certified registered nurse practitioner, or a certified nurse midwife subject to the rules of his/her licensure board.

(c) A written order for each exposure shall be prepared by the licensed practitioner of the healing arts, certified registered nurse practitioner or certified nurse midwife and provided to the individual administering the radiation. This order shall, at a minimum, include the following information:

1. Patient's name;

2. Date of birth;

3. Examination(s) requested;

4. Related diagnosis;

5. Name of the individual ordering the exposure; and

6. Date of the order.

(d) These rules specifically prohibit deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other purposes unless (a) there are also healing arts requirements and proper prescription has been provided, (b) the radiographs are made for the student's own training, (c) the radiographs are made only once with no more than two retakes and if only a small tissue volume (e.g. less than a skull) is exposed per radiograph, and (d) the images are properly interpreted and are made a part of the dental or medical record.

2. Exposure of an individual for the purpose of healing arts screening without prior written approval of the Agency. (Screening means an exposure of a person without prior examination or a determination of a specific individual need by a licensed practitioner).

(e) Personnel Monitoring. Each registrant shall provide personnel monitoring devices which shall be used by:

1. Each individual who receives, or is likely to receive, whole body dose in excess of 25 milliroentgens per week;

2. Each individual who enters a high radiation area;

3. Each individual who operates mobile x-ray equipment;

4. Each individual who operates fluoroscopic equipment;

5. Each individual while he services an operable x-ray producing machine.

(f) Use.

1. The registrant shall be responsible for assuring that all requirements of Rule 420-3-26-.03 are met.

2. The registrant shall assure that all x-ray equipment under his control is operated only by individuals adequately instructed in safe operating procedures and competent in safe use of the equipment.

3. After October 1, 1974, no registrant who services x-ray producing equipment shall permit any person to service such equipment, when operable, until such person has been appropriately instructed in the subjects outlined in Appendix A of Rule 420-3-26-.05 of these rules and shall have demonstrated an understanding thereof.

4. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objectives of the examination.

5. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation.

(g) Shielding.

1. Each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to assure compliance with 420-3-26-.03(2), 420-3-26-.03(5), and 420-3-26-.03(6). This requirement shall be deemed to be met if the thickness of such barriers is equivalent to those as computed in accordance with National Council on Radiation Protection and Measurements Report No. 49.[21]

(h) Darkroom Requirements. To reduce unnecessary re-exposures of patients resulting from film processing problems:

1. The darkroom shall be light-proof.

2. The area in which undeveloped films are handled for processing shall be devoid of light, during handling and processing, with the exception of light in the wave lengths having no specific effects on the radiographic film.

3. A thermometer and timer operable and appropriate to the type of film processing shall be in use in the darkroom.

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[21] Available from NCRP Publications, 7910 Woodmont Avenue, Suite 1016 Bethesda, Md. 20814

The use of properly maintained automatic film processing equipment shall meet this requirement for all film so processed.

(4) Fluoroscopic Installations.

(a) Equipment.

1. The tube housing shall be of diagnostic type.

2. The target-to-panel or target-to-table top distance of equipment installed before the effective date of these rules [22] shall not be less than twelve (12) inches, and shall not be less than fifteen (15) inches in equipment installed thereafter.

3. The total filtration permanently in the useful beam shall not be less than 2.5 millimeters aluminum equivalent. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 millimeters aluminum at normal operating voltages.

4. The equipment shall be so constructed that the entire cross section of the useful beam is attenuated by a primary barrier. This barrier is usually the viewing device, either a conventional fluoroscopic screen or an image intensification mechanism.

(i) For equipment installed before the effective date of the rules[23], the required lead equivalent of the barrier shall not be less than 1.5 millimeters for 100 kVp, shall not be less than 1.8 millimeters for 125 kVp or shall not be less than 2.0 millimeters for 150 kVp. For equipment installed or re-installed after the effective date of these rules 21 the required lead equivalent of the barrier shall not be less than 2.0 millimeters for 125 kVp, or shall not be less than 2.7 millimeters for 150 kVp. For conventional fluoroscopes the requirements of paragraph (i) may be assumed to have been met if the exposure rate measured at the viewing surface of the fluorescent screen does not exceed fifty (50) milliroentgens per hour with the screen in the primary beam of the fluoroscope without a patient, under normal operating conditions.

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[22] June 15, 1966.

[23] March 18, 1970.

(ii) Collimators shall be provided to restrict the size of the useful beam to less than the area of the barrier. For conventional fluoroscopes this requirement is met if, when the adjustable diaphragm is opened to its fullest extent, an unilluminated margin

is left on the fluorescent screen with the screen centered in the beam at a distance of fourteen (14) inches from the panel or table top. The margin requirement does not apply to installations where image intensifiers are used, but a protective shield shall be provided in these installations so that the useful beam does not produce a radiation hazard; however, the useful beam may not exceed the viewing area by more than 2% of the source to image receptor distance for any dimension.

(iii) The tube mounting and the barrier shall be so linked together that under conditions of fluoroscopic use, the barrier always intercepts the useful beam.

(iv) Collimators and adjustable diaphragms or shutters to restrict the size of the useful beam to the area of clinical interest and shall provide a minimum of 2.0 millimeters lead-equivalent protection for 100 kVp, 2.4 millimeters for 125 kVp, or 2.7 millimeters for 150 kVp.

5. The exposure switch shall be of the dead-man type.

6. A manual-reset, cumulative timing device shall be used which will either indicate elapsed time by an audible signal or turn off the apparatus when the total exposure exceeds a predetermined limit in one or a series of exposures. The device shall have a maximum time range of five minutes.

7. For fluoroscopy, the exposure rate measured at the panel or table top shall not exceed ten (10) roentgens per minute. This does not apply during cinegraphic procedures.

8. Unless measurements indicate otherwise, protective aprons of at least a quarter millimeter lead equivalent shall be worn by all persons in the fluoroscopic room except the patient.

9. Protective gloves of a least a quarter millimeter lead equivalent shall be worn by the fluoroscopist during every examination.

10. Mobile fluoroscopic equipment shall meet the requirements of this Rule where applicable, except that:

(i) In the absence of a table top, a cone or spacer frame shall limit the target-to-skin distance to not less than 20 centimeters.

(ii) Image intensification shall always be provided. Conventional fluoroscopic screens shall not be used.

(iii) It shall be impossible to operate a machine when the collimating cone or diaphragm is not in place.

(iv) The exposure rate measured at the 30 cm from image receptor shall not exceed ten (10) roentgens per minute.

(b) Structural Shielding. Ordinarily, only secondary barriers are necessary except for combined fluoroscopic-radiographic installations.

(5) Radiographic Installations Other than Dental and Veterinary Medicine.

(a) Equipment.

1. The tube housing shall be of a diagnostic type.

2.(i) Diaphragms or cones shall be provided for collimating the useful beam. When round collimators are used, the diameter of the beam at the film location shall be no greater than the diagonal dimension of the film plus three percent of the source to image receptor distance. For rectangular collimators, the beam size shall be no greater than the film dimension plus three percent of the source to image receptor distance. The diaphragms or cones shall provide the same degree of protection as the tube housing.

(ii) Adjustable collimators installed after the effective date of these rules 53 shall incorporate light beams to define the projected dimensions of the useful beam.

3.(i) Except when contraindicated for a particular medical purpose, for equipment operation at seventy (70) kVp, and below, the total filtration permanently in the useful beam shall be equivalent to at least 1.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 1.5 mm aluminum at normal operating voltages.

(ii) Except when contraindicated for a particular medical purpose, for equipment capable of operating above seventy (70) kVp the total filtration permanently in the useful beam shall be equivalent to at least 2.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 mm aluminum at normal operating voltages.

4. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. It shall not be possible to make an exposure when the timer is set to a zero or off position, if either position is provided.

5. A dead-man type of exposure switch shall be so arranged that it cannot be conveniently operated out of a shielded area. Exposure switches for "spot-film" devices used in conjunction with fluoroscopic tables are exempted from this shielding requirement.

(b) Structural Shielding.

1. All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of eighty-four (84) inches above the floor of the area being shielded.

2. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers or where the primary barrier's requirements are lower than the secondary barrier's requirements.

3. The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

4. A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposure, and shall meet the requirements of 420-3-26-.05, Appendix C 3.

(c) Operating Procedures.

1. No individual exposed to occupational radiation shall hold patients during exposures except during emergencies, nor shall any individual be regularly used for this service. If the patient must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and apron and he shall be so positioned that no part of his body will be struck by the useful beam.

2. Only the operators of radiographic equipment, other required individuals, and the patient shall be present during exposures. No unprotected parts of the operator's body shall be in the useful beam.

3. The useful beam shall be restricted to the area of clinical interest.

(6) Mobile Diagnostic Radiographic Equipment.

(a) Equipment.

1. All requirements of 420-3-26-.06(5)(a) apply except 420-3-26-.06(5)(a)5.

2. The exposure control switch shall be of the dead-man type and shall be so arranged that the operator can stand at least six (6) feet from the patient and well away from the useful beam.

(b) Structural Shielding.

1. When a mobile unit is used routinely in one location, it shall be considered a fixed installation subject to shielding requirements specified in 420-3-26-.06(3)(d) and 420-3-26-.06(5)(b).

(c) Operating Procedures.

1. All provisions of 420-3-26-.06(5)(c) apply except 420-3-26-.06(5)(c)2.

2. The target-to-skin distance shall not be less than twelve (12) inches.

(7) Chest Photofluorographic Installations.

(a) Equipment.

1. All provisions of 420-3-26-.06(5)(a) apply.

2. A collimator shall restrict the useful beam to the area of the photofluorographic screen.

(b) Structural Shielding.

1. All provisions of 420-3-26-.06(3)(d) and 420-3-26-.05(5)(b) apply.

(c) Operating Procedures.

1. All provisions of 420-3-26-.06(5)(c) apply.

2. All individuals except the patient being examined shall be in shielded positions during exposures.

(8) Dental Radiographic Installations.

(a) Equipment.

1. The tube housing shall be of diagnostic type.

2. Diaphragms or cones shall be used for collimating the useful beam and shall provide the same degree of protection as the housing. The diameter of the useful beam at the cone tip shall not be more than three (3) inches.

3. A cone or spacer frame shall provide a target-to-skin distance of not less than seven (7) inches with apparatus operating above fifty (50) kVp or four (4) inches with apparatus operating at fifty (50) kVp or below.

4.(i) For equipment operating up to seventy (70) kVp, the total filtration permanently in the useful beam shall be equivalent to at least 1.5 mm of aluminum. This requirement may be assumed to

have been met if the half-value layer is not less than 1.5 mm aluminum at normal operating voltages.

(ii) For equipment operating above seventy (70) kVp, the total filtration permanently in the useful beam shall be equivalent to at least 2.5 mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than 2.5 mm of aluminum at the normal operating voltages.

5. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. It shall not be possible to make an exposure when the timer is set at a zero or off position, if either position is provided. Except for dental panoramic systems, termination of exposure shall cause automatic resetting of the time to its initial setting or to zero.

6. The exposure control switch shall be of the dead-man type.

7. Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six (6) feet from the patient and well away from the useful beam.

(b) Structural Shielding.

1. Dental rooms containing x-ray machines shall be provided with primary barriers for all areas struck by the useful beam.

2. When dental x-ray units are installed, the rooms adjacent will be adequately protected.

NOTE: In most cases structural materials or ordinary walls suffice as a protective barrier without addition of special shielding material.

(c) Operating Procedures.

1. Neither the dentist nor his assistant shall be permitted to hold patients or films during exposure, nor shall any individual be regularly used for this service.

2. During each exposure, the operator shall stand at least six (6) feet from the patient or behind a protective barrier.

3. Only the patient shall be in the useful beam.

4. Neither the tube housing nor the pointer cone shall be hand-held during exposure.

5. Fluoroscopy shall not be used in dental examinations.

(9) Therapeutic X-ray Installations.

(a) Equipment.

1. The tube housing shall be of therapeutic type.

2. Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of protection as the tube housing. Adjustable or removable beam-defining diaphragms or cones shall transmit not more than five (5) percent of the useful beam obtained at the maximum kilovoltage and with maximum treatment filter.

3. Filters shall be secured in place to prevent them from dropping out during treatment. The filter slot shall be so constructed that the radiation escaping through it does not exceed one (1) roentgen per hour at one (1) meter, or if the radiation from the slot is accessible to the patient, thirty (30) roentgens per hour at five (5) centimeters from the external opening.

4. The x-ray tube shall be so mounted that it cannot turn or slide with respect to the aperture.

5. Means shall be provided to immobilize the tube housing during stationary portal treatment.

6. A timer shall be provided to terminate the exposure after a preset time regardless of what other exposure limiting devices are present.

7. Equipment utilizing shutters to control the useful beam shall have a shutter position indicator on the control.

8. There shall be on the control panel an easily discernible indicator which will give positive information as to whether or not the x-ray tube is energized.

(b) Structural Shielding.

1. All wall, floor, and ceiling areas that can be struck by the useful beam, plus a border of one foot, shall be provided with primary protective barriers.

2. All wall, floor, and ceiling areas that cannot be struck by the useful beam shall be provided with secondary barriers.

3. With equipment operating above one hundred and twenty-five (125) kVp, the required barriers shall be an integral part of the building.

4. With equipment operating above one hundred and fifty (150) kVp, the control panel shall be within a protective booth equipped with an interlocked door, or outside the treatment room.

5. Interlocks shall be provided for x-ray therapy equipment capable of operating above 150 kVp so that, when any door of the treatment room is opened, either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than two milliroentgens per hour and a maximum of ten milliroentgens per hour at a distance of one (1) meter in any direction from the target. After such shut off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

6. Provisions shall be made to permit continuous observation of patients during irradiation.

7. Windows, mirror systems, or closed-circuit television viewing screens used for observing the patient shall be so located that the operator may see the patient and the control panel from the same position.

(c) Operating Procedures.

1. All new installations shall have a protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the installation which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the installation and to the Agency (State Board of Health).

NOTE: Paragraph (c)1. of 420-3-26-.06(9), Rule 420-3-26-.06 was revised by the State Board of Health on March 19, 1979.

2. The installation shall be operated in compliance with any limitations indicated by the protection survey.

3. No individual who works with radiation, unless he is the patient, shall be in the treatment room during exposure. No other individual shall be there except when it is clinically necessary. If any individual is required to be in the treatment room with the patient during exposure, he shall be protected as much as possible from scattered radiation, and shall not be in the useful beam.

4. Records of surveys required by subparagraph (4) of this paragraph shall be maintained for two years after the facility has ceased to be used as described in the survey. If the survey was used to determine an individual's exposure, the record must be maintained until disposal is authorized by the Agency.

(d) All provisions of this Section apply to therapeutic veterinary installations.

(e) The output of each therapeutic x-ray machine shall be calibrated by, or under the direction of, a qualified expert. The calibration shall be repeated after any change in or replacement of components of the x-ray generating equipment which could cause

a change in x-ray output. Check calibrations shall be made at least one a year thereafter. Records of calibration shall be maintained by the registrant.

(10) X-ray Therapy Equipment Operated at Potentials of Sixty (60) KV and Below.

(a) Equipment.

1. All provisions of 420-1-26-.06(9)(a) apply, except for equipment used for "contact therapy", 420-3-26-.06(9)(a) in which instance the leakage radiation at the surface of the tube housing shall not exceed 0.1 roentgen per hour.

2. There shall be on the control panel some easily discernible device which will give positive indication as to whether or not the tube is energized.

(b) Operating Procedures.

1. Automatic timers shall be provided which will permit accurate presetting and determination of exposures as short as one second.

2. In the therapeutic application of apparatus constructed with beryllium or other low-filtration windows, the registrant shall insure that the unfiltered radiation reaches only the part intended and that the useful beam is blocked at all times except when actually being used.

3. Machines having an output of more than 1,000 roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the primary disconnecting means.

4. If the tube is hand-held during irradiation, the operator shall wear protective gloves and apron.

(11) Veterinary Medicine Radiographic Installations.

(a) Equipment.

1. The tube housing shall be of diagnostic type.

2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as required of the housing, as indicated in 420-3-26-.06(5)(a)2.(i) and (ii).

3. Except when contraindicated for a particular radiographic purpose, the total filtration permanently in the useful beam shall not be less than 1.5 millimeters aluminum-equivalent for equipment operating up to seventy (70) kVp and 2.0 millimeters aluminum-equivalent for machines operated in excess of seventy (70) kVp.

4. A device shall be provided to terminate the exposure after a preset time interval, preset product of current and time (mAs), a preset number of pulses, or a preset radiation exposure to the image receptor. It shall not be possible to make an exposure when the timer is set at a zero or off position, if either position is provided.

5. A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam at least six (6) feet from the animal during all x-ray exposures.

(b) Structural Shielding.

1. All wall, floor, and ceiling areas shall be provided with applicable protective barriers as required in 420-3-26-.06(5)(b).

(c) Operating Procedures.

1. The operator shall stand well away from the tube housing and the animal during radiographic exposures. Provisions shall be made so that it will not be necessary for the operator to stand in the useful beam. Hand-held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individual other than the persons involved in the operation shall be in the x-ray room while exposures are being made.

2. In any application in which the operator or an assistant is not located behind a protective barrier, a protective apron having a lead-equivalent of not less than 0.5 millimeter shall be worn.

3. No individual shall be regularly employed to hold or support animals or hold film during radiation exposures. Occupationally exposed individuals shall not perform this service except in cases in which no other method is available. Any individual holding or supporting an animal during radiation exposure shall wear protective gloves and apron having a lead-equivalent of not less than 0.5 millimeter.

Author: Aubrey V. Godwin, Director, Division of Radiation Control.

Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-7, 22-14-8.

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420-3-26-.07 **Use Of Radionuclides In The Healing Arts.**

(1) **Purpose and Scope.** This rule establishes requirements and provisions for the production, preparation, compounding and use of radionuclides in the healing arts and for issuance of licenses authorizing these activities. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of these rules are in addition to, and not in substitution for, others in these rules. The requirements and provisions of these rules apply to applicants and licensees subject to this rule unless specifically exempted.

(2) **Definitions.**

(a) "Address of use" means the building or buildings that are identified on the license and where radioactive material may be prepared, received, used, or stored.

(b) "Area of use" means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

(c) "As low as is reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed or registered sources of radiation in the public interest.

(d) "Associate Radiation Safety Officer" means an individual who:

1. Meets the requirement in 420-3-26-.07(26) and (30); and

2. Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

(i) A specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; or

(ii) A medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee.

(e) "Authorized medical physicist" means an individual who:

1. Meets the requirements in 420-3-26-.07(27) and 420-3-26-.07(30); or

2. Is identified as an authorized medical physicist or teletherapy physicist on:

(i) A U.S. Nuclear Regulatory Commission or Agreement State specific license that authorizes the medical use of radioactive material; or,

(ii) A U.S. Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit the medical use of radioactive material; or,

(iii) A permit issued by a U.S. Nuclear Regulatory Commission master material license broad medical use permittee;

3. Is identified as an authorized medical physicist or teletherapy physicist on a specific medical use license issued by the Agency; or,

4. Is identified as an authorized medical physicist or teletherapy physicist on a permit issued by an Agency specific medical use license of broad scope that is authorized to permit the use of radioactive material.

(f) "Authorized nuclear pharmacist" means a pharmacist who:

1. Meets the requirements in 420-3-26-.07(28) and 420-3-26-.07(30); or

2. Is identified as an authorized nuclear pharmacist on:

(i) A U.S. Nuclear Regulatory Commission or Agreement State specific license that authorizes medical use or the practice of nuclear pharmacy; or

(ii) A U.S. Nuclear Regulatory Commission or Agreement State specific license of broad scope that is authorized to permit medical use or the practice of nuclear pharmacy; and,

(iii) A permit issued by a U.S. Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist; or,

3. Has been approved to practice nuclear pharmacy by the Alabama State Board of Pharmacy; and

4. Is identified as an authorized nuclear pharmacist on a specific license that authorizes medical use, the practice of nuclear

pharmacy, commercial nuclear pharmacy or the manufacture and distribution of radiopharmaceuticals issued by the Agency; or

5. Is identified as an authorized nuclear pharmacist on a permit issued by an Agency specific license of broad scope that is authorized to permit the use of radioactive material.

(g) "Authorized user" means a physician, dentist, or podiatrist who:

1. Meets the requirements in 420-3-26-.07(30) and 420-3-26-.07(47), 420-3-26-.07(51), 420-3-26-.07(56), 420-3-26-.07(57), 420-3-26-.07(58), 420-3-26-.07(68), 420-3-26-.07(69), 420-3-26-.07(71), or 420-3-26-.07(89); or

2. Is identified as an authorized user on--

(i) A U.S. Nuclear Regulatory Commission or Agreement State specific license that authorized the medical use of radioactive material; or

(ii) A U.S. Nuclear Regulatory Commission or Agreement State specific license of broad scope, or a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, that is authorized to permit the medical use of radioactive material;

3. Is identified as an authorized user on a license issued by the Agency; or

4. Is identified as an authorized user on a permit issued by an Agency specific license of broad scope that is authorized to permit the medical use of radioactive material.

(h) "Brachytherapy" means a method of radiation therapy in which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

(i) "Brachytherapy source" means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

(j) "Client's address" means the address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with 420-3-26-.07(42).

(k) "Cyclotron" means a particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-1ife radionuclides for medical use.

(l) "Dedicated check source" means a radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

(m) "Dentist" means an individual licensed to practice dentistry by the Alabama Board of Dental Examiners.

(n) "Diagnostic clinical procedures manual" means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

(o) "High dose-rate remote afterloader" (HDR) means a brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the prescribed treatment site.

(p) "Low dose-rate remote afterloader"(LDR) means a brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the prescribed treatment site.

(q) "Management" means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee’s activities, or those persons’ delegate or delegates.

(r) "Manual brachytherapy" means a type of therapy in which brachytherapy sources are manually placed topically on, or inserted into, either the body cavities that are in close proximity to a treatment site, or directly into the tissue volume.

(s) "Medical institution" means an organization in which more than one medical discipline is practiced.

(t) "Medical use" means the intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

(u) "Medium dose-rate remote afterloader" (MDR) means a brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than, or equal to, 12 gray (1200 rads) per hour at the prescribed treatment site.

(v) "Misadministration" means an event that meets the criteria in 420-3-26-.07(120)(a) or (b).

(w) "Mobile medical service" means the transportation of radioactive material to, and its medical use at, the client’s address.

(x) "Ophthalmic Physicist" means an individual who:

1. Meets the requirements in 420-3-26-.07(65.1)(a)2 and (30); and

2. Is identified as an ophthalmic physicist on a:

(i) Specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State;

(ii) Permit issued by an Agency, the U.S. Nuclear Regulatory Commission, or Agreement State broad scope medical use licensee;

(iii) Medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or

(iv) Permit issued by a U.S. Nuclear Regulatory Commission master material licensee broad scope medical use permittee

(y) "Output" means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

(z) "Patient intervention" means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

(aa) "Pharmacist" means an individual licensed by the Alabama Board of Pharmacy.

(bb) "Physician" means a doctor of medicine or doctor of osteopathy licensed by the Alabama State Board of Medical Examiners to prescribe drugs in the practice of medicine.

(cc) "Podiatrist" means an individual licensed by the Alabama State Board of Podiatry.

(dd) "Positron Emission Tomography (PET) radionuclide production facility" is a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

(ee) "Preceptor" means an individual who provides, directs or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist or a Radiation Safety Officer, or an Associate Radiation Safety Officer.

(ff) "Prescribed dosage" means the specified activity or range of activity of a radioactive drug as documented:

1. In a written directive as specified in 420-3-26-.07(23); or

2. In accordance with the directions of the authorized user for procedures as specified in 420-3-26-.07(45) and 420-3-26-.07(48).

(gg) "Prescribed dose" means:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

2. For teletherapy, the total dose and dose per fraction as documented in the written directive;

3. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4. For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.

(hh) "Pulsed dose-rate remote afterloader" (PDR) means a special type of remote afterloading brachytherapy device that uses a single source capable of delivering dose rates in the high dose-rate” range, but:

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

2. Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

(ii) "Radiation Safety Officer" means an individual who:

1. Meets the requirements in 420-3-26-.07(26) and 420-3-26-.07(30), or

2. Is named as a Radiation Safety Officer on a specific medical use license issued by the U.S. Nuclear Regulatory Commission or Agreement State, or a medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or

3. Is named as a Radiation Safety Officer on an Agency license.

(jj) "Radioactive drug" means any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

(kk) "Sealed source" means any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

(ll) "Sealed Source and Device Registry" means the national registry that contains the registration certificates maintained by

the U.S. Nuclear Regulatory Commission that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

(mm) "Stereotactic radiosurgery" means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.

(nn) "Structured educational program" means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

(oo) "Teletherapy" as used in this rule, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

(pp) ”Temporary jobsite" as used in this rule, means a location where mobile medical services are conducted other than the location(s) of use authorized on the license.

(qq) "Therapeutic dosage" means a dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

(rr) "Therapeutic dose" means a radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

(ss) "Treatment site" means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

(tt) "Type of use" means use of radioactive material as specified under 420-3-26-.07(45), (48), (52), (60), (70), (72) or (90).

(uu) "Unit dosage" means a dosage prepared for medical use, to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

(vv) "Written directive" means an authorized user’s written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in 420-3-26-.07(23).

(3) Maintenance of Records.

Each record required by this rule must be legible throughout the retention period specified by each Agency regulation. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy

throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(4) **Provisions for Research Involving Human Subjects.** A licensee may conduct research involving human subjects using radioactive material provided:

(a) That the research is conducted, funded, supported, or regulated by a federal agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Agency license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

(b) The research involving human subjects authorized in 420-3-26-.07(4)(a) shall be conducted using radioactive material authorized for medical use in the license; and

(c) Nothing in 420-3-26-.07(4) relieves licensees from complying with the other requirements in this rule.

(5) **U.S. Food and Drug Administration, Federal, and State Requirements.** Nothing in this rule relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

(6) **Implementation.**

(a) When a requirement in this Rule differs from the requirement in an existing license condition, the requirement in this Rule shall govern.

(b) Any existing license condition that is not affected by a requirement in this Rule remains in effect until there is a license amendment or license renewal.

(c) If a license condition exempted a licensee from a provision of this Rule on its effective date, it will continue to exempt a licensee from the corresponding provision in this rule.

(d) If a license condition cites provisions in this rule that were deleted on the effective date of this rule, then the license

condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.

(e) Licensees shall continue to comply with any license condition that requires it to implement procedures required by 420-3-26-.07(75), 420-3-26-.07(81), 420-3-26-.07(82) and 420-3-26-.07(83) until there is a license amendment or renewal that modifies the license condition.

(7) **License Required.**

(a) A person shall only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Agency, or as allowed in 420-3-26-.07(7)(b) or 420-3-26-.07(7)(c).

(b) An individual may receive, possess, use, or transfer radioactive material in accordance with the regulations in this rule under the supervision of an authorized user as provided in 420-3-26-.07(22), unless prohibited by license condition.

(c) An individual may prepare unsealed radioactive material for medical use in accordance with the regulations in this rule under the supervision of an authorized nuclear pharmacist or authorized user as provided in 420-3-26-.07(22), unless prohibited by license condition.

(8) **Application for License, Amendment, or Renewal.**

(a) An application must be signed by the applicant’s or licensee’s management.

(b) An application for a license for medical use of radioactive material as described in 420-3-26-.07(45), (48), (52), (60), (70), (72) or (90) must be made by:

1. Filing an original of Agency Form RM that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and

2. Submitting procedures required by sections 420-3-26-.07(75), 420-3-26-.07(81), 420-3-26-.07(82) and 420-3-26-.07(83), as applicable.

(c) A request for a license amendment or renewal must be made by:

1. Submitting an original request in letter format.

2. Submitting procedures required by sections 420-3-26-.07(75), 420-3-26-.07(81), 420-3-26-.07(82) and 420-3-26-.07(83), as applicable.

(d) In addition to the requirements in 420-3-26-.07(8)(b) and 420-3-26-.07(8)(c), an application for a license or amendment for medical use of radioactive material as described in 420-3-26-.07(90) of this rule must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in 420-3-26-.07(1) through 420-3-26-.07(44), identification of and commitment to follow applicable radiation safety program requirements in 420-3-26-.07(45) though 420-3-26-.07(90); as well as any specific information on:

1. Radiation safety precautions and instructions;

2. Training and experience of proposed users;

3. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

4. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

(e) The applicant or licensee shall also provide any other information requested by the Agency in its review of the application.

(f) An applicant that satisfies the requirements specified in 420-3-26-.02(10)(e) may apply for a Type A specific license of broad scope.

(9) **Mobile Medical Service Administrative Requirements.**

(a) The Agency shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

(b) Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client’s address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

(c) A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

(d) A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

(e) A licensee providing mobile medical services shall retain the letter required in (9)(b) in accordance with 420-3-26-.07(102).

(f) A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:

1. The current operating and emergency procedures;

2. A copy of the license;

3. Copies of the letter required by (9)(b);

4. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

5. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding 30 calendar days.

(g) A mobile medical service licensee shall maintain all records required by rules 420-3-26-.03 and 420-3-26-.07 of these regulations at a location within the Agency's jurisdiction that is:

1. A single address of use:

(i) Identified as the records retention location; and

(ii) Staffed at all reasonable hours by individual(s) authorized to provide the Agency with access for purposes of inspection; or

2. When no address of use is identified on the license for records retention, the mobile unit:

(i) Identified in the license; and

(ii) Whose current client's address schedule and location schedule is reported to the Agency at a frequency specified by the Agency.

(10) **License Amendments.** A licensee shall apply for and must receive a license amendment:

(a) Before it receives, prepares or uses radioactive material for a type of use that is permitted under this rule, but that is not authorized on the licensee's current license issued pursuant to this rule;

(b) Before it permits anyone, except a visiting authorized user described in 420-3-26-.07(12), a visiting authorized medical physicist as described in 420-3-26-.07(13), or a visiting

authorized nuclear pharmacist as described in 420-3-26-.07(14) to work as an authorized user, authorized nuclear pharmacist, authorized ophthalmic physicist, or authorized medical physicist under the license.

(c) Before it changes Radiation Safety Officers, except as provided in 420-3-26-.07(19)(c);

(d) Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

(e) Before it receives radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

(f) Before it adds to or changes the areas of use identified in the application or on the license; Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate Radiation Safety Officer that differ from those for which this individual is authorized on the license;

(g) Before it changes the address(es) of use identified in the application or on the license;

(h) Before it changes statements, representations, and procedures which are incorporated into the license: and

(i) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

(11) **Notifications.** A licensee shall notify the Agency by letter no later than 30 days after:

(a) A Radiation Safety Officer, authorized user, authorized medical physicist or authorized nuclear pharmacist permanently discontinues performance of duties under the license, or has a name change;

(b) The licensee’s mailing address changes;

(c) The licensee’s name changes, but the name change does not constitute a transfer of control of the license as described in 420-3-26-.02(12)(b); or

(d) The licensee has added to or changed the areas where radioactive material is used in accordance with 420-3-26-.07(45),

or 420-3-26-.07(48), if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/ PET radioactive drug production area; or

(e) The licensee obtains sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in 420-3-26-.07(88). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(12) **Visiting Authorized User.**

(a) A licensee may permit a physician to act as a visiting authorized user and use licensed material for medical use under the terms and conditions of the licensee's license for 60 days each calendar year if:

1. The visiting authorized user has the prior written permission of the licensee's management, and the Radiation Safety Committee if one is required;

2. The licensee has a copy of:

(i) An Agency license that identifies the visiting authorized user, by name, as an authorized user for medical use; or

(ii) A permit issued by an Agency specific license of broad scope that identifies the visiting authorized user, by name, as an authorized user for medical use; and,

3. The visiting authorized user performs only those procedures:

(i) For which they are specifically authorized to perform on an Agency license; and,

(ii) Which are specifically approved on the licensee's license.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized user to use licensed material as described in 420-3-26-.07(12)(a).

(c) A licensee shall retain copies of the records specified in 420-3-26-.07(12)(a) for three years from the date of the last visit.

(13) **Visiting Authorized Medical Physicist.**

(a) A licensee may permit a medical physicist to act as a visiting authorized medical physicist and perform the duties of a medical physicist under the terms and conditions of the licensee's license for 60 days each calendar year if:

1. The visiting authorized medical physicist has the prior written permission of the licensee's management, and the Radiation Safety Committee if one is required; and,

2. The licensee has a copy of:

(i) An Agency license that identifies the visiting authorized medical physicist, by name, as an authorized medical physicist; or

(ii) A permit issued by an Agency specific license of broad scope that identifies the visiting authorized medical physicist, by name, as an authorized medical physicist.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized medical physicist to perform licensed duties as described in 420-3-26-.07(13)(a).

(c) A licensee shall retain copies of the records specified in 420-3-26-.07(13)(a) for three years from the date of the last visit.

(14) **Visiting Authorized Nuclear Pharmacist.**

(a) A licensee may permit a nuclear pharmacist to act as a visiting authorized nuclear pharmacist and perform the duties of a nuclear pharmacist under the terms and conditions of the licensee's license for 60 days each calendar year if:

1. The visiting authorized nuclear pharmacist has the prior written permission of the licensee's management, and the Radiation Safety Committee if one is required;

2. The licensee has a copy of:

(i) An Agency license that identifies the visiting authorized nuclear pharmacist, by name, as an authorized nuclear pharmacist; or

(ii) A permit issued by an Agency specific license of broad scope that identifies the nuclear pharmacist, by name, as an authorized nuclear pharmacist.

(b) A licensee need not apply for a license amendment in order to permit a visiting authorized nuclear pharmacist to perform licensed duties as described in 420-3-26-.07(14)(a).

(c) A licensee shall retain copies of the records specified in 420-3-26-.07(14)(a) for 3 years from the date of the last visit.

(15) **Exemptions Regarding Type A Specific Licenses of Broad Scope.** A licensee possessing a Type A specific license of broad scope for medical use is exempt from:

(a) The provisions of 420-3-26-.07(8)(d), regarding the need to file an amendment to the license for medical uses of radioactive material, as described in 420-3-26-.07(90);

(b) The provisions of 420-3-26-.07(10)(b);

(c) The provisions of 420-3-26-.07(10)(e) regarding additions to or changes in the areas of use at the addresses specified in the license;

(d) The provisions of 420-3-26-.07(11)(a) regarding notification to the Agency for authorized users, authorized medical physicists, authorized nuclear pharmacists, and ophthalmic physicists;

(e) The provisions of 420-3-26-.07(11)(c) and (d); and

(f) The provisions of 420-3-26-.07(25)(a).

(16) **License Issuance.**

(a) The Agency shall issue a license for the medical use of radioactive material if:

1. The applicant has filed an Agency Form RM in accordance with the instructions in 420-3-26-.07(8);

2. The applicant has paid any applicable fee;

3. The applicant meets the requirements of 420-3-26-.02 of these regulations; and

4. The Agency finds the applicant equipped and committed to observe the safety standards established by the Agency in these regulations for the protection of the public health and safety.

(b) The Agency shall issue a license for mobile services if the applicant:

1. Meets the requirements in 420-3-26-.07(16)(a); and

2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered, may be released following treatment in accordance with 420-3-26-.07(41).

(17) **Specific Exemptions.** The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this rule as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

(18) **ALARA Program.**

(a) Each licensee shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable in accordance with 420-3-26-.03(5)(b) of these rules.

(b) To satisfy the requirement of 420-3-26-.07(18)(a):

1. The management, Radiation Safety Officer and all authorized users shall participate in the establishment, implementation, and operation of the program as required by these regulations or required by the Radiation Safety Committee.

2. For licensees that are not medical institutions, management and all authorized users shall participate in the program as requested by the Radiation Safety Officer.

(c) The ALARA program shall include an annual review, by the Radiation Safety Committee for licensees that are medical institutions, or management and the Radiation Safety Officer for licensees that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material.

(d) The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

(e) The licensee shall retain a current written description of the ALARA program for the duration of the license.

The written description must include:

1. A commitment by management to keep occupational doses as low as reasonably achievable;

2. A requirement that the Radiation Safety Officer brief management once each year on the radiation safety program;

3. Personnel exposure action levels that, when exceeded, will initiate an investigation by the Radiation Safety Officer of the cause of the exposure; and

4. Personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

(19) **Authority and Responsibilities for the Radiation Protection Program.**

(a) In addition to the radiation protection program requirements of 420-3-26-.03(5) of these regulations, a licensee's management must approve in writing:

1. Requests for license application, renewal, or amendments before submittal to the Agency;

2. Radiation protection program changes that do not require a license amendment and are permitted under 420-3-26-.07(20); and

3. Any individual before allowing that individual to act as a visiting authorized user, visiting authorized medical physicist or a visiting authorized nuclear pharmacist.

(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee s management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

(c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in 420-3-26-.07(19)(e), provided the licensee takes the actions required in 420-3-26-.07(19)(b),(d), (e) and (h). A licensee may simultaneously appoint more than one temporary Radiation Safety Officer, if needed, to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different uses of radioactive material permitted by the license.

(d) A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

(e) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;

2. Initiate, recommend, or provide corrective actions;

3. Stop unsafe operations; and,

4. Verify implementation of corrective actions.

(f) Licensees that are authorized for two or more different types of radioactive material use under 420-3-26-.07(52), 420-3-26-.07(60), 420-3-26-.07(72) and 420-3-26-.07(90), or two or more types of units under 420-3-26-.07(72) shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license. The committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members as the licensee deems appropriate.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;

2. Initiate, recommend, or provide corrective actions;

3. Stop unsafe operations; and

4. Verify implementation of corrective actions.

(h) For record requirements, see 420-3-26-.07(91).

(20) **Radiation Protection Program Changes.**

(a) A licensee may revise its radiation protection program without Agency approval if:

1. The revision does not require an amendment under 420-3-26-.07(10);

2. The revision is in compliance with the regulations and the license;

3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee’s Radiation Safety Committee (if applicable); and

4. The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with 420-3-26-.07(92).

(21) **Duties of Authorized Users and Authorized Medical Physicists.**

(a) A licensee shall assure that only authorized users for the type of radioactive material used:

1. Select the patients to receive radiopharmaceuticals or radiation from radioactive materials;

2. Prescribe the radiopharmaceutical dosage and/or dose to be administered, in writing, through the issuance of a written directive as described in 420-3-26-.07(23) or by written reference to the diagnostic clinical procedures manual;

3. Direct, as specified in 420-3-26-.07(22) and 420-3-26-.07(23), or in license conditions, the administration of radiopharmaceuticals or radioactive material for medical use to patients or human research subjects;

4. Prepare and administer, or supervise the preparation and administration of radiopharmaceuticals or radioactive material for medical use, in accordance with 420-3-26-.07(7)(b), 420-3-26-.07(7) (c) and 420-3-26-.07(22); and

5. Perform the final interpretation of the results of tests, studies, or treatments.

(b) A licensee shall assure that only authorized medical physicists perform, as applicable:

1. Full calibration measurements as described in 420-3-26-.07(78), 420-3-26-.07(79) and 420-3-26-.07(80);

2. Periodic spot checks as described in 420-3-26-.07(81), 420-3-26-.07(82) and 420-3-26-.07(83); and

3. Radiation surveys as described in 420-3-26-.07(85).

(22) **Supervision.**

(a) A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user or as allowed by 420-3-26-.07(7)(b) shall:

1. In addition to the requirements in 420-3-26-.10(3) of these regulations, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this rule, and license conditions with respect to the use of radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written

directive procedures, regulations of this rule, and license conditions with respect to the medical use of radioactive material.

(b) A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by 420-3-26-.07(7)(c)., shall:

1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual’s involvement with radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the regulations of this rule, and license conditions.

(c) Unless physical presence as described in other sections of this rule is required, a licensee who permits supervised activities under 420-3-26-.07(22)(a) and 420-3-26-.07(22)(b) shall require an authorized user to be immediately available (by telephone within ten minutes) to communicate with the supervised individual, and able to be physically present within one hour of notification; and

(d) A licensee that permits supervised activities under 420-3-26-.07(22)(a) and 420-3-26-.07(22)(b) is responsible for the acts and omissions of the supervised individual.

(23) **Written Directives.**

(a) A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerel (30 microcuries), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

1. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing in the patient's record and a written directive is prepared within 48 hours of the oral directive.

(b) The written directive must contain the patient or human research subject’s name and the following:

1. For an administration of quantities greater than 1.11 megabecquerel (30 microcuries) of sodium iodide I-131, the dosage;

2. For any administration of therapeutic dosage of unsealed radioactive material other than sodium iodide I-131, the radioactive drug, dosage, and route of administration;

3. For gamma stereotactic radiosurgery, the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

4. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

5. For high dose rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

6. For permanent implant brachytherapy;

(i) Prior to implantation, the treatment site, the radionuclide, and the total source strength; and

(ii) After implantation but before the patient leaves the post-treatment recovery area the treatment site, the number of sources implanted, the total source strength implanted, and the date; or

7. For all other brachytherapy including LDR, MDR, and PDR:

(i) Prior to implantation: treatment site, the radionuclide, and dose; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, number of sources, and total source strength and exposure time (or, the total dose), and date.

(c) For all other medical uses of radioactive material that do not require a specific written directive, an authorized user shall prescribe the radiopharmaceutical dosage and/or dose from radioactive material to be administered in writing, or by written reference to the diagnostic clinical procedures manual.

(d)1. A written revision to an existing written directive or written prescription may be made provided that the revision is dated and signed by an authorized user prior to the administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

2. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive or written prescription would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

(e) The licensee shall retain the written directive in accordance with 420-3-26-.07(93).

(24) **Procedures for Administrations Requiring a Written Directive.**

(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. The patient's or human research subject's identity is verified before each administration; and

2. Each administration is in accordance with the written directive.

(b) The procedures required by 420-3-26-.07(24)(a) must, at a minimum, address the following items that are applicable for the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;

2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

3. Checking both manual and computer-generated dose calculations;

4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by 420-3-26-.07(72) and (90);

5. Determining if a misadministration as defined in 420-3-26-.07(120) has occurred; and

6. Determining for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

(25) **Suppliers for Sealed Sources or Devices for Medical Use.** For medical use, a licensee may only use:

(a) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 420-3-26-.02 of these regulations or the equivalent requirements of the U.S. Nuclear Regulatory Commission or an Agreement State;

(b) Sealed sources or devices noncommercially transferred from an Agency, U.S. Nuclear Regulatory Commission or Agreement State licensee: or

(c) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 420-3-26-.02 of these regulations or the equivalent requirements of the U.S. Nuclear Regulatory Commission or an Agreement State.

(26) **Training for Radiation Safety Officer and Associate Radiation Safety Officer.** Except as provided in 420-3-26-.07(29), the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in 420-3-26-.07(19)(b) to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements of paragraphs (d) of this section. The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1.(i) Hold a bachelor’s or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

(ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience), including at least 3 years in applied health physics; and

(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2.(i) Hold a master’s or doctor’s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics:

(I) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State; or

(II) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in 420-3-26-.07(29), 420-3-26-.07(51) or 420-3-26-.07(56); and

(iii) Pass an examination, administered by diplomats of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

(b)1. Has completed a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Radiation biology; and

(V) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on an Agency, U.S. Nuclear Regulatory Commission, Agreement State license, or permit issued by a U. S. Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized by an Agency, the U.S Nuclear Regulatory Commission, or an Agreement State license, or a permit issued by a U.S. Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must involve the following:

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

(III) Securing and controlling radioactive material;

(IV) Using administrative controls to avoid mistakes in the administration of radioactive material;

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

(VI) Using emergency procedures to control radioactive material; and

(VII) Disposing of radioactive material; and

2. This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive mate1ial for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (b)1 and (d) of this section, and is able to independently fulfill the radiation safety related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

(c)1. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State under 420-3-26-.07(27)(a) and has experience in radiation safety for similar types of use of radioactive material for which the licensee is seeking the approval of the individual as Radiation Safety Officer or Associate Radiation Safety Officer, and who meets the requirements in paragraphs 420-3-26-.07(26)(d) and (e); or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified by an Agency, U.S. Nuclear Regulatory Commission, or an Agreement State license, a permit issued by a U. S. Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, U.S. Nuclear Regulatory Commission, or an Agreement State licensee of broad scope, or a permit issued by a U. S. Nuclear Regulatory Commission master material broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements of paragraph 420-3-26-.07(26)(d); and

3. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same medical use license issued by the Agency. The individual must meet the requirements in paragraph 420-3-26-.07(26)(d).

(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical

physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

(27) **Training for Authorized Medical Physicist.** Except as provided in 420-3-26-.07(29), the licensee shall require the authorized medical physicist to be an individual who:

(a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 420-3-26-.07(27)(c). The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have 2 years of full-time practical training and/or supervised experience in medical physics:

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; or

(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in 420-3-26-.07(29), 420-3-26-.07(68) or 420-3-26-.07(89); and

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

(b)1. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies

greater than or equal to 1 million electron volts) and brachytherapy services and must include:

(i) Performing sealed source leak tests and inventories;

(ii) Performing decay corrections;

(iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

(iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(27)(b)1. and (c), and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in 420-3-26-.07(27), 420-3-26-.07(29) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and

(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

(28) **Training for an Authorized Nuclear Pharmacist.** Except as provided in 420-3-26-.07(29), the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Is certified by a specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC s Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed

the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

2. Hold a current, active license to practice pharmacy;

3. Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

4. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

(b)1. Has completed 700 hours in a structured educational program consisting of both:

(i) 200 hours of classroom and laboratory training in the following areas

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving

(I) Shipping, receiving, and performing related radiation surveys;

(II) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(III) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(IV) Using administrative controls to avoid medical events in the administration of radioactive material; and

(V) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

2. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in 420-3-26-.07(28)(b)1. and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

(29) **Provisions for Experienced Radiation Safety Officer, Medical Physicist, Authorized User, and Nuclear Pharmacist.**

(a)1. An individual identified on an Agency, a U.S. Nuclear Regulatory Commission or an Agreement State license, or a permit issued by an Agency, a U.S. Nuclear Regulatory Commission or an Agreement State broad scope license, or master material license permit, or by a master material license pe1mittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, or an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before November 14, 2021 need not comply with training requirements of 420-3-26-.07(26), 420-3-26-.07(27) or 420-3-26-.07(28), respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in 420-3-26-.07(26)(d) or 420-3-26-.07(28)(c), as appropriate for any material or uses for which they were not authorized prior to this date.

2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology· American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of 420-3-26-.07(26) to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on an Agency, a U.S. Nuclear Regulatory Commission, or an Agreement State license or U.S. Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in 420-3-26-.07(27), for those materials and uses that these individuals performed on or before October 24, 2005.

(b)1. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Agency, an Agreement State or U.S. Nuclear

Regulatory Commission, a permit issued by an Agency, Agreement State or U.S. Nuclear Regulatory Commission broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license broad scope permittee before January 14, 2019, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of this rule.

2. Physicians, dentists, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State, a permit issued by a U.S. Nuclear Regulatory Commission master material licensee, a permit issued by an Agency, a U.S. Nuclear Regulatory Commission, or an Agreement State broad scope licensee, or a permit issued by a U.S. Nuclear Regulatory Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of the rule for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

(i) For uses authorized under 420-3-26-.07(45) or 420-3-26-.07(48), or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;

(ii) For uses authorized under 420-3-26-.07(52), a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

(iii) For uses authorized under 420-3-26-.07(60) or 420-3-26-.07(72), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology, radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

(iv) For uses authorized under 420-3-26-.07(70), a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American

Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

(c) Individuals who meet the provisions for experienced Radiation Safety Officer, Authorized Medical Physicist, Authorized User or Authorized Nuclear Pharmacist may serve as a preceptor for, and supervisors of, applicants seeking authorization on Agency licenses for the same uses for which the preceptoring individual is authorized.

(30) **Recentness of Training.** The training and experience specified in this rule must have been obtained within the seven (7) years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

(31) **Quality Control of Diagnostic Equipment.** Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended, in writing, by equipment manufacturers or procedures which have been approved by the Agency. The licensee shall conduct quality control procedures in accordance with written procedures.

(32) **Possession, Use, and Testing of Instruments to Measure the Activity of Unsealed Radioactive Materials.**

(a) For direct measurements performed in accordance with 420-3-26-.07(34), a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive materials prior to administration to each patient or human research subject.

(b) A licensee shall:

1. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this section, the check must be done on a frequently used setting with a sealed source of not less than 3700 kilobecquerel (100 microcuries) for any photon-emitting radionuclide with a half-1ife greater than 90 days;

2. Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least 2 sealed sources containing different radionuclides, the activity of which the manufacturer has determined within 5 percent of the stated activity, with minimum activity of 3700 kilobecquerel (100 microcuries) for any photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

3. Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range

of use between 1.1 Megabecquerel (30 µCi) and the highest dosage that will be administered; and

4. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 µpercent if the dosage is greater than 1.1 Megabecquerel (30 Ci) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(d) A licensee shall also perform checks and tests required by 420-3-26-.07(32) following adjustment or repair of the dose calibrator.

(e) A licensee shall retain a record of each instrument test required by 420-3-26-.07(32) in accordance with 420-3-26-.07(96).

(33) **Calibration of Survey Instruments.**

(a) A licensee shall ensure that the survey instruments used to show compliance with 420-3-26-.07 and 420-3-26-.03 of these regulations have been calibrated before first use, annually, and following any repair that will affect the calibration.

(b) To satisfy the requirements of 420-3-26-.07(33)(a), the licensee shall:

1. Calibrate all required scale readings up to 10 millisieverts (1000 millirem) per hour with a radiation source;

2. Have each radiation survey instrument calibrated:

(i) At energies appropriate for use and at intervals not to exceed 12 months or after instrument servicing, except for battery changes;

(ii) For linear scale instruments, at two points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two points of at least one decade; and for digital instruments, at 3 points between 0.02 and 10 millisieverts (2 and 1000 millirem) per hour; and

(iii) For dose rate instruments, so that an accuracy within plus or minus 20 percent of the true radiation dose rate can be demonstrated at each point checked.

3. Conspicuously note on the instrument the date of calibration.

(c)The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than 20 percent.

(d) A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

(e) The licensee shall retain a record of each survey instrument calibration in accordance with 420-3-26-.07(97).

(34) **Determination of Dosages of Radioactive Material for Medical Use.**

(a) A licensee shall determine and record the activity of each dosage prior to medical use. For photon-emitting radioactive material, this determination shall be within 30 minutes prior to medical use. For all other radioactive material, this determination shall be within the period before medical use that is no greater than 10 percent of the physical half-1ife of the radioactive material.

(b) This determination must be made by direct measurement of radioactivity or by a combination of measurements of radioactivity and mathematical calculations or combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed pursuant to 420-3-26-.02 of these regulations, or equivalent provisions of the U.S. Nuclear Regulatory Commission or an Agreement State.

(c) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage differs from the prescribed dosage by more than 20 percent.

(d) A licensee shall retain a record of the dosage determination required by this rule in accordance with 420-3-26-.07(98).

(35) **Authorization for Calibration, Transmission and Reference Sources.**

(a) Any person authorized by 420-3-26-.07(7) for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission, and reference use:

1. Sealed sources manufactured and distributed by persons specifically licensed pursuant to 420-3-26-.02 or equivalent provisions of the U.S. Nuclear Regulatory Commission or an Agreement State and that do not exceed 1.11 gigabecquerels (30 millicurie) each;

2. Sealed sources, not exceeding 1.11 gigabecquerels (30 millicuries) each, redistributed by a license authorized to

redistribute the sealed sources manufactured and distributed by a person licensed pursuant to 420-3-26-.02 or equivalent provisions of the U.S. Nuclear Regulatory Commission or an Agreement State providing the redistributed sealed sources are in t11e original packaging and shielding and are accompanied by the manufacturer's approved instructions.

3. Any radioactive material with a half-1ife of 120 days or less in individual amounts not to exceed 555 megabecquerels (15 millicurie);

4. Any radioactive material with a half-1ife greater than 120 days in individual amounts not to exceed the smaller of:

(i) 7.4 megabecquerels (200 µCi); or

(ii) 1000 times the quantities in Appendix B of 420-3-26-.02; or

5. Technetium-99m in amounts as needed.

(b) Radioactive material in sealed sources authorized by this provision shall not be:

1. Used for medical use as defined in 420-3-26-.07(2) except in accordance with the requirements in 420-3-26-.07(70); or

2. Combined (i.e. bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

(c) A license using calibration, transmission, and reference sources in accordance with the requirements in 420-3-26-.07(35)(a) or (b) need not list these sources on specific medical use license.

(36) **Requirements for Possession of Sealed Sources and Brachytherapy Sources.**

(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Agency.

(b) A licensee in possession of a sealed source shall:

1. Test the source for leakage in accordance with 420-3-26-.03.

2. Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission in the Sealed Source and Device Registry.

(c) If the leak test reveals the presence of 185 µbecquerels (0.005 Ci) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of 420-3-26-.02 and 420-3-26-.03;

2. File a report with the Agency within 5 days of receiving the leak tests results in accordance with 420-3-26-.07(122).

(d) A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources. The licensee shall retain each inventory record in accordance with 420-3-26-.07(99).

(37) **Syringe Shields.**

(a) A licensee shall keep syringes that contain radioactive material to be administered in a radiation shield.

(b) A licensee shall require each individual who prepares or administers radiopharmaceuticals to use a syringe radiation shield unless the use of the shield is contraindicated for that patient.

(38) **Vial Shields.** A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

(39) **Labels.** Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

(40) **Surveys for Ambient Radiation Dose Rate and Contamination.**

(a) Except as provided in 420-3-26-.07(40)(b) of this section, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs were prepared for use or administered.

(b) A licensee shall survey with a radiation detection survey instrument once each week, or at other intervals authorized by the Agency, all areas where radioactive drugs, sealed sources or radioactive wastes are stored.

(c) A licensee shall conduct the surveys required by 420-3-26-.07(40)(a) and (b) so as to able to measure dose rates as low as 1 microsievert (0.1 millirem) per hour.

(d) A licensee shall establish dose rate action levels for the surveys required by 420-3-26-.07(40)(a) and (b) and shall require

that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

(e) A licensee shall survey for removable contamination at the end of each day of use, or at other intervals authorized by the Agency, all areas where radioactive drugs were prepared for use or administered. The licensee shall also survey for removable contamination each week all areas where radioactive materials are stored.

(f) A licensee shall conduct the surveys required by 420-3-26-.07(40)(e) so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).

(g) A licensee shall establish removable contamination action levels for the surveys required by 420-3-26-.07(40)(e) and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

(h) A licensee does not need to perform the surveys required by 420-3-26-.07(40)(a) in area(s) where patients or human research subjects are confined when they cannot be released pursuant to 420-3-26.07(41).

(i) A licensee shall retain a record of each survey in accordance with 420-3-26-.07(100).

(41) **Release of Individuals Containing Radioactive Drugs or Implants.**

(a) A licensee may authorize the release from its control of any individual who has been administered radioactive drugs or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable. If a breast-feeding infant or child could receive a radiation dose as a result of the release of the patient, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the potential consequences, if any, of failure to follow the guidance.

(c) Release of the patient must be approved by an individual listed as an authorized user on the Agency license, and who is

approved for the type of radioactive material use for which the patient being released has received.

(d) The licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with 420-3-26-.07(101).

(e) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with 420-3-26-.07(101).

(f) Notwithstanding 420-3-26-.07(41)(a), the licensee may be held responsible for the proper disposal of any individual's radioactive waste discovered in a solid waste stream that can be traced to the licensee.

(g) The licensee shall immediately notify the Agency in accordance with 420-3-26-.07(123) if a patient departs prior to an authorized release.

(h) The licensee shall notify the Agency in accordance with 420-3-26-.07(124):

1. When they are aware that a patient containing radioactive material and who has been released in accordance with 420-3-26-.07(41) dies; and,

2. If it is possible that any individual could receive exposures in excess of 5 millisieverts (500 millirem) as a result of the deceased's body.

(42) **Mobile Medical Service Technical Requirements.** A licensee providing mobile medical service shall:

(a) Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

(b) Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

(c) Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

(d) Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function shall include a constancy check.

(e) Check survey instruments for consistent response with a dedicated check source before use at each client's address;

(f) Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with 420-3-26-.03;

(g) Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Agency for compliance with airborne release standards; and,

(h) Retain a record of each survey required by 420-3-26-.07(42)(f) in accordance with 420-3-26-.07(102).

(43) **Storage of Volatiles and Gases.**

(a) A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.

(b) A licensee shall store and use a multi-dose container in a properly functioning fume hood.

(c) A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in 420-3-26-.03.

(d) The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

(e) A licensee shall only administer radioactive gases in rooms that are at negative pressure with respect to surrounding rooms.

(f) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Appendix B of 420-3-26-.03. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

(g) A licensee shall post the time calculated in 420-3-26-.07(43)(f) at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

(h) A licensee shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed 6 months. Records of these checks and measurements shall be maintained for 3 years.

(i) A copy of the calculations required in 420-3-26-.07(43)(f) shall be recorded and retained for the duration of the license.

(44) **Decay-in-Storage.**

(a) A licensee may hold radioactive material with a physical half-1ife of less than or equal to 120 days for decay-in-storage

before disposal without regard to its radioactivity if the licensee:

1. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

2. Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and

3. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

(b) For radioactive material disposed in accordance with 420-3-26-.07(44)(a), the licensee shall retain a record of each disposal in accordance with 420-3-26-.07(103).

Specific Requirements for the Use of Radioactive Material for Uptake, Dilution, or Excretion Studies

(45) **Use of Unsealed Radioactive Material for Uptake, Dilution, or Excretion Studies for Which a Written Directive is Not Required.** A licensee may use any unsealed radioactive material, in quantities that do not require a written directive, for a diagnostic use involving measurements of uptake, dilution, or excretion that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to 420-3-26-.02 or equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 420-3-26-.07(51) or 420-3-26-.07(56), and 420-3-26-.07(51)(c)1(ii)(VII), or an individual under the supervision of either as specified in 420-3-26-.07(22); or

(c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or an Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the U.S. Food and Drug Administration; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by the U.S. Food and Drug Administration for use in research.

(46) **Possession of Survey Instrument.** A licensee authorized to use radioactive material for uptake, dilution, and excretion studies

shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirem) per hour. The instrument shall be operable and calibrated in accordance with 420-3-26-.07(33).

(47) **Training for Uptake, Dilution, and Excretion Studies.** Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(45) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs 420-3-26-.07(47)(c)(1)(i) and (c)(1)(ii); and

2. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under 420-3-26-.07(51) or (56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(c)1. Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies. The training and experience must include:

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(47), 420-3-26-.07(51), 420-3-26-.07(56) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, involving

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(VI) Administering dosages of radioactive drugs to patients or human research subjects; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph 420-3-26-.07(47)(c)(1) and is able to fulfill the radiation safety related duties as an authorized user for the medical uses authorized under 420-3-26-.07(45). The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(47) or 420-3-26-.07(51), or 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(47), 420-3-26-.07(51), or 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 420-3-26-.07(41)(c)1.

Specific Requirements for the Use of Radioactive Material for Imaging and Localization Studies

(48) **Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive is Not Required.** A licensee may use, for imaging and localization studies, any radioactive material prepared for medical use, in quantities that do not require a written directive as described in 420-3-26-.07(23) that is:

(a) Obtained from a manufacturer or preparer licensed pursuant to 420-3-26-.02 or equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 420-3-26-.07(51), or 420-3-26-.07(56) and 420-3-26-.07(51)(c)(ii)(VII), or an individual under the supervision of either as specified in 420-3-26-.07(22); or

(c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or an Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration; or

(d) Provided the conditions of 420-3-26-.07(43) are met, a licensee shall use radioactive aerosols or gases only if specific application is made to and approved by the Agency.

(49) **Radionuclide Contaminants.**

(a) A licensee shall not administer to humans a radioactive drug containing:

1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of molybdenum-99 per millicurie of technetium-99m);

2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of strontium-82 per millicurie of rubidium-82 chloride);

3. More than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of strontium-85 per millicurie of rubidium-82);

(b) To demonstrate compliance with 420-3-26-.07(49) (a), the licensee preparing radioactive drugs from radionuclide generators shall:

1. Measure the concentration of radionuclide contaminant in the first eluate after receipt of a molybdenum-99/technetium-99m generator;

2. Measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for other generator systems.

(c) To demonstrate compliance with 420-3-26-.07(49)(a), the licensee that uses a strontium-82/rubidium-82 generator for preparing a rubiclium-82 radiopharmaceutical shall, before the first patient use of the day, measure the concentration of radionuclides strontium-82 and strontium-85.

(d) If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations the licensee shall retain a record of each measurement in accordance with 420-3-26-.07(104).

(e) A licensee shall report immediately to the Agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in 420-3-26-.07(49)(a).

(50) **Possession of Survey Instruments.** A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 millirem) per hour to 10 millisieverts (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(33).

(51) **Training for Imaging and Localization Studies.** Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(48) to be a physician who:

(a) Is certified by a medical specialty board whose ce1tification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in 420-3-26-.07(51)(c)1(i) and (ii); and

2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

(b) Is an authorized user under 420-3-26-.07(56) and meets the requirements in 420-3-26-.07(51)(c)1(ii)(VII), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(c)1. Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. The training and experience must include, at a minimum

(i) Classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use;

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user, who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(51), or 420-3-26-.07(51)(c)1(ii)(VII) and 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in 420-3-26-.07(28) or 420-3-26-.07(29) may provide the supervised work experience under 420-3-26-.07(51)(c)1(ii)(VII). Work experience must involve:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

(VI) Administering dosages of radioactive drugs to patients or human research subjects; and

(VII) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclide purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in 420-3-26-.07(51)(c)l and is able to independently fulfill the radiation safety- related duties as an authorized user for the medical uses authorized under 420-3-26-.07(45) and (48). The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(51) or 420-3-26-.07(56), and 420-3-26-.07(51)(c)1(ii)(VII), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements of 420-3-26-.07(29), 420-3-26-.07(51) or 420-3-26-.07(56), and 420-3-26-.07(5l)(c)l(ii)(VII), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency progran1 director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada of the Council on Postdoctoral Training of the Ame1ican Osteopathic Association and must include experience specified in 420-3-26-.07(5l)(c)l.

Radioactive Material - Written Directive Required

(52) **Use of Unsealed Radioactive Material for Which a Written Directive is Required.** A licensee may use any unsealed radioactive material identified in 420-3-26-.07(56)(b)l(ii)(VII) prepared for medical use for which a written directive is required that is: Obtained from:

1. a manufacturer or preparer licensed in accordance with 420-3-26-.02 or equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

2. A PET radioactive drug producer licensed under 420-3-26-.02(10)(a)5 or equivalent regulations of another Agreement State or the U.S. Nuclear Regulatory Commission; or

(b) Excluding production of PET radionuclides, prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in 420-3-26-.07(51) or 420-3-26-.07(56), or an individual under the supervision of either as specified in 420-3-26-.07(22); or

(c) Obtained from and prepared by an Agency, U.S. Nuclear Regulatory Commission or an Agreement State licensee in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by the U.S. Food and Drug Administration for use in research; or

(d) Prepared by the licensee in accordance with a Radioactive Drug Research Committee-approved application or an IND protocol accepted by U.S. Food and Drug Administration for use in research.

(53) **Safety Instruction.** In addition to the requirements of 420-3-26-.10(3):

(a) A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a radioactive drug, and cannot be released in accordance with 420-3-26-.07(41). The training must be provided initially and at least annually. The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;

2. Visitor control to include the following:

(i) Routine visitation to hospitalized individuals in accordance with 420-3-26-.03;

(ii) Contamination control;

(iii) Waste control; and

(iv) Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with 420-3-26-.07(105).

(54) **Safety Precautions.**

(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with 420-3-26-.07(41), a licensee shall:

1. Quarter the patient or the human research subject either in:

(i) A private room with a private sanitary facility; or

(ii) A room, with a private sanitary facility, with another individual who also has received radiopharmaceutical therapy and who cannot be released in accordance with 420-3-26-.07(41); and,

2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

3. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

(b) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency. The licensee shall also notify the Agency in accordance with 420-3-26-.07(124) if it is possible that any individual could receive exposures in excess of 420-3-26-.03(14) as a result of the deceased's body.

(55) **Possession of Survey Instruments.** A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 millirem) per hour to 10 millisieverts (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(33).

(56) **Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required.** Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under 420-3-26-.07(52) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraphs 420-3-26-.07(56)(b)1.(ii)(VII). The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described in paragraphs 420-3-26-.07(56)(b)1.(i) through (b)1.(ii)(V). Eligible training programs must be approved by the Residency Review Committee of the

Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

(b)1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

(i) Classroom and laboratory training in the following areas

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity;

(IV) Chemistry of radioactive material for medical use; and

(V) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 420-3-26-.07(56)(b) must also have experience in administering dosages in the same dosage category or categories (i.e., 420-3-26-.07(56)(b)1.(ii)(VII)) as the individual requesting authorized user status. The work experience must involve:

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(III) Calculating, measuring, and safely preparing patient or human research subject dosages;

(IV) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(V) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

(VI) [Reserved]

(VII) Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under 420-3-26-.07(90). This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status;

(A) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(B) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131[24];

(C) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in 420-3-26-.07(56)(b) and is able to independently fulfill the radiation safety- related duties as an authorized user for the

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[24] Experience with at least 3 cases in (56)(b)1.(ii)(VII)(B) also satisfies the requirement in (56)(b)1.(ii)(VII)(A).

medical uses authorized under 420-3-26-.07(52) for which the individual is requesting authorized user status. The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the

same dosage category or categories as the individual requesting authorized user status, and concurs the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in 420-3-26-.07(56)(b)1.

(57) **Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less than or Equal to 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.** Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 420-3-26-.07(57)(c)1. and (c)2. and whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

(b) Is an authorized user under 420-3-26-.07(56)(a), 420-3-26-.07(56)(b) for uses listed in 420-3-26-.07(56)(b)1(ii)(VII)(A) or (B), 420-3-26-.07(58) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(c)1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(57), 420-3-26-.07(58) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user who meets the requirements in

420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)1.(ii) (VII)(A) or (B). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(57)(c)1. and (c)2., and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) or sodium iodide I-131 for medical uses authorized under 420-3-26-.07(52). The written attestation must be obtained from either.

(i) A preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(57), 420-3-26-.07(58), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(57), 420-3-26-.07(58), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in 420-3-26-.07(56)(b)1(ii)(VII)(A) or (B), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral

Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)1 and (c)2 of this section.

(58) **Training for the Oral Administration of Sodium Iodide I-131 in Quantities Greater than 1.22 Gigabecquerels (33 millicuries) for which a Written Directive is Required.** Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities greater than 1.22 gigabecquerels (33 millicuries), to be a physician who:

(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs 420-3-26-.07(58)(c)1. and (c)2., and whose certification has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

(b) Is an authorized user under 420-3-26-.07(56)(a), 420-3-26-.07(56)(b) for uses listed in 420-3-26-.07(56)(b)1.(ii)(VII)(B), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(c)1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(58), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in 420-3-26-.07(56)(b), must also have experience in administering dosages as specified in 420-3-26-.07(56)(b)1(ii)(VII)(B). The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(v) Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(57)(c)1. and (c)2., and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) or sodium iodide I-131 for medical uses authorized under 420-3-26-.07(52). The written attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(57), 420-3-26-.07(58), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(57), 420-3-26-.07(58), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in 420-3-26-.07(56)(b)1(ii)(VII)(A) or (B), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)1 and (c)2 of this section

(59) **Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive.** Except as provided in 420-3-26-.07(29), the licensee shall require an

authorized user for the parenteral administration requiring a written directive, to be a physician who:

(a) Is an authorized user under 420-3-26-.07(56) for uses listed in 420-3-26-.07(56)(b)1.(ii)(VII)(C), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(b) Is an authorized user under 420-3-26-.07(68) or 420-3-26-.07(89), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements and who meets the requirements in paragraph 420-3-26-.07(59)(d) of this section; or

(c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under 420-3-26-.07(68) or 420-3-26-.07(89) and who meets the requirements in paragraph 420-3-26-.07(59)(d) of this section.

(d)1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in 420-3-26-.07(56)(b)l(ii)(VII)(C). The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of radioactive material for medical use; and

(v) Radiation biology; and

2. Has work experience under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(59), or equivalent U.S Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administrations listed in 420-3-26-.07(56)(b)l(ii)(VII)(C). A supervising authorized user who meets the requirements in 420-3-26-.07(56), 420-3-26-.07(59), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve:

(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

(v) Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration as specified in 420-3-26-.07(56)(b)1(ii)(VII)(C); and

(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(59)(d)1 and (d)2 of this section, and is able to independently fulfill the radiation safety related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The written attestation must be obtained from a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(59), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user, who meets the requirements in 420-3-26-.07(56) must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or.

(i) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(56), 420-3-26-.07(59), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (d)(1) and (2) of this section.

Manual Brachytherapy

(60) **Use of Sealed Sources for Manual Brachytherapy.** A licensee shall use only brachytherapy sources:

(a) As approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used

in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 420-3-26-.07(25)(a) are met.

(61) **Surveys After Source Implant and Removal.**

(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

(c) A licensee shall retain a record of the surveys in accordance with 420-3-26-.07(106).

(62) **Brachytherapy Sources Inventory.**

(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

(b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with 420-3-26-.07(107).

(63) **Safety Instruction.** In addition to the requirements of 420-3-26-.10(3):

(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with 420-3-26-.07(41). Instruction must be commensurate with the duties of the personnel and shall include the following:

1. Size and appearance of the brachytherapy sources;

2. Safe handling and shielding instructions;

3. Patient or human research subject control;

4. Visitor control, including both:

(i) Routine visitation of hospitalized individuals in accordance with 420-3-26-.03(14)(a)1.; and

(ii) Visitation authorized in accordance with 420-3-26-.03(14)(b); and

5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency. The licensee shall also notify the Agency in accordance with 420-3-26-.07(124) if it is possible that any individual could receive exposures in excess of 420-3-26-.03(14) as a result of the deceased's body.

(b) A licensee shall retain a record of individuals receiving instruction in accordance with 420-3-26-.07(105).

(64) **Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy.**

(a) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with 420-3-26-.07(41), a licensee shall:

1. Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

2. Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

(b) A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

1. Dislodged from the patient; or

2. Lodged within the patient following removal of the source applicators.

(c) The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

(65) **Calibration Measurements of Brachytherapy Sealed Sources.**

(a) Prior to the first medical use of a brachytherapy sealed source on or after June 23, 2006, a licensee shall perform the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of 420-3-26-.07(77);

2. Determine source positioning accuracy within applicators; and

3. Use published protocols accepted by nationally recognized bodies to meet the requirements of 420-3-26-.07(65)(a)1. and (a)2.

(b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with 420-3-26-.07(65)(a).

(c) A licensee shall mathematically correct the outputs or activities determined in 420-3-26-.07(65)(a) of this section for physical decay at intervals consistent with 1.0 percent physical decay.

(d) An authorized medical physicist shall perform or review the calculation measurements made pursuant to 420-3-26-.07(65)(a), (b) and (c).

(e) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined in accordance with paragraphs 420-3-26-.07(65)(a), (b) and (c).

(f) A licensee shall retain a record of each calibration in accordance with 420-3-26-.07(108).

(g) A licensee shall retain a record of decay calculations required by 420-3-26-.07(65)(e) in accordance with 420-3-26-.07(109).

(65.1) **Strontium-90 Sources for Ophthalmic Treatments.**

(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either:

1. An authorized medical physicist; or

2. An individual who:

(i) Is identified as an ophthalmic physicist on a specific medical use license issued by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State; permit issued by an Agency, a U.S. Nuclear Regulatory Commission, or Agreement State broad scope medical use licensee; medical use permit issued by a U.S. Nuclear Regulatory Commission master material licensee; or permit issued by a U.S. Nuclear Regulatory Commission master material licensee broad scope medical use permittee; and

(ii) Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

(iii) Has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

(iv) Has documented training in:

(I) The creation, modification, and completion of written directives;

(II) Procedures for administrations requiring a written directive; and

(III) Performing the calibration measurements of brachytherapy sources as detailed in 420-3-26-.07(65).

(b) The individuals who are identified in paragraph (a) of this section must:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under 420-3-26-.07(65); and

2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

3. Licensees must retain a record of the activity of each strontium-90 in accordance with 420-3-26-.07(109).

(66) **Therapy-related Computer Systems.** The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays; and

(d) The accuracy of the software used to determine radioactive source positions from radiographic images.

(67) **Possession of Survey Instruments.** A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of 10 microsieverts (1 millirem) per hour to 10 millisieverts (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(33).

(68) **Training for Use of Manual Brachytherapy Sources.** Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under 420-3-26-.07(60) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

(b)1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements at a medical institution authorized to use radioactive material under 420-3-26-.07(60), involving

(I) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(II) Checking survey meters for proper operation;

(III) Preparing, implanting, and removing brachytherapy sources;

(IV) Maintaining running inventories of radioactive material on hand;

(V) Using administrative controls to prevent a medical event involving the use of radioactive material;

(VI) Using emergency procedures to control radioactive material; and

2. Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph 420-3-26-.07(68)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(68)(b)1 and (b)2 of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under 420-3-26-.07(60). The attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user

who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include 1 training and experience specified in paragraph (b) and (b)2 of this section.

(69) **Training for Ophthalmic Use of Strontium-90.** Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a strontium-90 source for ophthalmic uses authorized under 420-3-26-.07(60) to be a physician who:

(a) Is an authorized user under 420-3-26-.07(68), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(b)1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include:

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity; and

(iv) Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve:

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(68) or 420-3-26-.07(69), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed 1 the requirements in paragraphs (b) and 2 of this section, and is able to independently

fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

Sealed Sources For Diagnosis

(70) **Use of Sealed Sources and Medical Devices for Diagnosis.**

(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 420-3-26-.07(25)(a) are met.

(71) **Training for Use of Sealed Sources and Medical Devices for Diagnosis.** Except as provided in 420-3-26-.07(29), the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under 420-3-26-.07(70) to be a physician, dentist, or podiatrist who:

(a) Is certified by a specialty board whose certification process includes all of the requirements in 420-3-26-.07(71)(c) and (d) and whose certification has been recognized by an Agreement State or the U.S. Nuclear Regulatory Commission. The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or

(b) Is an authorized user for uses in 420-3-26-.07(48) or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements; or

(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity;

4. Radiation biology; and

(c) Has completed training in the use of the device for the uses requested.

Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

(72) **Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit.**

(a) A licensee shall use sealed sources:

1. As approved in the Sealed Source and Device Registry in photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses; or

2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 420-3-26-.07(25)(a) are met.

(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of 420-3-26-.07(25)(a) are met.

(73) **Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit.**

(a) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the

source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

(b) A licensee shall retain a record of the surveys in accordance with 420-3-26-.07(106).

(74) **Installation, Maintenance, Adjustment, and Repair.**

(a) Only a person specifically licensed by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

(d) A licensee shall retain a record of the installation, maintenance, adjustment and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with 420-3-26-.07(110).

(75) **Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

3. Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to

place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

(ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by 420-3-26-.07(75)(a)4. must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of:

1. The location of the procedures required by 420-3-26-.07(75)(a)4.; and

2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d)1. Prior to the first use of patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that the vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

2. A licensee shall provide operational and safety instructions, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual’s assigned duties, in:

(i) The procedures identified in 420-3-26-.07(75)(a)4. of this section; and

(ii) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

(f) A licensee shall retain a record of individuals receiving instruction required by 420-3-26-.07(75)(d), in accordance with 420-3-26-.07(105).

(g) A licensee shall retain a copy of the procedures required by 420-3-26-.07(75)(a)4. and (d)2. In accordance with 420-3-26-.07(111).

(76) **Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall control access to the treatment room by a door at each entrance.

(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

2. Cause the source(s) to be shielded promptly when an entrance door is opened; and

3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

(e) For licensed activities where sources are placed within the patient’s or human research subject’s body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in 420-3-26-.07(76)(a) through (e), a licensee shall:

1. For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event

of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

2. For high dose-rate remote afterloader unit, require:

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

4. Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

(g) A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

1. Remains in the unshielded position; or

2. Lodges within the patient following completion of the treatment.

(77) **Dosimetry Equipment.**

(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.

1. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or

2. The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was

calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee’s facility.

(b) The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with 420-3-26-.07(77)(a). This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in 420-3-26-.07(77)(a).

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with 420-3-26-.07(112).

(78) **Full Calibration Measurements on Teletherapy Units.**

(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one year.

(b) To satisfy the requirement of 420-3-26-.07(78)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use;

2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in 420-3-26-.07(77)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 420-3-26-.07(78)(b)1 may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by 420-3-26-.07(78)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in 420-3-26-.07(78)(b)1. for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by 420-3-26-.07(78)(a) and physical decay corrections required by 420-3-26-.07(78)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with 420-3-26-.07(113).

(79) **Full Calibration Measurements on Remote Afterloader Units.**

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-1ife exceeds 75 days; and

4. At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of 420-3-26-.07(79)(a), full calibration measurements must include, as applicable, determination of:

1. The output within +/- 5 percent;

2. Source positioning accuracy to within +/- 1 millimeter;

3. Source retraction with backup battery upon power failure; and

4. Length of the source transfer tubes;

5. Timer accuracy and linearity over the typical range of use;

6 Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in 420-3-26-.07(77)(a) to measure the output.

(d) A licensee shall make full calibration measurements required by 420-3-26-.07(79)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in 420-3-26-.07(79)(b), a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with 420-3-26-.07(79)(a) through (e).

(g) A licensee shall mathematically correct the outputs determined in 420-3-26-.07(79)(b)1. for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by 420-3-26-.07(79)(a) and physical decay corrections required by 420-3-26-.07(79)(VII) must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with 420-3-26-.07(113).(80)

Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

3. At intervals not exceeding 1 year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

(b) To satisfy the requirement of 420-3-26-.07(80)(a), full calibration measurements must include determination of:

1. The output within +/-3 percent;

2. Relative helmet factors;

3. Isocenter coincidence;

4. Timer accuracy and linearity over the range of use;

5. On-off error;

6. Trunnion centricity;

7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

8. Helmet microswitches;

9. Emergency timing circuits; and

10. Stereotactic frames and localizing devices (trunnions).

(c) A licensee shall use the dosimetry system described in 420-3-26-.07(77)(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in 420-3-26-.07(80)(b)1. may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by 420-3-26-.07(80)(a) in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in 420-3-26-.07(80)(b)1. at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.

(f) Full calibration measurements required by 420-3-26-.07(80)(a) and physical decay corrections required by 420-3-26-.07(80)(e) must be performed by the authorized medical physicist.

(g) A licensee shall retain a record of each calibration in accordance with 420-3-26-.07(113).

(81) **Periodic Spot-Checks for Teletherapy Units.**

(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy, and timer linearity over the range of use;

2. On-off error;

3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

4. The accuracy of all distance measuring and localization devices used for medical use;

5. The output for one typical set of operating conditions measured with the dosimetry system described in 420-3-26-.07(77)(b); and

6. The difference between the measurement made in 420-3-26-.07(81)(a)5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by 420-3-26-.07(81)(a) in accordance with procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized

medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;

2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

4. Viewing and intercom systems;

5. Treatment room doors from inside and outside the treatment room; and

6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) If the results of the checks required in 420-3-26-.07(81)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each spot-check required by 420-3-26-.07(81)(a) and (d), in accordance with 420-3-26-.07(114).

(82) **Periodic Spot-Checks for Remote Afterloader Units.**

(a) A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

1. At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;

2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and

3. After each source installation.

(b) The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks

required in 420-3-26-.07(82)(a). The authorized medical physicist need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot check.

(d) To satisfy the requirements of 420-3-26-.07(82) (a), spot-checks must, at a minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems in each high dose-rate, medium dose-rate and pulsed dose-rate remote afterloader facility;

4. Emergency response equipment;

5. Radiation monitors used to indicate the source position;

6. Timer accuracy;

7. Clock (date and time) in the unit’s computer; and

8. Decayed source(s) activity in the unit’s computer.

(e) If the results of the checks required in 420-3-26-.07(82)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by 420-3-26-.07(82)(d) in accordance with 420-3-26-.07(115).

(83) **Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.**

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;

2. At the beginning of each day of use; and

3. After each source installation.

(b) The licensee shall have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in 420-3-26-.07(83)(a); and

2. Review the results of each spot-check required by 420-3-26-.07(83)(a) within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spotcheck.

(c) To satisfy the requirements of 420-3-26-.07(83)(a) 1., spot-checks must, at a minimum:

1. Assure proper operation of:

(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

(ii) Helmet microswitches;

(iii) Emergency timing circuits; and

(iv) Stereotactic frames and localizing devices (trunnions).

2. Determine:

(i) The output for one typical set of operating conditions measured with the dosimetry system described in 420-3-26-.07(77)(b);

(ii) The difference between the measurement made in 420-3-26-.07(83)(c)2.(i) and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

(iii) Source output against computer calculation;

(iv) Timer accuracy and linearity over the range of use;

(v) On-off error; and

(vi) Trunnion centricity.

(d) To satisfy the requirements of 420-3-26-.07(83) (a)2. and 3., spot-checks must assure proper operation of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

3. Viewing and intercom systems;

4. Timer termination;

5. Radiation monitors used to indicate room exposures; and

6. Emergency off buttons.

(e) A licensee shall arrange for prompt repair of any system identified in 420-3-26-.07(83)(c) that is not operating properly.

(f) If the results of the checks required in 420-3-26-.07(83)(d) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(g) A licensee shall retain a record of each check required by 420-3-26-.07(83)(c) and (d) in accordance with 420-3-26-.07(116).

(84) **Additional Technical Requirements for Mobile Remote Afterloader Units.**

(a) A licensee providing mobile remote afterloader service shall:

1. Check survey instruments before medical use at each address of use or on each day of use, which ever is more frequent; and

2. Account for all sources before departure from a client's address of use.

(b) In addition to the periodic spot-checks required by 420-3-26-.07(82), a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems;

4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

5. Radiation monitors used to indicate room exposures;

6. Source positioning (accuracy); and

7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

(c) In addition to the requirements for checks in 420-3-26-.07(84)(b), a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

(d) If the results of the checks required in 420-3-26-.07(84)(b) indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(e) A licensee shall retain a record of each check required by 420-3-26-.07(84)(b) in accordance with 420-3-26-.07(117).

(85) **Radiation Surveys.**

(a) In addition to the survey requirements in 420-3-26-.03 of these regulations, a person licensed pursuant to this rule shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by 420-3-26-.07(85)(a) at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph(a) of this section in accordance with 420-3-26-.07(118).

(86) **Full Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Agency, an Agreement State or the U.S. Nuclear Regulatory Commission.

(c) A licensee shall keep a record of the inspection and servicing in accordance with 420-3-26-.07(119).

(87) **Therapy-Related Computer Systems.** The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine radioactive source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(88) **Possession of Survey Instruments.**

A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of 1 microsievert (0.1 millirem) per hour to 500 microsieverts (50 millirems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 millirem) per hour to 10 millisieverts (1000 millirems) per hour. The instruments shall be operable and calibrated in accordance with 420-3-26-.07(33).

(89) **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units.** Except as provided in 420-3-26-.07(29), the licensee shall require an authorized user of a sealed source for a use authorized under 420-3-26-.07(72) to be a physician who:

(a) Is certified by a medical specialty board whose certification process has been recognized by the Agency, the U.S. Nuclear Regulatory Commission or an Agreement State and who meets the requirements in 420-3-26-.07(89)(c). The names of board certifications that have been recognized by the Agency, the U.S. Nuclear Regulatory Commission, or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical

Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or

(b)1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

(i) 200 hours of classroom and laboratory training in the following areas:

(I) Radiation physics and instrumentation;

(II) Radiation protection;

(III) Mathematics pertaining to the use and measurement of radioactivity; and

(IV) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(89), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements at a medical facility that is authorized to use radioactive material in 420-3-26-.07(72), involving:

(I) Reviewing full calibration measurements and periodic spot-checks;

(II) Preparing treatment plans and calculating treatment doses and times;

(III) Using administrative controls to prevent a misadministration involving the use of radioactive material;

(IV) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(V) Checking and using survey meters; and

(VI) Selecting the proper dose and how it is to be administered; and

2. Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(89), or equivalent

U.S. Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph 420-3-26-.07(89)(b)1.(ii); and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs 420-3-26-.07(89)(b)1., (b)2., and (c), and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be obtained from either:

(i) A preceptor authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(89), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; or

(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in 420-3-26-.07(29), 420-3-26-.07(89), or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (b)1 and (b)2 of this section.

(c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

Other Medical Uses of Radioactive Material or Radiation from Radioactive Material

(90) **Other Medical Uses of Radioactive Material or Radiation From Radioactive Material.** A licensee may use radioactive material or a

radiation source approved for medical use that is not specifically addressed in this rule if:

(a) The applicant or licensee has submitted the information required by 420-3-26-.07(8)(b), 420-3-26-.07(8)(c) and 420-3-26-.07(8)(d); and

(b) The applicant or licensee has received written approval from the Agency in a license and uses the material in accordance with the regulations and specific conditions the Agency considers necessary for the medical use of the material.

Records

(91) **Records of Authority and Responsibilities for Radiation Protection Programs.**

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with 420-3-26-.07(19)(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by 420-3-26-.07(19)(d), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by 420-3-26-.07(19)(b). The record must include the signature of the Radiation Safety Officer and licensee management.

(c) For each Associate Radiation Safety Officer appointed under 420-3-26-.07(19)(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

(d) The minutes of each Radiation Safety Committee meeting held in accordance with 420-3-26-.07(19)(g) shall include:

1. The date of the meeting;

2. Members present;

3. Members absent; and

4. Summary of deliberations and discussions.

(92) **Records of Radiation Protection Program Safety Changes.** A licensee shall retain a record of each radiation protection program change made in accordance with 420-3-26-.07(20)(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

(93) **Records of Written Directives.** A licensee shall retain a copy of each written directive as required by 420-3-26-.07(23) for 3 years.

(94) **Records of Misadministrations.** A licensee shall retain a record of misadministrations reported in accordance with 420-3-26-.07(120) for 3 years. The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(95) **Record of a Dose to an Embryo/Fetus or a Nursing Child.** A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with 420-3-26-.07(121) for 3 years. The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

(96) **Records of Calibrations of Instruments Used to Measure the Activity of Unsealed Radioactive Material.** A licensee shall maintain a record of instrument tests required by 420-3-26-.07(32) for 3 years. The records must include the model and serial number of the instrument, the date of the test, the results of the test, and the name of the individual who performed the test.

(97) **Records of Survey Instrument Calibrations.** A licensee shall maintain a record of survey instrument calibrations required by 420-3-26-.07(33) for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

(98) **Records of Dosages of Unsealed Radioactive Material for Medical Use.** A licensee shall maintain a record of dosage determinations required by 420-3-26-.07(34) for 3 years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30

microcuries); the date and time of the dosage determination; and the name of the individual who determined the dosage.

(99) **Records of Possession of Sealed Sources and Brachytherapy Sources.** A licensee shall retain a record of the semi-annual physical inventory of sealed sources and brachytherapy sources required by 420-3-26-.07(36)(d) for 3 years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

(100) **Records of Surveys for Ambient Radiation Exposure Rate.** A licensee shall retain a record of each survey required by 420-3-26-.07(40) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(101) **Records of the Release of Individuals Containing Radioactive Drugs or Implants Containing Radioactive Material.**

(a) A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual, for 3 years after the date of release.

(b) A licensee shall retain a record, for 3 years after the date of release, that the instructions required by 420-3-26-.07(41)(b) were provided to a breast-feeding woman.

(102) **Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services.**

(a) A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client’s address of use, as required by 420-3-26-.07(9)(b), for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by 420-3-26-.07(42)(f) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

(103) **Records of Decay-in-Storage.** A licensee shall maintain records of the disposal of licensed materials, as required by 420-3-26-.07(44), for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

(104) **Records of Radionuclide Purity.** A licensee shall maintain a record of the radionuclide contaminant concentration tests required by 420-3-26-.07(49) for 3 years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as microcuries of contaminant per millicurie of desired radionuclide (kilobecquerel/megabecquerel), or microgram of contaminant per millicurie of desired radionuclide (microgram/megabecquerel), the time and date of the measurement, and the name of the individual who made the measurement.

(105) **Records of Safety Instruction and Training.** A licensee shall maintain a record of safety instructions and training required by 420-3-26-.07(53), 420-3-26-.07(63), and operational and safety instruction required by 420-3-26-.07(75) for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

(106) **Records of Radiation Surveys of Patients and Human Research Subjects.** A licensee shall maintain a record of the surveys required by 420-3-26-.07(61) and 420-3-26-.07(73) for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

(107) **Records of Brachytherapy Source Inventory.**

(a) A licensee shall maintain a record of brachytherapy source accountability required by 420-32-6-.07(62) for 3 years.

(b) For temporary implants, the record must include:

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

2. The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage.

(c) For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

2. The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

3. The number and activity of sources permanently implanted in the patient or human research subject.

(108) **Records of Calibration Measurements on Brachytherapy Sources.** A licensee shall maintain a record of the calibrations on brachytherapy sources required by 420-3-26-.07(65) for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist.

(109) **Records of Decay of Strontium-90 Sources for Ophthalmic Treatments.** The licensee shall maintain a record of the activity of a strontium-90 source required by 420-3-26-.07(65) for the life of the source. The record must include the date and initial activity of the source as determined under 420-3-26-.07(65), and for each decay calculation, the date, the source activity and the signature of the authorized medical physicist.

(110) **Records of Installation, Maintenance, Adjustment, and Repair of Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units.** A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by 420-3-26-.07(74) for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

(111) **Records of Safety Procedures.** A licensee shall retain a copy of the procedures required by 420-3-26-.07(75)(a)4. and 420-3-26-.07(75)(d)2. until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

(112) **Records of Dosimetry Equipment.**

(a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with 420-3-26-.07(77) for the duration of the license.

(b) For each calibration, intercomparison, or comparison, the record must include:

1. The date;

2. The manufacturer’s name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by 420-3-26-.07(77)(a) and (b);

3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

4. The names of the individuals who performed the calibration, intercomparison, or comparison.

(113) **Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations.**

(a) A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by 420-3-26-.07(78), 420-3-26-.07(79) and 420-3-26-.07(80) for 3 years.

(b) The record must include:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

3. The results and assessments of the full calibrations;

4. The results of the autoradiograph required for low dose-rate remote afterloader units; and

5. The signature of the authorized medical physicist who performed the full calibration.

(114) **Records of Periodic Spot-Checks for Teletherapy Units.**

(a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by 420-3-26-.07(81) for 3 years.

(b) The record must include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

3. An assessment of timer linearity and constancy;

4. The calculated on-off error;

5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

6. The determined accuracy of each distance measuring and localization device;

7. The difference between the anticipated output and the measured output;

8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(115) **Records of Periodic Spot-Checks for Remote Afterloader Units.**

(a) A licensee shall retain a record of each spot-check for remote afterloader units required by 420-3-26-.07(82) for 3 years.

(b) The record must include, as applicable:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

3. An assessment of timer accuracy;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit’s computer; and

5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(116) **Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units.**

(a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by 420-3-26-.07(83) for 3 years.

(b) The record must include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

3. An assessment of timer linearity and accuracy;

4. The calculated on-off error;

5. A determination of trunnion centricity;

6. The difference between the anticipated output and the measured output;

7. An assessment of source output against computer calculations;

8. Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(117) **Records of Additional Technical Requirements for Mobile Remote Afterloader Units.**

(a) A licensee shall retain a record of each check for mobile remote afterloader units required by 420-3-26-.07(84) for 3 years.

(b) The record must include:

1. The date of the check;

2. The manufacturer's name, model number, and serial number of the remote afterloader unit;

3. Notations accounting for all sources before the licensee departs from a facility;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

5. The signature of the individual who performed the check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

(118) **Records of Surveys of Therapeutic Treatment Units.**

(a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with 420-3-26-.07(85) for the duration of use of the unit.

(b) The record must include:

1. The date of the measurements;

2. The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels;

3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

4. The signature of the individual who performed the test.

(119) **Records of Full Inspection Servicing for Teletherapy and Gamma Stereotactic Surgery Units.**

(a) A licensee shall maintain a record of the full inspections servicing for teletherapy and gamma stereotactic radiosurgery units required by 420-3-26-.07(86) for the duration of use of the unit.

(b) The record must contain:

1. The inspector's radioactive materials license number;

2. The date of inspection;

3. The manufacturer's name and model number and serial number of both the treatment unit and source;

4. A list of components inspected and serviced, and the type of service; and

5. The signature of the inspector.

Reports

(120) **Reports and Notifications of Misadministrations.**

(a) Other than events that result from intervention by a patient or human research subject, a licensee shall report any event in which the administration of radioactive material or radiation from radioactive material results in:

1. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dose by more than 5 millisieverts (500 millirem) effective dose equivalent, 0.05 sieverts (5 rem) to an organ or tissue, or 0.05 sieverts (5 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

2. A dose that exceeds 5 millisieverts (500 millirem) effective dose equivalent, 0.05 sieverts (5 rem) to an organ or tissue, or 0.05 sieverts (5 rem) shallow dose equivalent to the skin from any of the following:

(i) An administration of a wrong radioactive drug or the wrong radionuclide for a brachytherapy procedure;

(ii) An administration of a radioactive drug containing radioactive material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

3. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

(i) 0.05 sieverts (5 rem) or more than the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

(ii) 50 percent or more than the dose expected to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

4. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive; or

(ii) The total source strength administered outside the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or

(iii) An administration that includes any of the following:

(I) The wrong radionuclide;

(II) The wrong individual or human research subject;

(III) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

(IV) A leaking sealed source resulting in a dose that exceeds 0.05 Sv (5 rem) to an organ or tissues

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify the Agency by telephone no later than the next calendar day after discovery of the misadministration.

(d) The licensee shall submit a written report to the Agency within 15 days after discovery of the misadministration.

1. The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) Actions, if any, that have been taken, or are planned, to prevent recurrence;

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2. The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform

the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

1. Retain a record of a misadministration in accordance with 420-3-26-.07(94).

2. Annotate a copy of the report provided to the Agency with the:

(i) Name of the individual subject to the misadministration; and

(ii) Identification number or if no other number is available, the social security number of the individual subject to the misadministration;

3. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after discovery of the misadministration.

(121) **Report and Notification of a Dose to an Embryo/Fetus or a Nursing Child.**

(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 millisieverts (500 millirem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

(b) A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user,

that is a result of an administration of radioactive material to a breast feeding individual that:

1. Is greater than 5 millisieverts (500 millirem) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

(c) The licensee shall notify by telephone the Agency no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in 420-3-26-.07(121)(a) or (b).

(d) The licensee shall submit a written report to the Agency within 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in 420-3-26-.07(121)(a) or (b).

1. The written report must include:

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the embryo/fetus or the nursing child;

(vi) What actions, if any, have been taken, or are planned, to prevent recurrence; and

(vii) Certification that the licensee notified the pregnant individual or mother (or the mother’s or child’s responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child’s name or any other information that could lead to identification of the individual or child.

(e) The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under 420-3-26-.07(121) (a) or (b), unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful. The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the

licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) A licensee shall:

1. Retain a record of a dose to an embryo/fetus or a nursing child in accordance with 420-3-26-.07(95).

2. Annotate a copy of the report provided to the Agency with the:

(i) Name of the pregnant individual or the nursing child that is subject to the event; and

(ii) Identification number or if no other identification number is available, the social security number of the individual who is subject to the event; and

3. Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

(122) R**eports of Leaking Sources.** A licensee shall file a report with the Agency within 5 days if a leakage test required by 420-3-26-.07(36) reveals the presence of 185 becquerel (0.005 microcuries) or more of removable contamination. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

(123) **Reports of Patient Departure Prior to Authorized Release.**

(a) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject has departed from the licensee's facility without authorization under 420-3-26-.07(41)(a).

(b) The licensee shall submit a written report to the Agency within 30 days after discovery of the unauthorized departure. The written report must include:

1. The licensee's name;

2. The date and time of the unauthorized departure;

3. The projected date and time when release would have occurred;

4. The address of the patient's or human research subject's home or anticipated destination following departure;

5. The radionuclide, chemical and physical form and calculated activity at time of departure;

6. The apparent reason(s) for the departure prior to authorized release; and

7. A description of any changes in the licensee's patient release criteria or patient instructions that are designed to avoid a recurrence of such an event.

(124) **Notification of Deceased Patients or Human Research Subjects Containing Radioactive Material.**

(a) The licensee shall notify the Agency by telephone immediately upon discovery that a patient or human research subject containing radioactive material has died, and it is possible that any individual could receive exposures in excess of 5 millisieverts (500 millirem) as a result of the deceased's body.

(b) The licensee shall submit a written report to the Agency within 30 days after discovery that the patient or human research subject referenced in 420-3-26-.07(124)(a) has died. The written report must include:

1. The licensee's name;

2. The date of death;

3. The radionuclide, chemical and physical form and calculated activity at time of death; and,

4. The names (or titles) and address(es) of known individuals who might have received exposures exceeding 5 millisieverts (500 millirem).

(125) **Report and Notification for an Eluate Exceeding Permissible Molybdenum- 99, Strontium-82, and Strontium-85 Concentrations**.

(a) The licensee shall notify by telephone the Agency and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in 420-3-26-.07(49)(a) at the time of generator elution. The telephone report to the Agency must include the manufacturer model number, and serial number (or lot number) of the generator the results of the measurement; the date of the measurement; whether dosages were administered to patients of human research

subjects; when the distributor was notified; and the action plan taken.

(b) The licensee shall submit a written report to the Agency within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures, or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section.
Author: Karl David Walter; David A. Turberville
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, as amended.
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420-3-26-.08 The Registration Of Particle Accelerators.

(1) **Purpose.** This Rule, 420-3-26-.08, provides for the registration of particle accelerators.

(2) **Scope.** No person shall receive, possess, use, transfer, own, operate, or acquire a particle accelerator except as authorized in a Notice of Registration or as otherwise provided for in this Rule, 420-3-26-.08.

(3) **Definitions.** As used in this Rule, 420-3-26-.08:

(a) "Act" means Act No. 582, Alabama Law, Regular Session, 1963, codified as 22-14-1, Code of Ala. 1975.

(b) "Agency" means the State Board of Health.

(c) "Authorized medical physicist" means an individual who:

1. Meets the requirements in 420-3-26-.08(10)(a)3. and 4. or, is identified as an authorized medical physicist on an Agreement State or Licensing State accelerator registration that authorizes the medical use of accelerators; and

2. Is identified as an authorized medical physicist on a medical use accelerator registration issued by the Agency.

(d) "Authorized user" means a physician who:

1. Meets the requirements in 420-3-26-.08(10)(a)2. and 4. or is identified as an authorized user on an Agreement State or Licensing State registration that authorizes the medical use of accelerators; and

2. Is identified as an authorized user on a medical use accelerator registration issued by the Agency.

(e) "Industrial Radiography" means the examination of the macroscopic structure of materials by nondestructive methods utilizing a particle accelerator.

(4) **Registration Procedures.** No registration shall be complete or valid until the person applying for registration has received a written Notice of Registration which shall be issued by the Agency in accordance with this Rule, 420-3-26-.08, or is exempted from such requirement by this Rule, 420- 3-26-.08.

(5) **Notice of Registration-Exemptions.** A Notice of Registration is not required:

(a) To transfer, own, receive, acquire, or possess a particle accelerator when such devices are in storage or disassembled, or otherwise incapable of intentional or accidental operation. Each person receiving such particle accelerator shall, within thirty (30) days after the receipt of the particle accelerator, notify the Agency of the type of particle accelerator and the name and address of the person supplying the particle accelerator.

(b) For electrical equipment that is not primarily intended to produce radiation and does not produce a radiation level greater than 0.5 mrem per hour at any readily accessible point 5 centimeters from the surface. Such equipment shall not be exempt if it is used or handled in such a manner that any individual might receive a radiation dose exceeding the limits specified in these rules.

(6) **Transfer of Particle Accelerators.** Any person transferring a particle accelerator shall, within thirty (30) days after the end of the calendar quarter in which any particle accelerator is transferred, notify the Agency of the type of particle accelerator and the name and address of the person to whom the particle accelerator was supplied.

(7) **Filing of Application for Notice of Registration.**

(a) Application for a Notice of Registration shall be filed on a form prescribed by the Agency.

(b) The Agency may at any time after the filing of the original application, and before the expiration of the Notice of Registration, require further statements in order to enable the Agency to determine whether the application should be granted or denied, or whether the Notice of Registration should be modified or revoked.

(c) Each application shall be signed by the applicant or registrant or a person duly authorized to act for and on his behalf.

(d) An application for a Notice of Registration may include a request for the registration of one or more activities.

(e) Applications and documents submitted to the Agency may be made available for public inspection except that the Agency may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

(8) **Application for Amendments to Notices of Registration.** In addition to the requirements specified in 420-3-26-.08(15), a registrant shall apply for, and shall receive, an amendment before:

(a) Making any change in the accelerator room shielding;

(b) Making any change in the location of the Particle Accelerator within the accelerator room;

(c) Using the Particle Accelerator in a manner that could result in increased radiation levels in areas outside the accelerator room;

(d) Relocating the Particle Accelerator;

(e) Allowing an individual who is not a visiting medical physicist pursuant to 420-3-26-.09(8)(h) or is not listed on the Notice of Registration to perform the duties of a medical physicist; or

(f) Allowing any physician who is not a visiting authorized user pursuant to 420-3-26-.09(8)(k) or is not listed on the Notice of Registration to prescribe radiation treatments for humans.

(9) **General Requirements for the Issuance of a Notice of Registration.** A registration application will be approved if the Agency determines that:

(a) The applicant is qualified by reason of training and experience to use the particle accelerator and any associated radioactive material[25] for the purpose requested, in accordance with these rules, in such a manner as to minimize danger to public health and safety or property;

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[25] See Rule 420-3-26-.02 for the licensing of such radioactive material.

(b) The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

(c) The issuance of the Notice of Registration will not be harmful to the health and safety of the public;

(d) The applicant has appointed a radiation safety officer who will advise and assist on radiological safety problems;

(e) The applicant and the applicant's staff have substantial experience in the use of particle accelerators;

(f) The applicant has an adequate training program for operators of particle accelerators;

(g) The applicant has established and submits to the Agency satisfactory written operating and emergency procedures; and

(h) The applicant satisfies any applicable special requirements in this Rule, 420-3-26-.08.

(10) **Special Requirements for Issuance of a Notice of Registration for Particle Accelerators.**

(a) Human Use. In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for human use of a particle accelerator in the practice of medicine will be issued only if:

1. The applicant has access to adequate facilities for the clinical care of patients.

2. The registrant requires the authorized user to be a physician who:

(i) Is certified in:

(I) Radiation oncology or therapeutic radiology by the American Board of Radiology or Radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology prior to 1976; or

(II) Radiation oncology by the American Osteopathic Board of Radiology; or

(III) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology;" or

(IV) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(ii) Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five-hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

(I) To satisfy the requirement for instruction, the classroom and laboratory training shall include:

I. Radiation physics and instrumentation;

II. Radiation protection;

III. Mathematics pertaining to the use and measurement of ionization radiation; and

IV. Radiation biology.

(II) To satisfy the requirement for supervised work experience, training shall be under the supervision of an authorized user and shall include:

I. Review of the full calibration measurements and periodic quality assurance checks;

II. Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;

III. Using administrative controls to prevent misadministrations;

IV. Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

V. Checking and using radiation survey meters.

(III) To satisfy the requirement for a period of supervised clinical experience, training shall include one (1) year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the

supervision of an authorized user. The supervised clinical experience shall include:

I. Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/ contraindications;

II. Selecting proper dose and how it is to be administered;

III. Calculating the therapeutic radiation machine doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by patients' reaction to radiation; and

IV. Post-administration follow-up and review of case histories.

(iii) A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Agency.

3. The applicant has designated a medical physicist on the application. The registrant for any therapeutic radiation machine subject to 420-3-26-.08(10) shall require the Medical Physicist to:

(i) Be certified by the American Board of Radiology in:

(I) Therapeutic radiological physics; or

(II) Roentgen-ray and gamma-ray physics; or

(III) X-ray and radium physics; or

(IV) Radiological physics; or

(ii) Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

(iii) Be certified by the Canadian College of Medical Physics; or

(iv) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and have completed one (1) year of full time training in medical physics and an additional year of full-time work experience under the supervision of an Authorized Medical Physicist. This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). To meet this requirement, the individual shall have performed the tasks listed in 420-3-26-.09(8)(d)(g) and (i)

under the supervision of an Authorized Medical Physicist during the year of work experience.

4. The training and experience specified in this rule must have been obtained within the seven (7) years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

5. Visiting Authorized User.

(i) A registrant may permit a physician to act as a visiting authorized user of a particle accelerator in the practice of medicine under the terms and conditions of the registrant's registration for 60 days each calendar year if:

(I) The visiting authorized user has the prior written permission of the registrant's management, and the Radiation Safety Committee if a committee is required;

(II) The registrant has a copy of an Agency registration that identifies the visiting authorized user, by name, as an authorized user of a particle accelerator in the practice of medicine; and

(III) The visiting authorized user performs only those procedures:

I. For which they are specifically authorized to perform on an Agency registration; and,

II. Which are specifically approved on the registrant's registration.

(ii) A registrant need not apply for a registration amendment in order to permit a visiting authorized user to use a particle accelerator in the practice of medicine.

(iii) A registrant shall retain copies of the records specified in 420-3-26-.08(10)(a)5.(i) for 3 years from the date of the last visit.

6. Visiting Authorized Medical Physicist.

(i) A registrant may permit a medical physicist to act as a visiting authorized medical physicist and perform the duties of a medical physicist under the terms and conditions of the registrant's registration for 60 days each calendar year if:

(I). The visiting authorized medical physicist has the prior written permission of the registrant's management, and the radiation safety committee if a committee is required; and,

(II) The registrant has a copy of an Agency registration that identifies the visiting authorized medical physicist, by name, as an authorized medical physicist.

(ii) A registrant need not apply for a registration amendment in order to permit a visiting authorized medical physicist to perform registered duties as described in 420-3-26-.09.

(iii) A registrant shall retain copies of the records specified in 420-3-26-.08(10)(a)6.(i) for 3 years from the date of the last visit.

(b) Research and Development. In addition to the requirements of 420-3-26-.08(9) above, a Notice of Registration for the use of a particle accelerator in research and development will be issued only if:

1. The applicant's staff has substantial experience in the use of particle accelerators for a variety of research and development uses;

2. The applicant has established a radiation safety committee (composed of such persons as a radiation safety officer, one or more persons trained or experienced in the safe use of particle accelerators, and a representative of management or the administration) which will review and approve, in advance, proposals for research, diagnostic, and therapeutic uses.

(c) Industrial Radiography. In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for use of a particle accelerator in industrial radiography will be issued only if;

1. The licensee or registrant does not permit any individual to act as a radiographer using a particle accelerator until the individual has received at least 40 hours of training in the subjects outlined in 420-3-26-.08(10)(e)7., in addition to on the job training consisting of hands-on experience under the supervision of a radiographer, is certified through a radiographer certification program by a certifying entity in accordance with the criteria specified in Appendix A of Rule 420-3-26-.04, and has on their person a valid certification ID card issued by a certifying entity. The on the job training shall include a minimum of 160 hours of active participation in the performance of industrial radiography utilizing radiation machines.

2. In addition, the registrant may not permit any individual to act as a radiographer until the individual:

(i) Has received copies of and instruction in the requirements described in the applicable sections of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, 420-3-26-.08, 420-3-26-.09 and 420-3-26-.10, in the registration under which the

radiographer will perform industrial radiography, and the registrant’s operating and emergency procedures;

(ii) Has demonstrated an understanding of items in 420-3-26-.08(10)(e)2.(i) by successful completion of a written or oral examination;

(iii) Has received training in the use of the registrant's radiation machines, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(iv) Has demonstrated understanding of the use of the equipment described in 420-3-26-.08(10)(e)2.(iii)by successful completion of a practical examination.

3. The registrant may not permit any individual to act as a radiographer's assistant until the individual:

(i) Has received copies of and instruction in the applicable sections of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.04, 420-3-26-.08, 420-3-26-.09 and 420-3-26-.10, in the registration under which the radiographer's assistant will perform industrial radiography, and the registrant's operating and emergency procedures;

(ii) Has demonstrated an understanding of items in 420-3-26-.08(10)(e)3.(i) by successful completion of a written or oral examination;

(iii) Under the personal supervision of a radiographer, has received training in the use of the registrant's radiation machines, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments; and

(iv). Has demonstrated understanding of the use of the equipment described in 420-3-26-.08(10)(e)3.(iii) by successful completion of a practical examination.

4. The registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed 12 months.

5. Except as provided in 420-3-26-.08(10)(c)5.(iv), the radiation safety officer or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Agency rules, registration requirements, and operating and emergency procedures are followed. The inspection program must:

(i) Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed 6 months; and

(ii) Provide that, if a radiographer or a radiographer's assistant has not participated in an industrial radiographic operation for more than 6 months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of 420-3-26-.08(10)(e)2.(i) and the radiographer's assistant must demonstrate knowledge of the training requirements of 420-3-26-.08(10)(e)3.(i) by a practical examination before these individuals can next participate in a radiographic operation.

(iii) The Agency may consider alternatives in those situations where the individual serves as both radiographer and radiation safety officer.

(iv) In those operations where a single individual serves as both radiographer and radiation safety officer, and performs all radiography operations, an inspection program is not required.

6. The registrant shall maintain records of the required training to include certification documents, written, oral and practical examinations, refresher safety training and inspections of job performance for three (3) years following termination of employment.

7. The registrant shall include the following subjects in their forty (40) hour training program:

(i) Fundamentals of radiation safety including:

(I) Characteristics of gamma and x-radiation;

(II) Units of radiation dose;

(III) Hazards of exposure to radiation;

(IV) Levels of radiation from sources of radiation; and

(V) Methods of controlling radiation dose (time, distance, and shielding);

(ii) Radiation detection instruments including:

(I) Use, operation, calibration, and limitations of radiation survey instruments;

(II) Survey techniques; and

(III) Use of personnel monitoring equipment;

(iii) Equipment to be used including:

(I) Operation and control of radiation machines; and

(II) Inspection and maintenance of equipment.

(iv) The requirements of pertinent state and federal regulations; and

(v) Case histories of accidents in radiography.

8. The applicant has established and submits to the Agency satisfactory written operating and emergency procedures as described in 420-3-26-.04(17); and,

9. The applicant submits to the Agency a description of his overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program.

(d) Production of Radioactive Materials.[26] In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for the production of multiple quantities or types of radioactive materials by a particle accelerator will be issued only if:

1. The applicant's staff has substantial experience in the use of particle accelerators to produce a variety of radioactive materials;

2. The applicant has an adequate training program for particle accelerator operators consisting of;

(i) Initial training;

(ii) Periodic training;

(iii) On-the-job training; and

(iv) A means to be used by the applicant to determine the operator's knowledge and understanding of and ability to comply with or use:

I. Agency rules;

_____

[26] See Rule 420-3-26-.02 for the licensing requirements for the possession of such radioactive materials.

II. Applicant's operating and emergency procedures;

III. Survey instruments as required by these rules; and,

IV. Personnel monitoring equipment:

3. The applicant has an adequate training program for staff personnel for possession and use of radioactive materials produced by the accelerator.

(e) Modification of the Structure, Chemical Composition, or Bacterial Composition of Materials. In addition to the requirements set forth in 420-3-26-.08(9) above, a Notice of Registration for the modification of the structure, chemical composition, or bacterial composition of materials by a particle accelerator will be issued only if:

1. The applicant's staff has substantial experience in the modification of materials;

2. The applicant has an adequate training program for the training of the particle accelerator operators consisting of:

(i) Initial training;

(ii) Periodic training;

(iii) On-the-job training;

(iv) A means of determining the operator's knowledge and understanding of and ability to comply with or use:

I. Agency rules;

II. The applicant's operating and emergency procedures;

III. Survey instruments as required by these rules; and

IV. Personnel monitoring equipment.

(10) **Issuance of a Notification of Registration.**

(a) Upon a determination that an application meets the requirements of the Act and the rules of the Agency, the Agency will issue a Notice of Registration authorizing the proposed activity.

(b) The Agency may incorporate in any Notice of Registration at the time of issuance, or thereafter by appropriate rule, regulation, or order, such additional requirements with respect to the registrant's particle accelerator subject to the Rule 420-3-26-.08 as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property;

2. Require the maintenance of specific records and the reporting of specific information to the Agency; and

3. Require necessary inspections, calibrations and output checks.

(12) **Specific Terms and Conditions of the Notice of Registration.**

(a) Each Notice of Registration issued pursuant to this Rule 420-3-26-.08 shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules, regulations, and orders of the Agency.

(b) Each person registered by the Agency pursuant to this Rule 420-3-26-.08 shall confine his use and possession of the particle accelerator registered to the locations and purposes authorized in the Notice of Registration.

(13) **Expiration of Registration.** Except as provided in 420-3-26-.08(14)(b), each Notice of Registration shall expire at the end of the day, in the month and year stated therein.

(14) **Renewal of Registration.**

(a) Applications for renewal of a Notice of Registration shall be filed in accordance with 420-3-26-.08(7).

(b) In any case in which a registrant, not less than thirty (30) days prior to expiration of his existing Notice of Registration, has filed an application in proper form for renewal or for a new Notice of Registration authorizing the same activities, such existing Notice of Registration shall not expire until the application has been finally determined by the Agency.

(15) **Amendment of Notice of Registration at Request of Registrant.** Applications for amendment of a Notice of Registration shall be filed in accordance with 420-3-26-.08(8) and shall specify the respects in which the registrant desires his Notice of Registration to be amended and the grounds for such amendment.

(16) **Agency Action on Application to Renew or Amend.** In considering an application by a registrant to renew or amend his Notice of Registration, the Agency will apply the criteria set forth in 420-3-26-.08(9), and 420-3-26-.08(10) as applicable.

(17) **Inalienability of Notice of Registration.** No Notice of Registration issued or granted under this Rule and no right to utilize a particle accelerator granted by any Notice of Registration issued pursuant to this Rule shall be transferred, assigned, or in any manner disposed of, either voluntarily, directly, or indirectly, through transfer of control of any Notice of Registration to any persons unless the agency shall, after securing full information find that the transfer is in accordance with the provisions of the act, and shall give its consent in writing.

(18) **Modification, Revocation, and Termination of a Notice of Registration.**

(a) A Notice of Registration shall be subject to amendment, revision, or modification or the Notice of Registration may be suspended or revoked by reason of amendments to the Act, or by reason of rule, regulations, or orders issued by the Agency.

(b) Any Notice of Registration may be revoked, suspended, modified in whole or part, for any material false statement in the application, or any statement of fact required under provisions of the Act, or because of conditions revealed by the application, or any statement of fact, or by any report, records, or inspection or other means, such that said conditions which would warrant the Agency to refuse to grant a Notice of Registration on an original application, or for violation of, or failure to observe any of, the terms and conditions of the Act, or the Notice of Registration, or of any rule, regulation, or order of the Agency.

(c) Except in cases of willfulness, or those in which the public health, interest or safety requires otherwise, no Notice of Registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

(d) The Agency may terminate a Notice of Registration upon request submitted by the registrant to the Agency in writing.
Author: Karl David Walter
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, 22-14-14, also 22-2-1, 22-2-2, 22-2-5, 22-2-6.
History: New March 18, 1970. Repromulgated August 21, 1974; Revised January 18, 1978. **Recodified** June 11 1978. Revised and Repromulgated October 21, 1981. Repromulgated effective December 31, 1983. Revised and Repromulgated effective January 31, 1990. **Amended:** Filed December 20, 1996; effective January 24, 1997. **Repealed and New Rule:** Filed October 20, 2014; effective November 24, 2014; operative December 1, 2014.

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420-3-26-.09 Radiation Safety Requirements For Users Of Particle Accelerators.

(1) **Scope.** Rule 420-3-26-.03 establishes standards for the use of all radiation sources. The provisions of this Rule 420- 3-26-.09 are in addition to, and not in substitution for, other applicable provisions of these rules.

(2) **Definitions.**

(a) "Absorbed dose (D)" means the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

(b) "Absorbed dose rate" means absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

(c) “Accelerator” means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. For purposes of this definition, “particle accelerator”, “linear accelerator” and “cyclotron” are equivalent terms.

(d) “Agency” means the Alabama State Board of Health.

(e) "Air kerma (K)" means the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

(f) “Authorized medical physicist” means an individual who meets the requirements of Rule 420-3-26-.08(10)(a)3. and 4.

(g) “Authorized user” means a practitioner of the healing arts who meets the requirements of Rule 420-3-26-.08(10)(a)2.and 4.

(h) "Barrier" see "Protective barrier."

(i) “Beam scatter filter” means a filter used in order to scatter a beam of electrons.

(j) “Central axis of the beam” means a line passing through the virtual source and the center of the plane figure formed by the edge of the first beam limiting device.

(k) “Dose monitoring system” means a system of devices for the detection, measurement, and display of quantities of radiation.

(l) “Dose monitor unit” means a unit response from the dose monitoring system from which the absorbed dose can be calculated.

(m) “Emergency procedures” means the written preplanned steps to be taken in the event of, or the potential for actual or suspected, unplanned exposure of individuals to radiation. This

procedure should include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring device.

(n) "Field size" means the dimensions along the major axes of an area in a plane perpendicular to the specified direction of the beam of incident radiation at the normal treatment distance, and defined by the intersection of the major axes and the 50 percent isodose line. Material shall be placed in the beam such that dose maximum is produced at the normal treatment distance when field size is being determined.

(o) "Gantry" means that part of the system supporting and allowing possible movements of the radiation head.

(p) "Half-value layer (HVL)" means the thickness of a specified material which attenuates X-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

(q) "High Radiation Area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour at thirty (30) centimeters from the radiation source or from any surface that the radiation penetrates.

(r) "Intensity Modulated Radiation Therapy (IMRT)" means radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

(s) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

(t) "Interruption of Irradiation" means the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

(u) "Irradiation" means the exposure of a living being or matter to ionizing radiation.

(v) "Isocenter" means a fixed point in space located at the center of the smallest sphere through which the central axis of the beams passes in all conditions.

(w) "Kilovolt (kV) [kilo electron volt (keV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum.

(x) "Leakage radiation" means radiation emanating from the radiation therapy system except for the useful beam.

(y) "Light field" means the area illuminated by light, simulating the radiation field.

(z) "mA" means milliampere.

(aa) "Megavolt (MV) [mega electron volt (MeV)]" means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum.

(bb) “Misadministration” means the administration of a Therapeutic Particle Accelerator Dose:

1. Involving the wrong patient, wrong treatment modality or wrong treatment site; or

2. When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent (30%); or

3. When the calculated total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose.

(cc) “Moving beam radiation therapy” means radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

(dd) "Nominal treatment distance" means:

1. for electron irradiation, the distance from the scattering foil, virtual source or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

2. for x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

(ee) “Operating procedures” means detailed written instructions including, but not limited to, the normal operation of movable shielding, closing of interlock circuits, manipulation of accelerator controls, radiation monitoring procedures, wearing of dosimeters, testing of interlocks, and record keeping requirements.

(ff) "Operator" means a person qualified by training and experience to assume responsibility for the safe operation of a particle accelerator.

(gg) "Periodic quality assurance check" means a procedure which is performed to ensure that a previous parameter or condition continues to be valid.

(hh) "Personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received such as film badges and pocket dosimeters.

(ii) "Phantom" means an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

(jj) "Prescribed dose" means the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

(kk) "Primary dose monitoring system" means a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitoring units have been delivered.

(ll) "Protective Barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1. "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

2. "Secondary protective barrier" means the material which attenuates stray radiation.

(mm) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (5 millirems) (0.05 mSv) in one (1) hour at 30 centimeters from the radiation source or from the surface that the radiation penetrates.

(nn) "Radiation head" means the structure from which the useful beam emerges.

(oo) "Radiographer" means any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the registrant for assuring compliance with the

requirements of these rules and all conditions of the registration.

(pp) "Redundant beam monitoring system" means a combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

(qq) "Scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

(rr) "Secondary dose monitoring system" means a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

(ss) "Shadow tray" means a device attached to the radiation head to support auxiliary beam limiting material.

(tt) "Stationary beam therapy" means radiation therapy without relative displacement of the useful beam and the patient during irradiation.

(uu) "Target" means that part of a radiation head which, by design, intercepts a beam of accelerated particles with subsequent emission of other radiation.

(vv) "Termination of irradiation" means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(ww) "Useful Beam" means the radiation emanating from the tube housing port or the radiation head and passing though the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic machine to produce radiation.

(xx) "Visiting authorized medical physicist" means a medical physicist who meets the requirements of Rule 420-3-26-.08(10)(a)6.

(yy) "Visiting authorized user" means an authorized user who meets the requirements of Rule 420-3-26-.08(10)(a)5.

(zz) "Virtual source" means a point from which radiation appears to originate.

(aaa) "Wedge filter" means a filter which effects continuous change in transmission over all or part of the useful beam.

(bbb) "Written directive" means an order in writing for the administration of radiation to a specific patient or human research subject as specified in 420-3-26-.09(8)(j).

GENERAL REQUIREMENTS

(3) **Records.** In addition to the records required elsewhere in these rules, each registrant shall maintain records of any tests or surveys required by this Rule 420-3-26-.09.

(4) **General Safety Provisions.**

(a) The Agency may waive compliance with the specific requirements of this Part by an existing machine or installation if the registrant demonstrates, to the Agency's satisfaction, achievement through other means of radiation protection equivalent to that required by these rules.

(b) Personnel Monitoring. Each registrant shall provide personnel monitoring devices which shall be calibrated for the appropriate radiations and energies of radiation produced by the particle accelerator and shall be used by:

1. Each individual who receives, or is likely to receive, a whole body dose in excess of 10 millirems per week; and,

2. Each individual who enters a high radiation area.

(c) Shielding.

1. Each installation shall be provided with such primary protective barriers and/or secondary protective barriers as are necessary to assure compliance with 420-3-26-.03(6), 420-3-26-.03(12), 420-3-26-.03(13), and 420-3-26-.03(14) of these rules. All protective barriers shall be fixed except for entrance doors or beam interceptors.

(d) Controls and Safety Devices.

1. Only the particle accelerator operator at the control panel located outside the shielded room shall be capable of turning on particle accelerator beams that are capable of producing exposure rates in excess of two (2) millirems per hour.

2. All entrances into a target room, treatment room, or other high radiation areas shall be provided with safety interlocks that shut down the machine under conditions of barrier penetration.

3. Each safety interlock shall be on a circuit which shall allow it to operate independently of all other safety interlocks.

4. When any interlock is interrupted, broken, or tripped, either the particle accelerator will shut off automatically or the

radiation level within the room will be reduced to less than two (2) millirems per hour at a distance of one (1) meter in any direction from any accessible portion of the particle accelerator system.

5. Interlocks shall not be used to routinely shut off the particle accelerator.

6. An emergency cut-off switch shall be located in all high radiation areas. This switch shall be readily identifiable. This switch shall be capable of automatically causing the particle accelerator to either shut off or reduce the radiation level to less than two (2) millirems per hour at a distance of one (1) meter in any direction from any accessible portion of the particle accelerator system. Such cut-off switch shall include a manual reset at each such switch which must be reset at the switch before the particle accelerator may be restarted by the operator at the control panel. Radiation levels produced by radioactive materials shall not be considered as the radiation levels to be reduced.

7. All locations designated as high radiation areas shall be equipped with easily observable flashing or rotating warning lights and/or audible warning devices that operate when, and only when, radiation is being produced. Each entrance to such area shall have a visual warning device, which need not be flashing or rotating, that operates when and only when radiation is being produced.

8. Except for facilities designed for human exposure, each high radiation area shall have an audible warning device which shall be activated for 15 seconds prior to the possible creation of a high radiation area. Such warning device shall be clearly discernible in all high radiation areas.

9. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be posted in accordance with 420-3-26-.03 of these rules.

10. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

11. The particle accelerator control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, make the particle accelerator incapable of producing any area in which radiation exposure is in excess of two (2) millirems per hour.

12. There shall be available at each facility, appropriate portable radiation monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced by the facility. Such equipment shall be tested for proper operation daily and calibrated for the appropriate radiations at intervals

not to exceed one (1) year and after each instrument servicing and repair.

13. There shall be present at the control panel a device which shall give a continuous indication of the radiation levels being produced in the target area or areas.

14. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems and capable of providing a readout at the control panel.

15. All area monitors shall be calibrated at intervals not to exceed one year and after each servicing and repair.

16. Electrical circuit diagrams of the accelerator and the associated interlock systems shall be kept current and maintained for inspection by the Agency and shall be available to the operator at each accelerator facility.

(e) Operation.

1. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

2. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency, or to test interlocks.

3. Interlocks may be prevented from operation only to test, adjust, maintain, and/or rearrange equipment provided a clear indication of such condition is made at the control panel. This paragraph does not authorize the operation of a particle accelerator with the high radiation area warning devices incapable of proper operation.

4. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

(i) Authorized in writing by the radiation safety committee or the radiation safety officer;

(ii) Recorded in a permanent log and a notice posted at the accelerator control console; and

(iii) Terminated as soon as possible.

5. No individual shall be permitted to enter an area, access to which is controlled by interlocks, while such interlocks are prevented from operation, to test, adjust, maintain, and/or rearrange equipment and/or parts of the particle accelerator unless such individual is utilizing appropriate personnel monitoring equipment which will give an audible indication when a

dose-rate of 25 millirem per hour is exceeded. The personnel monitoring equipment referred to in this paragraph is in addition to that required elsewhere in these rules.

(5) **Operator Training.**

(a) No registrant shall permit any person to act as an operator as defined in this Rule 420-3-26-.09 until such person;

1. Has been instructed in the subjects outlined in Appendix A of this Rule 420-3-26-.09 and shall have demonstrated understanding thereof;

2. Has received copies of and instruction in the rules contained in this Rule 420-3-26-.09 and the applicable sections of Rule 420-3-26-.03, Agency Notice of Registration and the registrant's operating and emergency procedures, and shall have demonstrated understanding thereof;

3. Has demonstrated competence to use the particle accelerators, related equipment, and survey instruments which will be employed in their assignment.

(b) Each registrant shall maintain records that document the training of each accelerator operator as required by this rule.

(c) The radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to minimize danger to public health and safety or property.

(6) **Operating and Emergency Procedures.** A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel. These operating and emergency procedures shall include instructions in at least the following:

(a) The use of particle accelerators such that no person is likely to be exposed to radiation doses in excess of the limits established in Rule 420-3-26-.03 "Standards for Protection Against Radiation";

(b) Methods and occasions for conducting radiation surveys;

(c) Methods for controlling access to high radiation areas;

(d) Methods and occasions for locking the control panel of the particle accelerators;

(e) Personnel monitoring and the use of personnel monitoring equipment;

(f) Minimizing exposure of persons in the event of an accident;

(g) The procedures for notifying proper persons in the event of an accident; and

(h) Maintenance of records.

(7) **Tests and Surveys.**

(a) All safety and warning devices, including interlocks, shall be checked for proper operation at intervals not to exceed three (3) months.

(b) A radiation protection survey shall be performed and documented by an authorized medical physicist or a qualified expert as defined in 420-3-26-.01(2)(a)79. when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

(c) Any interlock which has been bypassed or otherwise prevented from operation shall be tested to determine it is functioning properly immediately upon its return to normal use.

(d) The registrant shall retain records of the tests specified in 420-3-26-.09(7)(a), (b), and (c) for inspection by the Agency for two years.

(e) A survey shall be made of each radiation area upon initial entry by personnel into these areas following the operation of the particle accelerator. The registrant shall not be required to make a record of the survey required by this paragraph.

(8) **Therapeutic Particle Accelerator Installations.**

(a) Operation.

1. Administrative Controls. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the Agency. The registrant or the registrant's agent shall ensure that the requirements of 420-3-26-.09 are met in the operation of the therapeutic radiation machine(s).

2. No individual who receives occupational doses of radiation shall be in the room during irradiation unless he is the patient. No other individual shall be there except when it is clinically necessary.

3. Written safety procedures and rules shall be developed by an authorized medical physicist or a qualified expert and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules.

4. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

5. The operator shall have at the control panel a copy of the emergency procedures which shall include instructions for:

(i) Turning off the accelerator beam;

(ii) Removing the patient from the treatment room;

(iii) Securing the room against unauthorized entry; and

(iv) Notifying the responsible physicians and/or radiation safety officer.

6. Users of particle accelerators for the treatment of humans shall not be required to have surveys made as required by 420-3-26-.09(7)(e), provided all interlocks and warning lights are operational and functional.

(b) Equipment.

1. Possession of Survey Instrument(s). Each facility location authorized to use a therapeutic radiation machine in accordance with these rules shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range one (1) mrem (10 µSv) per hour to 1000 mrem (10 mSv) per hour.

2. Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

(i) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two (2) meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters (100 cm2) at a minimum of sixteen (16) points uniformly distributed in the plane;

(ii) Except for the area defined in Rule 420-3-26-.09(8)(b)2.(i), the absorbed dose due to leakage radiation (excluding neutrons) at one (1) meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters (100 cm2);

(iii) For equipment manufactured after **(insert effective date of this rule)**, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 (available for purchase at www.web.ansi.org); and

(iv) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in Rule 420-3-26-.09(8)(b)2. (i) through (iii) for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the facility for inspection by the Agency.

3. Stray Radiation in the Useful Beam. For equipment manufactured after the effective date of these rules, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 (available for purchase at www.web.ansi.org).

4. Leakage Radiation Through Beam Limiting Devices

(i) Photon Radiation. All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed 2 percent of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm2 radiation field, or maximum available field size if less than 100 cm2;

(ii) Electron Radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

(I) A maximum of 2 percent and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven (7) centimeters outside the periphery of the useful beam; and

(II) A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two (2) centimeters outside the periphery of the useful beam.

(iii) Measurement of Leakage Radiation.

(I) Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two (2) tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters (10 cm2);

(II) Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one (1) square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one (1) centimeter of water equivalent build up material.

5. Filters/Wedges

(i) Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

(ii) If the absorbed dose rate information required by 420-3-26-.09(8)(b)10. relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

(iii) For equipment manufactured after December 1, 2014 which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

(I) Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

(II) An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

(III) A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), and/or interchangeable beam scattering foil(s) in use; and

(IV) An interlock shall be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter and/or beam scattering foil selection operation carried out at the treatment control panel.

6. Beam Quality. The registrant shall determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met:

(i) The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table I. Linear interpolation shall be used for values not stated.

Table I

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.1
50	0.20

(ii) Compliance 420-3-26-.09(8)(b)6.(i) shall be determined using:

I. a measurement within a phantom with the incident surface of the phantom at the normal treatment distance and perpendicular to the central axis of the beam;

II. the largest field size available which does not exceed 15 by 15 centimeters; and

III. a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

(iii) The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, shall not exceed the limits stated in Table II. Linear interpolation shall be used for values not stated.

Table II

Maximum Photon Energy in MeV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

(iv) Compliance with 420-3-26-.09(8)(b)6.(iii) shall be determined by measurements made:

I. within a phantom using an instrument which will allow extrapolation to the surface absorbed dose;

II. using a phantom whose size and placement meet the requirements of 420-3-26-.09(8)(b)6.(ii);

III. after removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and

IV. using the largest field size available which does not exceed 15 by 15 centimeters.

(v) The registrant shall determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding scattered neutron radiation, for specified operating conditions.

7. All therapy systems shall be provided with radiation detectors in the radiation head.

(i) Equipment manufactured after December 1, 2014 shall be provided with at least two radiation detectors. The detectors shall be incorporated into two separate dose monitoring systems.

(ii) Equipment manufactured on or before December 1, 2014 shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

(iii) The detector and the system into which that detector is incorporated shall meet the following requirements:

I. Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

II. Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

III. Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

IV. For equipment manufactured after December 1, 2014, the design of the dose monitoring systems shall assure that:

A. The malfunctioning of one system shall not affect the correct functioning of the second system; and

B. The failure of any system shall terminate irradiation or prevent the initiation of radiation.

V. Each dose monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after December 1, 2014, each display shall:

A. maintain a reading until intentionally reset to zero;

B. have only one scale and no scale multiplying factors;

C. utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an over dosage of radiation, the absorbed dose may be accurately determined; and

D. in the event of power failure, the dose monitoring information required in 420-3-26-.09(8)(b)7.(iii)V displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20-minute period of time.

8. Beam Symmetry. In equipment manufactured after December 1, 2014 inherently capable of producing useful beams with asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

9. Selection and Display of Dose Monitor Units.

(i) Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

(ii) The pre-selected number of dose monitor units shall be displayed at the treatment control panel until it is reset manually for the next irradiation.

(iii) After termination of irradiation, it shall be necessary to reset the dosimeter display to zero before a subsequent treatment can be initiated.

(iv) For equipment manufactured after December 1, 2014, after termination of irradiation, it shall be necessary to manually reset the pre-selected dose monitor units before irradiation can be initiated.

10. Air Kerma Rate/Absorbed Dose Rate. For equipment manufactured after December 1, 2014, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. (The radiation detectors specified in 420-3-26-.09(8)(b)7. may form part of this system.) In addition:

i. The dose monitor unit rate shall be displayed at the treatment control panel;

ii. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more

than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

iii. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

iv. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in 420-3-26-.09(8)(b)10.ii. and iii. for the specified operating conditions. Records of these maximum value(s) shall be maintained at the installation for inspection by the Agency.

11. Termination of Irradiation by the Dose Monitoring System or Systems During Stationary Beam Therapy.

(i) Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

(ii) If original design of the equipment included a second dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent, or 40 dose monitor units, above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(iii) For equipment manufactured after December 1, 2014, a second dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent, or 25 dose monitoring units, above the pre-selected number of dose monitor units set at the control panel has been detected by the second dose monitoring system.

(iv) For equipment manufactured after December 1, 2014, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

12. Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an

interruption, irradiation and equipment movements shall be automatically terminated.

13. Termination Switches. It shall be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time from the operator's position at the treatment control panel.

14. Timer.

(i) A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

(ii) The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

(iii) For equipment manufactured after December 1, 2014, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

(iv) The timer shall terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

15. Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

(i) Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel.

(ii) An interlock system shall be provided to insure that the equipment can emit only the radiation type which has been selected.

(iii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(iv) An interlock system shall be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted.

(v) An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

(vi) The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

16. Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

(i) Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

(ii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(iii) The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation, and shall continue to be displayed until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

(iv) Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

(iv) For equipment manufactured after December 1, 2014, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1 (available for purchase at www.web.ansi.org).

17. Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

(i) Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

(ii) An interlock system shall be provided to insure that the equipment can operate only in the mode which has been selected.

(iii) An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

(iv) The mode of operation shall be displayed at the treatment control panel.

(v) For equipment manufactured after December 1, 2014, an interlock system shall be provided to terminate irradiation if:

I. Movement of the gantry occurs during stationary beam therapy; or

II. Movement of the gantry stops during moving beam therapy unless such stoppage is a pre-planned function.

(vi) Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement. For equipment manufactured after December 1, 2014:

I. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or 1 cm of linear motion differs by more than 20 percent from the selected value.

II. Where gantry angle terminates the irradiation in moving beam radiation therapy, the dose monitor units shall differ by less than 5 percent from the dose monitor unit value selected.

III. An interlock shall be provided to prevent motion of more than five (5) degrees or one (1) cm beyond the selected limits during moving beam radiation therapy;

IV. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy.

V. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

(vii) Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation shall be as required by 420-3-26-.09(8)(b)12.

18. Absorbed Dose Rate. For equipment manufactured after December 1, 2014, a system shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. In addition:

(i) The dose monitor unit rate shall be displayed at the treatment control panel.

(ii) If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated shall be in a record maintained by the registrant.

19. Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

(i) The x-ray target or the virtual source of x-rays; and

(ii) The electron window or the virtual source of electrons if the system has electron beam capabilities.

20. System Checking Facilities. Capabilities shall be provided so that all radiation safety interlocks can be checked for correct operation. When pre-selection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed.

21. Exemption. Users of particle accelerators for the treatment of humans shall not be required to have portable radiation monitoring equipment as required by 420-3-26-.09(4)(d)12., provided all interlocks and warning lights are operational and functional.

(c) Facility.

1. Viewing Systems. Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator may observe the patient from the control panel.

2. Aural Communications. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication shall be used.

3. Exemption. A particle accelerator used only for the treatment of humans shall not be required to have an audible warning device within the treatment room as required by 420-3-26-.09(4)(d)8.

(d) Surveys.

1. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with 420-3-26-.03(17)(b). The radiation protection survey shall be performed by, or under the direction of, an authorized medical physicist as defined in 420-3-26-.08(3) or a qualified expert as defined in 420-3-26-.01(2)(a), and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically

available treatment field and with a scattering phantom in the useful beam of radiation:

(i) Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in Rule 420-3-26-.03(6)(a); and

(ii) Radiation levels in unrestricted areas do not exceed the limits specified in Rule 420-3-26-.03(14)(a) and (b).

2. In addition to the requirements of Rule 420-3-26-.09(8)(d)1., a radiation protection survey shall also be performed prior to any subsequent medical use and:

(i) After making any change in the treatment room shielding;

(ii) After making any change in the location of the therapeutic radiation machine within the treatment room;

(iii) After relocating the therapeutic radiation machine; or

(iv) Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

3. The survey record shall indicate all instances where the facility, in the opinion of the authorized medical physicist or qualified expert, is in violation of applicable regulations. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instrument(s) used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one (1) week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey.

4. If the results of the surveys required by this rule indicate any radiation levels in excess of the respective limit specified in 420-3-26-.09(8)(d)1., the registrant shall lock the control in the "OFF" position and not use the unit:

(i) Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(ii) Until the registrant has received a specific exemption from the Agency.

(e) Modification of Radiation Therapy Unit or Room Before Beginning a Treatment Program. If the survey required by

420-3-26-.09(8)(d) indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 420-3-26-.03(14)(a) and (b) of these regulations, before beginning the treatment program the registrant shall:

1. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with 420-3-26-.03(14)(a) and (b) of these regulations;

2. Perform the survey required by 420-3-26-.09(8)(d) again; and

3. Include in the report required by 420-3-26-.09(8)(f) the results of the initial survey, a description of the modification made to comply with 420-3-26-.09(8)(e)1. and the results of the second survey; or

4. Request and receive a registration amendment under 420-3-26-.03(14)(c) of these regulations that authorizes radiation levels in unrestricted areas greater than those permitted by 420-3-26-.03(14)(a) and (b) of these regulations.

(f) Reports of External Beam Radiation Therapy Surveys and Measurements. The registrant for any therapeutic radiation machine subject to these rules shall furnish a copy of the records required in 420-3-26-.09(8)(d) and (e) to the Agency within thirty (30) days following completion of the action that initiated the record requirement.

(g) Calibrations.

1. The calibration of systems subject to this rule shall be performed in accordance with the protocol published by the American Association of Physicists in Medicine, or a user submitted protocol having the prior approval of the Agency, before the system is first used for irradiation of patients and thereafter at time intervals which do not exceed one year and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam.

2. The calibration shall be performed under the direct supervision of an authorized medical physicist as defined in 420-3-26.08(3), and who is physically present at the facility during the calibration.

3. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). The calibration shall have been performed within the previous twenty-four (24) months and after any servicing that may have affected system calibration.

(i) For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for Cobalt-60;

(ii) For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

4. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the license and/or registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by 420-3-26-.09(8)(g)3.; the correction factors that were determined; the names of the individuals who performed the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of an authorized medical physicist.

5. Calibrations shall be in sufficient detail that the absorbed dose at a reference point in soft tissue may be calculated to within an uncertainty of 5 percent.

6. The calibration of the teletherapy beam shall include but not be limited to the following determinations:

(i) Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry and jaw system, and beam flatness and symmetry at the specified depth.

(ii) The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with the therapy beam.

(iii) The uniformity of the radiation field and any dependency upon the direction of the useful beam.

(iv) Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

(v) Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators.

7. Records of calibration measurements required by 420-3-26-.09(8)(g)1. and dosimetry system calibrations required by 420-3-26-.09(8)(g)3. shall be maintained for 5 years after completion of the full calibration.

8. A copy of the latest calibration performed pursuant to 420-3-26-.09(8)(g)1 shall be available in the area of the control panel.

(h) Reserved.

(i) Spot Checks. Spot checks shall be performed on all systems subject to 420-3-26-.09 that are utilized to treat humans. Such spot checks shall meet the following requirements:

1. The spot-check procedures shall be in writing, shall have been developed by an authorized medical physicist, shall have been submitted to the Agency, and shall have received Agency approval prior to implementation.

2. If an authorized medical physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by an authorized medical physicist within 35 days. If any significant changes, as defined by the registrant's spot check procedures, are observed the authorized medical physicist shall be contacted immediately.

3. The spot-check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

4. At intervals not to exceed 1 week, spot checks shall be made of absorbed dose measurements at a typical treatment depth in a phantom. At intervals not to exceed one month, spot checks shall be made of absorbed dose measurements at no less than two depths in a phantom.

5. Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.

6. The cause for a parameter exceeding a tolerance set by the authorized medical physicist shall be investigated and corrected before the system is used for patient irradiation.

7. Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot-check procedures, the system shall be recalibrated as required in 420-3-26-.09(8)(g).

8. Records of spot-check measurements and of any corrective actions taken shall be maintained by the registrant for a period of 3 years after completion of the spot-check measurements.

9. Where a spot check involves a radiation measurement, such measurement shall be obtained using a measurement system

satisfying the requirements of 420-3-26-.09(8)(g)3. or a measurement system which has been intercompared within the previous year with a system meeting those requirements.

(j) Documentation of Treatments.

1. Treatment Plans:

(i) A written treatment plan must be dated and signed by an authorized user prior to the administration of radiation.

(ii) The written treatment plan must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

(iii) A written revision to an existing written treatment plan may be made provided that the revision is dated and signed by an authorized user prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

(iv) The registrant shall retain a copy of the written treatment plan.

2. Procedures for Administrations. The registrant shall develop, implement, and maintain written procedures to provide high confidence that:

(i) Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written treatment plan;

(ii) Each administration is in accordance with the written treatment plan;

(iii) Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written treatment plan by:

(I) Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the treatment plan; and

(II) Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(iv) Any unintended deviation from the treatment plan is identified, evaluated and appropriate action is taken; and

(v) The registrant retains a copy of the procedures for administrations for the duration of the registration.

4. Each treatment plan shall be reviewed at least once each week or after every five consecutive treatments to ensure that treatments are being delivered according to the plan.

(k) Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the Agency:

1. Report of acceptance testing;

2. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by this rule, as well as the name(s) of person(s) who performed such activities;

3. Records of maintenance and/or modifications performed on the therapeutic radiation machine after the December 1, 2014, as well as the name(s) of person(s) who performed such services;

4. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

(l) All records required by this rule shall be retained until disposal is authorized by the Agency unless another retention period is specifically authorized in this rule. All required records shall be retained in an active file from at least the time of generation until the next Agency inspection. Any required record generated prior to the last Agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the Agency authorizes final disposal.

(m) Records and Reports of Misadministration.

1. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

2. Other than events that result from intervention by a patient or human research subject, when a misadministration, as defined by 420-3-26-.09(2), occurs the registrant shall notify the Agency by telephone no later than the next calendar day after the discovery of a misadministration. The registrant shall also provide notification of the misadministration to the affected patient's referring physician, and the patient or a responsible relative or guardian, unless the referring physician agrees to inform the patient or believes, based on medical judgment, that telling the patient or the patient's responsible relative or guardian would be harmful to one or the other, respectively. These notifications

must be made within 24 hours after the registrant discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within 24 hours, the registrant shall notify them as soon as practicable. The registrant is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the registrant shall not delay medical care, including any necessary remedial care, for the patient because of this. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

3. Within fifteen (15) days after an initial misadministration notification to the Agency, the licensee shall submit a written report to the Agency and to the referring physician. The written report must include:

(i) The Registrant's name;

(ii) The prescribing authorized user’s name;

(ii) The referring physician's name;

(iii) A brief description of the event;

(iv) Why the event occurred;

(iv) The effect on the patient;

(v) Actions, if any, that have been taken, or are planned, to prevent a recurrence;

(vi) Certification that the registrant informed the patient or the patient's responsible relative or guardian, and if not, why not.

4. Each registrant shall retain a record of each misadministration for ten (10) years. The record must contain:

(i) The registrant’s name and the names of all individuals involved in the event including the physician, allied health personnel, the patient, and the patient's referring physician,

(ii) The patient's social security number or identification number if one has been assigned,

(iii) A brief description of the event and why it occurred,

(iv) The effect on the patient,

(v) The actions, (if any), taken, or planned, to prevent recurrence.

(vi) Whether the registrant notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

5. Aside from the notification requirement, nothing in this rule shall affect any rights or duties of registrants, and physicians in relation to each other, patients, or responsible relatives or guardians.

APPENDIX A

INSTRUCTION FOR OPERATORS

I. Fundamentals of Radiation Safety

A. Characteristics of alpha, beta, gamma, neutrons, and x-radiation

B. Units of radiation dose (mrem)

C. Biological effects of radiation

D. Methods of controlling radiation dose

1. Working time

2. Working distance

3. Shielding

II. Radiation Detection Instrumentation to be Used

A. Use of radiation survey instruments

1. Operation

2. Calibration

3. Limitations

B. Survey Techniques

1. Methods of surveys

2. Records which must be made and retained

C. Use of personnel monitoring equipment

III. Operation and Control of Particle Accelerators

IV. The Requirements of State Regulations

V. The Registrant's Written Operating and Emergency Procedures

Author: Karl David Walter
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-7, 22-14-8.
History: New March 18, 1970. Repromulgated August 21, 1974. Revised January 18, 1978. **Recodified** June 11, 1978. Revised and Repromulgated October 21, 1981. Revised and Repromulgated effective December 31, 1983. Revised and Repromulgated effective January 31, 1990. **Amended:** Filed December 20, 1996; effective

January 24, 1997. **Repealed and New Rule (Text and Appendix):** Filed October 20, 2014; effective November 24, 2014; operative December 1, 2014.

Ed. Note: Filed September 1, 1982. Readopted with amendments filed October 24, 1983. **Amended:** Filed January 19, 1990.

420-3-26-.10 Notices, Instructions, And Reports To Workers; Inspections.

(1) Purpose and Scope. This Rule 420-3-26-.10 establishes requirements for notices, instructions, and reports by licensees or registrants to individuals participating in registered or licenses activities and options available to such individuals in connection with Agency inspections of licensees or registrants to ascertain compliance with the provisions of the Act and rules, orders, and licenses issued thereunder regarding radiological working conditions. The sections in this Rule 420-3-26-.10 apply to all persons who receive, possess, use, own or transfer material licensed by or registered with the Agency pursuant to the rules in Rules 420-3-26-.02, 420-3-26-.03, 420-3-26-.05, and 420-3-26-.08.

(2) Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

1. The rules in this Rule 420-3-26-.10 and Rule 420-3-26-.03;

2. The license, Notice of Registration, conditions or documents incorporated into the license by reference and amendments thereto;

3. The operating procedures applicable to work under the license or registration;

4. Any notice of violation involving radiological working conditions; or order issued pursuant to Rules 420-3-26-.02, 420-3-26-.05, or 420-3-26-.08 and any response from the licensee or registrant.

(b) If posting of a document specified in paragraph (a)1., 2., or 3. of this section is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

(c) Agency Form X "Notice to Employees" shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area or is otherwise required by these rules.

(d) Documents, notices or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(e) Agency documents posted pursuant to paragraph (a)4, of this section shall be posted within 2 working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted with 2 working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum or 5 working days or until action correcting the violation has been completed, whichever is later.

(3) Instructions to Workers. All individuals working in or frequenting any portion of a restricted area shall be kept informed of the storage, transfer, or use of radioactive materials or of radiation in such portions of the unrestricted area; shall be instructed in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of Agency rules and licenses for the protection of personnel from exposures to radiation or radioactive materials occurring in such areas; shall be instructed of their responsibility to report promptly to the licensee or registrant any conditions which may lead to or cause a violation of Agency rules and the licenses or unnecessary exposure to radiation or radioactive material; shall be instructed in the appropriate response to warnings made in the event of an unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and shall be advised as to the radiation exposure reports which workers may request pursuant to 420-3-26-.10(4). The extent of these instructions shall be commensurate with potential radiological health protection problems in the restricted area.

(4) Notification and Reports to Individuals.

(a) Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this rule. The information reported shall include data and results obtained pursuant to Agency rules, orders, or license conditions, as shown in records maintained by the licensee or registrant pursuant to Agency rules. Each notification and report shall be in writing, include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, the individual's social security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under Chapter 420-3-26, Radiation Control, Rule 420-3-26-.10. You should preserve this report for future reference."

(b) Each licensee or registrant shall advise such worker annually of the worker's exposure to radiation or radioactive material as shown in records maintained by the licensee or registrant pursuant to 420-3-26-.03(46).

(c) Each licensee or registrant shall furnish a report of the worker's exposure to sources of radiation at the request of a worker formally engaged in activities controlled by the licensee or registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to Rule 420-3-26-.03(18) of these rules. Such report shall be furnished within 30 days from the date of the request, or within 30 days after the dose of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(d) When a licensee or registrant is required pursuant to 420-3-26-.03(53) or (54) to report to the Agency any exposure of an individual, or to a member of the public, to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his or her exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Agency.

(e) At the request of a worker who is terminating employment during the current year with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's facility in that calendar year, each licensee or registrant shall provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at the time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

(5) Presence of Representatives of Licensees or Registrants and Workers During Inspections.

(a) Each licensee or registrant shall afford to the Agency at all reasonable times an opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these rules.

(b) During an inspection, Agency inspectors may consult privately with workers as specified in 420-3-26-.10(6). The licensee or registrant may accompany Agency inspectors during other phases of an inspection.

(c) If, at any time of inspection, an individual has been authorized by the workers to represent them during Agency inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the worker's representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each worker's representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in 420-3-26-.10(3).

(e) Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one worker's representative at a time may accompany the inspector.

(f) With approval of the licensee or registrant and the worker's representative an individual who is not routinely engaged in work under control of the licensee or registrant, for example a consultant to the licensee or registrant or to the worker's representative, shall be afforded the opportunity to accompany Agency inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this rule, Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the worker's representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

(6) Consultation with Workers During Inspections.

(a) Agency inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Agency rules and licenses to the extent the inspectors deem necessary for the conduct of an effective and through inspection.

(b) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Act, these rules, or license or registration condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the

licensee's or registrant's control. Any such notice in writing shall comply with the requirements of 420-3-26-.10(7)(a).

(c) The provisions of paragraph (b) of this section shall not be interpreted as authorization to disregard instructions pursuant to 420-3-26-.10(3).

(7) Requests by Workers for Inspections.

(a) Any worker or representative of workers who believes that a violation of the Act, these rules, or license conditions exists or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Agency. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the licensee or registrant by the Agency no later than at the time of inspection except that upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Agency, except for good cause shown.

(b) If, upon receipt of such notice, the State Health Officer or the Director of the Division of Radiation Control determines that the complaint meets the requirements set forth in paragraph (a) of this section, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this Section need not be limited to matters referred to in the complaint.

(c) No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this Rule 420-3-26-.10.

(8) Inspections Not Warranted; Informal Review.

(a) If the Director of the Office of Radiation Control determines, with respect to a complaint under 420-3-26-.10(7), that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, he shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the State Health Officer who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the

complainant, the name of the complainant. The licensee or registrant may submit an opposing written statement of position with the State Health Officer who will provide the complainant with a copy of such statements by certified mail. Upon the request of the complainant, the State Health Officer may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the State Health Officer shall affirm, modify, or reverse the determination of the Director of the Division of Radiation Control and furnish the complainant and the licensee or registrant a written notification of his decision and the reason therefore.

(b) If the Director of the Division of Radiation Control determines that an inspection is not warranted because the requirements of 420-3-26-.10(7)(a) have not been met, he shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of 420-3-26-.10(7)(a).
Author: Karl David Walter, Office of Radiation Control, Bureau of Health Care Standards, Alabama Department of Public Health.
Statutory Authority: Code of Ala. 1975, §§22-2-2, 22-14-4, 22-14-6, 22-14-7, 22-14-8.
History: New May 21, 1975. Revised January 18, 1978. **Recodified** June 11, 1978. Revised and Repromulgated October 21, 1981. Repromulgated effective December 31, 1983. Revised and Repromulgated effective January 31, 1990. Revised and Repromulgated Filed: April 22, 1994; effective May 29, 1994.
Amended: Filed July 27, 2010; effective August 31, 2010.

Ed. Note: Filed September 1, 1982. Readopted with amendments filed October 24, 1983. Amended filed January 19, 1990.

420-3-26-.11 Radiation Safety Requirements For Analytical X-Ray Equipment.

(1) Purpose and Scope. This Rule 420-3-26-.11 provides special requirements for analytical x-ray equipment; provided, however, that nothing in this Rule shall apply to x-ray equipment used to detect, measure, gauge or control the density, level, interface location, thickness of materials, or equipment used for industrial radiography as defined in Rule 420-3-26-.04, or sources of radiation used in the healing arts. The requirements of this Rule are in addition to, and not in substitution for applicable requirements in other Rules. Note that Rules 420-3-26-.01, 420-3-26-.03, 420-3-26-.05, and 420-3-26-.10 also apply to analytical x-ray equipment users.

(2) Definitions.

(a) "Analytical x-ray equipment" means any device which utilizes x-rays for the purpose of examining the microstructure of materials. This includes all types of x-ray diffraction, fluorescence, and spectographic analysis equipment.

(b) "Analytical x-ray system" means a group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, gonimeters, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

(c) "Fail-safe characteristics" means a design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon a failure of a safety or warning device.

(d) "Normal operating procedures" means operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.

(e) "Open-beam configuration" means an analytical x-ray system in which an individual could accidentally place some part of his body in the primary beam path during normal operation.

(f) "Positive visual warning light" means a warning light which has redundant lights so that a single failure will not prevent the warning light from functioning.

(g) "Primary Beam" means ionizing radiation which passes through the aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

(h) "Unattended operation" means any operation in which the analytical x-ray system is generating x-rays and an operator trained in accordance with 420-3-26-.11(6) of this Rule 420-3-26-.11 is not physically present in the area sufficiently near the local components to prevent any operation which could cause an individual to exceed the limits given in 420-3-26-.03(6) of these rules.

(3) Equipment Requirements.

(a) A device such as a guard or interlock which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its

path shall be provided on all open-beam configurations. Prior to operation a registrant may apply to the Agency for an exemption from the requirements of a safety device. Such application shall include a description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

(b) Warning Devices.

1. A positive visible warning light labeled with the words "X-RAY ON," or words having a similar intent, shall be located;

(i) Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; and

(ii) At a conspicuous location that may be visible at all local components; and

2. Open-beam configurations shall be provided with a readily discernible indication of;

(i) x-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; and/or

(ii) shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

Warning devices shall be labeled so that their purpose is easily identified. On equipment transferred after January 1, 1977, warning devices shall have fail-safe characteristics.

(c) Unused ports on radiation source housings shall be secured in the closed position in the manner which will prevent casual opening.

(d) All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "CAUTION-HIGH INTENSITY X-RAY BEAM," or words having a similar intent on the x-ray source housing; and

2. "CAUTION RADIATION-THIS EQUIPMENT PRODUCES X-RAYS WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube and at a conspicuous location if the radiation source is an x-ray tube.

(e) On open-beam configurations transferred after January 1, 1977, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a shielding coupling has been connected to the port.

(f) Each x-ray tube housing shall be so constructed that with all shutters closed the leakage radiation measured at a distance of 5 cm from its surface is not capable of producing a dose in excess of 2.5 mrem in one hour at any specified tube rating.

(g) Each x-ray generator, including high voltage rectifiers, transformers, and amplifiers, shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour.

(h) Each entrance to a room containing analytical x-ray equipment in unattended operations shall have a warning light with the words "X-RAY ON" or words having a similar intent. In addition, for an open beam configuration unattended operation, there shall be a device to shut off analytical x-ray equipment upon the entrance of any person not trained in accordance with 420-3-26-.11(6) of this Rule.

(4) Area Requirements.

(a) The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in 420-3-26-.03(6) of these rules. These levels shall be met at any specified rube rating.

(b) Surveys. Radiation surveys with appropriate radiation detection devices as required by 420-3-26-.03(9), of all operable analytical x-ray systems sufficient to show compliance with paragraph 420-3-26-.11(4)(a) shall be performed quarterly and;

1. Upon installation of the equipment;

2. Following any change in the initial arrangement, number, or type of local components in the system;

3. Following any maintenance requiring the disassembly or removal of a local component in the system;

4. During the performance of maintenance and alignment procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

5. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

6. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in 420-3-26-.03(2).

7. Notwithstanding the radiation survey requirements in 420-3-26-.11(4)(b), quarterly radiation surveys are not required for devices with a maximum energy of 70kVp or less.

(c) Each area or room containing analytical x-ray equipment that is not under constant surveillance shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION--X-RAY EQUIPMENT," or words having a similar intent.

(5) Operating Requirements.

(a) Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the individual designated to the Agency as the Radiation Safety officer.

(b) No person shall bypass a safety device unless such person has obtained the approval of the designated Radiation Safety Officer. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

(6) Personnel Requirements.

(a) Instruction. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instructions in and demonstrated competence as to:

1. Identification of radiation hazards associated with the use of the equipment.

2. Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases.

3. Proper operating procedures for the equipment.

4. Biological effects of radiation, including symptoms of an acute localized exposure; and

5. Proper procedures for reporting an actual or suspected exposure.

(b) Personnel Monitoring. Finger or wrist dosimetric devices shall be provided to and shall be used by:

1. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device, and

2. Personnel maintaining analytical x-ray equipment, if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed. In reporting dose values, due consideration should be given to the energy of the x-ray beam and the size of the x-ray beam.
Author: Karl David Walter
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-7, 22-14-8.
History: New September 15, 1976. **Recodified** June 11, 1978. Revised and Repromulgated October 21, 1981. Repromulgated effective December 31, 1983. Revised and Repromulgated effective January 31, 1990. **Amended:** Filed October 20, 2014; effective November 24, 2014; operative December 1, 2014.

Ed. Note: Filed September 1, 1982. Readopted with amendments filed October 24, 1983. Amended Filed January 19, 1990.

420-3-26-.12 Radiation Safety Requirements For Wireline Service Operations And Subsurface Tracer Studies.

(1) **Purpose.** This Rule establishes radiation safety requirements for persons using sources of radiation for wireline service operations including mineral logging, radioactive markers, uranium sinker bars, subsurface tracer studies, and fishing operations. The requirements of this Rule are in addition to, and not in substitution for, the requirements of Rules 420-3-26-.01, 420-3-26-.02, 420-3-26-.03, 420-3-26-.10, and 420-3-26-.13 of these rules.

(2) **Scope.** This Rule applies to all licensees or registrants who use sources of radiation for wireline service operations including mineral logging, radioactive markers, uranium sinker bars, or subsurface tracer studies. This Rule also applies during fishing operations that are performed to recover lost or lodged radioactive sources or devices from a well. This Rule does not apply to the use of radioactive material in tracer studies involving multiple wells, such as field flood studies, or to the use of sealed sources auxiliary to well-logging but not lowered into wells.

(3) **Definitions.** As used in this Rule, the following definitions apply:

(a) "Energy compensated source (ECS)" means a small sealed source with an activity not exceeding 100 microcuries (3.7 megabecquerels), used within a logging tool or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

(b) "Field station" means a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

(c) "Fishing or fishing operations" means those activities associated with the recovery from downhole of a well devices or sources containing radioactive materials which has become lodged and/or disconnected from the equipment normally connecting the source or device with the surface.

(d) "Fresh water aquifer", for the purpose of this rule, means a geological formation that is capable of yielding fresh water to a well or spring.

(e) "Injection tool" means a device used for controlled subsurface injection of radioactive tracer material.

(f) "Irretrievable well-1ogging source" means any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

(g) "Logging assistant" means any individual who, under the personal supervision of a logging supervisor, handles sources of radiation including sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by this rule.

(h) "Logging supervisor" means the individual who provides personal supervision of the utilization of sources of radiation at a temporary job site, and who is responsible to the licensee or registrant for assuring compliance with the requirements of the Agency rules and the conditions of the license or registration.

(i) "Logging tool" means a device used subsurface to perform well-1ogging.

(j) "Mineral logging" means any logging performed for the purpose of mineral exploration other than oil or gas.

(k) "Personal supervision" means guidance and instruction by the logging supervisor who is physically present at a temporary job site and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

(l) "Radiation monitor badge" means an individual personnel dosimeter used to measure the radiation dose to the individual's whole body and is processed and evaluated by a dosimetry processor meeting the requirements of 420-3-26-.03(17)(c)1. and 2.

(m) "Radioactive marker" means radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

(n) “Safety review” means a periodic review provided by the licensee or registrant for its employees on radiation safety aspects of well-logging. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, accidents of errors that have been observed, and opportunities for employees to ask safety questions.

(o) "Source holder" means a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

(p) "Subsurface tracer study" means the release of unsealed radioactive material or a substance tagged with radioactive material for the purpose of tracing the movement or position of the radioactive material or tagged substance in the well-bore or adjacent formation.

(q) “Surface casing for protecting fresh water aquifers” means a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

(r) "Temporary job site" means a location to which radioactive materials have been dispatched to perform wire-line service operations or subsurface tracer studies.

(s) “Tritium neutron generator target source” means a tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

(t) “Uranium sinker bar” means a weight containing depleted uranium used to pull a logging tool down toward the bottom of the well.

(u) "Well-bore" means a drilled hole in which wireline service operations and subsurface tracer studies are performed.

(v) "Well-logging" means the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well and/or adjacent formations.

(w) "Wireline" means a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

(x) "Wireline service operation" means any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

(4) **Prohibition.** No licensee shall perform wireline service operations with a sealed source(s) unless, prior to commencement of the operation, the licensee has a written agreement with the well operator, well owner, drilling contractor, or land owner. The licensee shall retain a copy of the written agreement for three years after the well logging operation has been completed. The written agreement must identify who will meet the following requirements:

(a) In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made;

(b) A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture;

(c) In the event a decision is made to abandon the sealed source downhole, the requirements of 420-3-26-.12(25)(c) shall be met and implemented within 30 days;

(d) The radiation monitoring required in 420-3-26-.12(25)(b) will be performed;

(e) If the environment, any equipment to be used by non-1icensed individuals, or personnel are contaminated with licensed radioactive material, they must be decontaminated before release from the site or released for unrestricted use; and

(f) Persons performing fishing operations will have had at least twelve months experience in tool recovery operations. Note, this experience does not necessarily have to be with radioactive devices or sources and the fishing company will release all recovered radioactive material to the logging supervisor as soon as practicable. Equipment Control

(5) **Limits on Levels of Radiation.** Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of Rule 420-3-26-.02 and the dose limitation requirements of Rule 420-3-26-.03 of these rules are met.

(6) **Storage Precautions.**

(a) Each source of radiation, except accelerators, shall be provided with a storage and/or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

(b) Sources of radiation shall be stored in a manner which will minimize danger from explosion and/or fire.

(7) **Transport Precautions.** Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

(8) **Radiation Survey Instruments.**

(a) The licensee or registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station and temporary job site to make physical radiation surveys as required by this Rule and by 420-3-26-.03(17) of these rules. Instrumentation shall be capable of measuring 0.1 milliroentgen per hour through at least 50 milliroentgens per hour.

(b) Each radiation survey instrument shall be calibrated:

1. At intervals not to exceed 6 months and after each instrument servicing;

2. At energies and radiation levels appropriate for use;

3. For linear scale instruments, at two points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of a least one decade; and for digital instruments, at appropriate points; and

4. So that accuracy within plus or minus 20 percent of the true radiation level can be demonstrated on each scale.

(c) Calibration records shall be maintained for a period of 3 years for inspection by the Agency.

(d) The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them in a timely manner from a second party.

(9) **Leak Testing of Sealed Sources.**

(a) **Requirements.** Each licensee using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries and maintained for inspection by the Agency for 3 years after the leak test is performed.

(b) **Method of Testing.** Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State. The test sample shall be taken from the nearest accessible point to the sealed source where contamination might accumulate. The test sample shall be analyzed for radioactive contamination,

and the analysis shall be capable of detecting the presence of 0.005 microcuries of radioactive material on the test sample.

(c) **Interval of Testing.** Each sealed source of radioactive material, except energy compensated sources (ECS) shall be tested at intervals not to exceed 6 months. Each ECS not exempted by paragraph (e) of this section shall be tested at intervals not to exceed 3 years. In the absence of a certificate from a transferor indicating that a test has been made within 6 months prior to the transfer, the sealed source shall not be put into use until tested. If for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

(d) **Leaking or Contaminated Sources.** If the test reveals the presence of 0.005 microcuries or more of leakage or contamination, the licensee shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with these rules. The licensee shall check the equipment associated with the leaking or contaminated source for radiation contamination and, if contaminated, have it decontaminated or disposed of by a person specifically licensed to perform such activity. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the Agency.

(e) **Exemptions.** The following sources are exempted from the periodic leak test requirements of this section:

1. Hydrogen-3 (tritium) sources;

2. Sources of radioactive material with a half-1ife of 30 days or less;

3. Sealed sources of radioactive material in gaseous form;

4. Sources of beta- and/or gamma-emitting radioactive material with an activity of 100 microcuries or less; and

5. Sources of alpha-emitting radioactive material with an activity of 10 microcuries or less.

(10) **Quarterly Inventory.** Each licensee or registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for 3 years from the date of the inventory for inspection by the Agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

(11) **Utilization Records.** Each licensee or registrant shall maintain current records, which shall be kept available for

inspection by the Agency for 3 years from the date of the recorded event, showing the following information for each source of radiation:

(a) Make, model number, and a serial number or a description of each source of radiation used;

(b) The identity of the logging supervisor or field unit to whom assigned;

(c) Locations where used and dates of use; and

(d) In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well and the disposition of any unused tracer materials.

(12) **Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.**

(a) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations shall be certified by the manufacturer, or other testing organization acceptable to the Agency, to meet the following minimum criteria:

1. Be of doubly encapsulated construction;

2. Contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical, and

3. Has been prototype tested in accordance with the requirements of the U.S. Nuclear Regulatory Commission as provided in 10CFR39.41(a)(3)[27].

(b) For sealed sources, except those containing radioactive material in gaseous form, acquired after December 31, 1984, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of (a) above, the sealed source shall not be put into use until such determinations and testing have been performed.

(c) Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after December 31, 1983 shall be certified by the manufacturer, or other testing organization acceptable to the Agency, as meeting the sealed source performance requirements for oil well-1ogging as contained in the American National Standard N542," Sealed Radioactive Sources Classification" in effect on December 31, 1983.

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[27] See footnote 4. in 420-3-26-.2.

(d) Certification documents shall be maintained for inspection by the Agency for a period of 2 years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the Agency authorizes disposition.

(e) The requirements in paragraphs (a), (b), (c) and (d) of this section do not apply to sealed sources that contain radioactive material in gaseous form.

(f) The requirements in paragraphs (a), (b), (c) of this section do not apply to energy compensation sources.

(13) **Labeling**

(a) Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER[28] RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

(b) Each storage container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER[26] NOTIFY CIVIL AUTHORITIES (OR NAME OF COMPANY)

(14) **Inspection and Maintenance.**

(a) Each licensee or registrant shall visually check source holders, logging tools, and source handling tools for defects before first use to ensure that the equipment is in good working condition and that the required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: the date of the check, name of inspector, equipment involved, defects found, and repairs made. These records must be retained for 3 years after the defect is found.

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[28] Or CAUTION

(b) Each licensee or registrant shall conduct, at intervals not to exceed 6 months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper label and physical conditions. Records of inspection and maintenance shall be maintained for a period of 3 years for inspection by the Agency.

(c) If any inspection conducted pursuant to (a) or (b) above reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

(d) If a sealed source is stuck in the source holder, the licensee shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the Agency, the U. S. Nuclear Regulatory Commission or an Agreement State to perform this operation.

(e) The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State.

(14A) **Use of a Sealed Source in a Well Without a Surface Casing.** A licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved for each well by the Agency.

Requirements for Personnel Safety

(15) **Training Requirements.**

(a) No licensee or registrant shall permit any individual to act as a logging supervisor as defined in this Rule until such individual has:

1. Successfully completed, in a course recognized by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State consisting of at least 24 hours of formal training in the subjects outlined in Appendix A of this Rule.

2. Received copies of and instruction in the rules contained in this part and the applicable sections of Rules 420-3-26-.01, 420-3-26-.03, and 420-3-26-.10, or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures.

3. Demonstrated understanding of the requirements in 1. and 2. by successfully completing a written examination administered by the licensee or registrant;

4. Completed two months of on-the-job training under the supervision of a logging supervisor; and

5. Demonstrated through a field evaluation, competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(b) No licensee or registrant shall permit any individual to act as a logging assistant until such individual has:

1. Received copies of and instruction in the rules contained in this part and the applicable sections of Rules 420-3-26-.01, 420-3-26-.03, and 420-3-26-.10, or their equivalent, conditions of appropriate license or certificate of registration, and the licensee's or registrant's operating and emergency procedures; and

2. Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

(c) The licensee shall provide an annual radiation safety review for all logging supervisors and logging assistants.

(d) The licensee or registrant shall maintain records documenting the training and reviews required by (a), (b) and (c) for inspection by the Agency for 3 years following termination of employment.

16. **Operating and Emergency Procedures.** The licensee's or registrant's operating and emergency procedures shall include instructions in at least the following:

(a) Handling and use of sources of radiation including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;

(b) Methods and occasions for conducting radiation surveys, including surveys for detecting contamination;

(c) Methods and occasions for locking and securing sources of radiation;

(d) Personnel monitoring and the use of personnel monitoring equipment;

(e) Transportation to temporary job sites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation to prevent accidental loss, tampering or unauthorized removal;

(f) Minimizing exposure of individuals in the event of an accident, including exposures from inhalation and ingestion of radioactive material;

(g) Procedure for notifying proper personnel in the event of an accident;

(h) Maintenance of records;

(i) Inspection and maintenance of sealed sources, source holders, logging tools, source handling tools, storage containers, transport containers, injection tools and uranium sinker bars;

(j) Procedure to be followed in the event a sealed source is lodged downhole;

(k) Procedures to be used for picking up, receiving, and opening packages containing radioactive material;

(l) The monitoring of any well discharge line for contamination by the logging supervisor;

(m) Actions to be taken in the event of a ruptured sealed source to prevent the spread of contamination and to minimize the inhalation and/or ingestion of radioactive material;

(n) The use of remote handling tools for handling sealed sources, and radioactive tracer material except log-activity calibration sources;

(o) Identifying and reporting to the Agency defects and noncompliance as required by 10 CFR Part 21 of the U. S. Nuclear Regulatory Commission regulations;

(p) For the use of tracers, decontamination of the environment, equipment and personnel; and

(q) Maintenance of records generated by logging personnel at temporary job sites.

(17) **Personnel Monitoring.**

(a) No licensee or registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears a radiation monitor badge. Each radiation monitor badge shall be assigned to and worn by only one individual.

(b) A licensee shall provide bioassay services to individuals using radioactive materials in tracer studies if required by the license.

(c) Personnel monitoring records and bioassay results shall be maintained for inspection until the Agency authorizes disposition.

Precautionary Procedures in Logging and Subsurface Tracer Operations

(18) **Security.**

(a) During each logging or tracer application, except when radiation sources are below ground or in a shipping or storage container, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized and/or unnecessary entry into a restricted area, as defined in Rule 420-3-26-.01 of these Rules.

(b) A logging supervisor must be physically present at a temporary job site whenever radioactive materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the job site in order to obtain assistance if a source becomes lodged downhole.

(19) **Handling Tools.** The licensee shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

(20) **Subsurface Tracer Studies.**

(a) Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material and to avoid contamination of field stations and temporary job sites.

(b) No licensee shall cause the injection of radioactive material for subsurface tracer studies without prior authorization from the Alabama Oil and Gas Board.

(21) **Particle Accelerators.** No licensee or registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging which results in the production of radiation, except in areas or facilities controlled or shielded so that the requirements of 420-3-26-.03(6) and 420-3-26-.03(14) of these rules as applicable, are met.

(21A) **Radioactive Markers.** A licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in Schedule B of Rule 420-3-26-.02. The use of radioactive markers is subject to requirements of 420-3-26-.12(10) of these rules.

(21B) **Uranium Sinker Bars.** A licensee may use a uranium sinker bar in well-logging only if it is legibly impressed with the words

"CAUTION - RADIOACTIVE - DEPLETED URANIUM" and "NOTIFY CIVIL AUTHORITIES (or COMPANY NAME) IF FOUND."

(21C) **Energy Compensated Sources.**

(a) A licensee may use an energy compensated source (ECS) which is contained within a logging tool, or other tool component, only if the ECS contains quantities of radioactive material not exceeding 100 microcuries.

(b) For well-1ogging applications with a surface casing for protecting fresh water aquifers, the use of ECS is only subject to the requirements of 420-3-26-.12(9), 420-3-26-.12(10) and 420-3-26-.12(11) of these rules.

(c) For well-1ogging applications without a surface casing for protecting fresh water aquifers, the use of ECS is only subject to the requirements of 420-3-26-12(4), 420-3-26-.12(9), 420-3-26-.12(10), 420-3-26-.12(11), 420-3-26-.12(14a) and 420-3-26-.12(25) of these rules.

(21D) **Tritium Neutron Target Sources.**

(a) The use of a tritium neutron target source containing quantities not to exceed 30 curies and in a well with a surface casing to protect fresh water aquifers is subject to the requirements in these rules except 420-3-26-.12(4), 420-3-26-.12(12) and 420-3-26-.12(25) of these rules.

(b) The use of a tritium neutron target source containing quantities exceeding 30 curies or in a well without a surface casing to protect fresh water aquifers is subject to the requirements in these rules except 420-3-26-.12(12) of these rules.

Radiation Surveys and Records

(22) **Radiation Surveys.**

(a) Radiation surveys shall be made and recorded for each area where radioactive materials are stored.

(b) Before transporting radioactive material, radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

(c) After removal of the sealed source from the logging tool and before departing the job site, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

(d) Radiation surveys shall be made and recorded at the job site or well-head for each tracer operation, except those using hydrogen-3, carbon-14, and sulfur-35. These surveys shall include measurements of radiation levels before and after the operation to confirm the absence of contamination.

(e) Records required pursuant to (a) through (d) above, shall include the dates, the identification of individual(s) making the survey, the identification of survey instrument(s) used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the Agency for 3 years after completion of the survey.

(23) **Documents and Records Required at Field Stations**. Each licensee or registrant shall maintain, for inspection by the Agency, the following documents and records for the specific devices and sources used at the field station:

(a) Appropriate license, certificate of registration, or equivalent document;

(b) Operating and emergency procedures;

(c) Applicable rules;

(d) Records of the latest survey instrument calibrations pursuant to 420-3-26-.12(8);

(e) Records of the latest leak test results pursuant to 420-3-26-.12(9);

(f) Quarterly inventories required pursuant to 420-3-26-.12(10);

(g) Utilization records required pursuant to 420-3-26-.12(11);

(h) Records of inspection and maintenance required pursuant to 420-3-26-.12(14);

(i) Survey records required pursuant to 420-3-26-.12(22);

(j) Training records required pursuant to 420-3-26-.12(15);

(k) Shipping papers of the transportation of radioactive material;

(l) Records of receipt, transfer and disposal of radioactive material at the field station; and

(m) Records of personnel monitoring required pursuant to 420-3-26-.12(17) for personnel employed at the field station.

(24) **Documents and Records Required at Temporary Job Sites**. Each licensee or registrant conducting operations at a temporary job

site shall have the following documents and records available at that site for inspection by the Agency:

(a) Operating and emergency procedures;

(b) Survey records required pursuant to 420-3-26-.12(22) for the period of operation at the site;

(c) Evidence of current calibration for the radiation survey instruments in use at the site;

(d) When operating in the State under reciprocity, a copy of the appropriate license, certificate of registration, or equivalent document(s); and

(e) Shipping papers for the transportation of radioactive material.

(25) **Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources.**

(a) Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of Rule 420-3-26-.03 of these rules.

(b) Whenever a sealed source or device containing radioactive material is lodged downhole, the licensee shall:

1. Monitor at the surface, including the circulating fluids from the well if any, for the presence of radioactive contamination with a radiation survey instrument or logging tool during logging tool recovery operations;

2. Immediately initiate the emergency procedures required by 420-3-26-.12(16) if there is evidence that a sealed source has ruptured or radioactive contamination is present. Emergency procedures shall include the decontamination of all work areas, equipment and unrestricted areas, as applicable;

3. Notify the Agency immediately by telephone. Such notice shall;

(i) Indicate the well location,

(ii) Identify persons conducting fishing operations and the procedures to be followed to assure that the radioactive material is not likely to be released, and

(iii) The estimated depth of the source.

4. Notify the Agency immediately by telephone and subsequently within 30 days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the

magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

(c) When it becomes apparent that efforts to recover the radioactive source will not be successful, the licensee shall:

1. Develop an appropriate method of abandonment, which shall include:

(i) A method to immobilize and seal with a cement plug each irretrievable well logging source;

(ii) A means to prevent inadvertent intrusion on the source, unless the source is not accessible to any subsequent drilling operations; and

(iii) The mounting of a permanent identification plaque, at the surface of the well, containing the appropriate information required by (d);

2. Advise the well-operator of these rules and those of the Alabama Oil and Gas Board, and the proposed method of abandonment;

3. Notify the Agency by telephone, giving the circumstances of the loss; and

(i) Request approval of the proposed abandonment procedures; or

(ii) State that the licensee implemented abandonment procedures before receiving Agency approval because the licensee believed there was an immediate threat to public health and safety; and

4. File a written report with the Agency within 30 days of the abandonment, setting forth the following information:

(i) Date of occurrence and a brief description of attempts to recover the source,

(ii) A description of the radioactive source involved, including radionuclide, quantity, and chemical and physical form,

(iii) Surface location and identification of well,

(iv) Results of efforts to immobilize and set the source in place,

(v) Depth of the radioactive source,

(vi) Depth of the top of the cement plug,

(vii) Depth of the well,

(viii) Information contained on the permanent identification plaque,

(ix) The immediate threat to public health and safety justification for implementing abandonment if prior Agency approval was not obtained in accordance with 420-3-26-.12(25)(c)3., and

(x) The names of state agencies receiving a copy of this report.

(d) Whenever a sealed source containing radioactive material is abandoned downhole, the licensee shall provide a permanent plaque[29] for posting the well or well-bore. This plaque shall:

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[29] An example of a suggested plaque is shown in Appendix B of this rule 420-3-26-.12.

(i) Be constructed of long-1asting material, such as stainless steel, brass, bronze or monel;

(ii) Be mounted at the surface of the well or well-bore, unless the mounting of the plaque is not practical;

(iii) Have a size of at least 17 cm (7 inches) square and 3 mm (3/8 inches) thick; and

(iv) Contain the following information engraved on its face:

(I) The word "CAUTION",

(II) The radiation symbol without the conventional color requirement,

(III) The date of abandonment,

(IV) The name of the well operator or well owner,

(V) The well name and well identification number(s) or other designation,

(VI) The sealed source(s) by radionuclide and quantity of activity,

(VII) The source depth and the depth to the top of the plug, and

(VIII) An appropriate warning, depending on the specific circumstances of each abandonment.[30]

(e) The licensee shall immediately notify the Agency by telephone and subsequently by confirming letter if the licensee knows or has reason to believe that radioactive material has been lost in or to

an underground potable water source. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

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[30] Appropriate warnings may include: (a) "Do not drill below plug back depth"; (b) "do not enlarge casing"; or (c) "do not re-enter hole", followed by the words, "before contacting the Office of Radiation Control, Alabama Department of Public Health."

420-3-26-.12
APPENDIX A

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

I. Fundamentals of Radiation Safety

A. Characteristics of radiation

B. Units of radiation dose and quantity of radioactivity

C. Significance of radiation dose

1. Radiation protection standards

2. Biological effects of radiation dose

D. Levels of radiation from sources of radiation

E. Methods of minimizing radiation dose

1. Working time

2. Working distances

3. Shielding

F. Radiation Safety Practices

1. Prevention of contamination

2. Methods of decontamination

II. Radiation Detection Instrumentation to be Used

A. Use of radiation survey instruments

1. Operation

2. Calibration

3. Limitations

B. Survey techniques

C. Use of personnel monitoring equipment

III. Equipment to be Used

A. Handling equipment

1. Source handling equipment

2. Remote handling tools

B. Sources of radiation

1. Storage

2. Control

3. Disposal

C. Storage and control of equipment

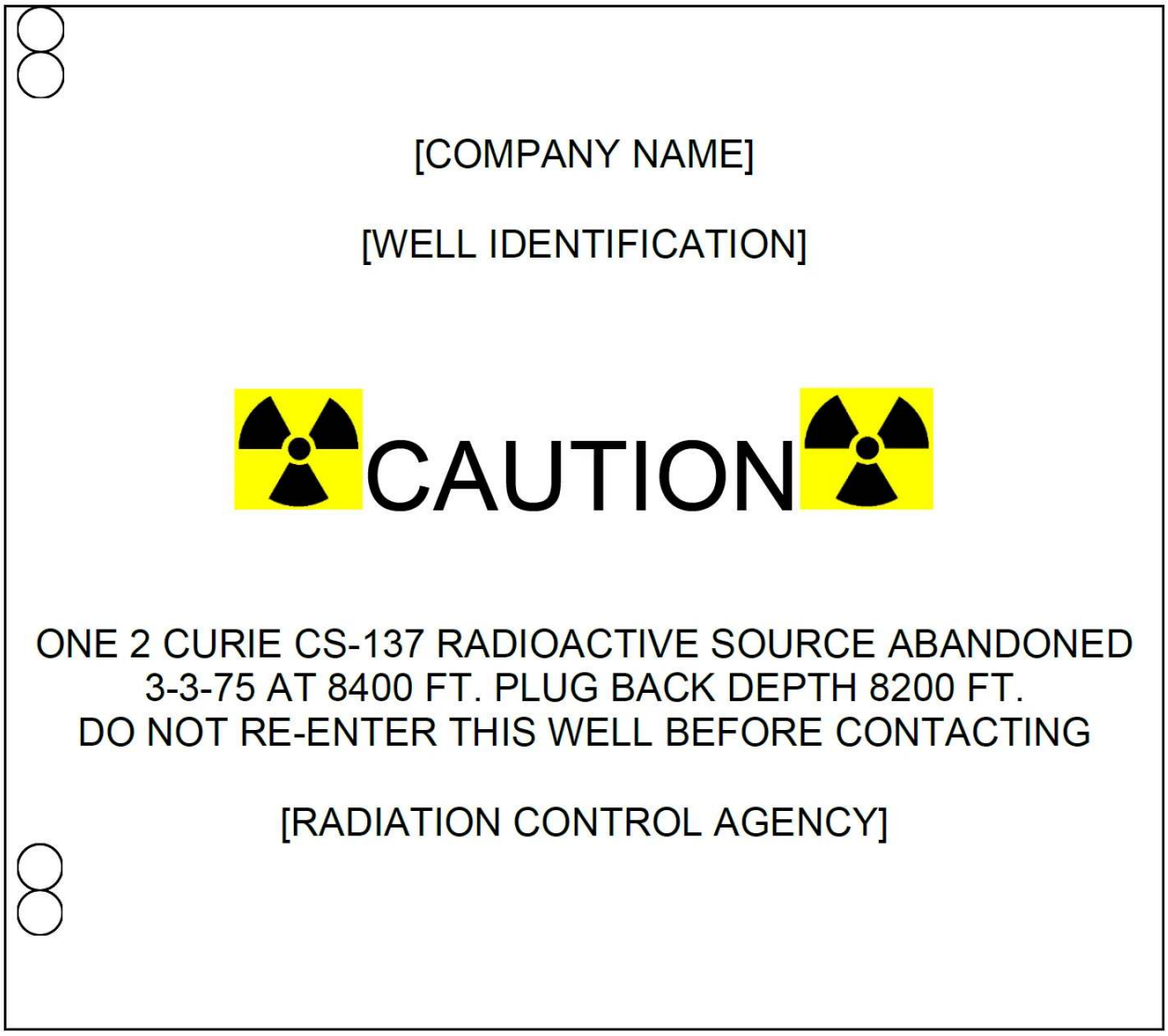
D. Operation and control of equipment

IV. Pertinent State and Federal Regulations

V. Case Histories of Accidents in Well Logging

420-3-26-.12
APPENDIX B

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE



The size of this plaque should be convenient for use on active or inactive wells, e.g., a 7-inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., ½-inch and 1/4-inch letter size, respectively.
Author: David Turberville, Office of Radiation Control, Alabama Department of Public Health 30 Appropriate warnings may include: (a) "Do not drill below plug back depth"; (b) "do not enlarge casing"; or (c) "do not re-enter hole", followed by the words,

"before contacting the Office of Radiation Control, Alabama Department of Public Health."
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-11.
History: Adopted effective December 31, 1983. Revised and Repromulgated effective January 31, 1990. **Revised:** Effective October 1, 1991. **Amended (Text and Appendices):** Filed May 19, 2006; effective June 23, 2006.

420-3-26-.13 Administrative Procedures.

(1) Purpose and Scope. This Rule establishes the administrative procedures for the Agency as the Radiation Control Agency and describes the organization, methods of conducting business, and interpretations as required by the Alabama Administrative Procedures Act.

(2) Organization and Method of Conducting Business.

(a) Organization. The State Board of Health is designated in Code of Ala. 1975, §22-14-4, as the State Radiation Control Agency with the State Health Officer as Director. The Director has designated the Division of Radiation Control to implement Chapter 14 of Title 22, Code of Ala. 1975. The State Health Officer as Director may delegate certain duties to the Division of Radiation Control and its Director. These duties are:

1. To inspect, process applications to register x-ray facilities, and investigate accidents, incidents, and overexposures as may be required to assure the safe use of x-ray equipment as is defined in these rules.

2. To inspect, the use of particle accelerators and radioactive material, process applications to register particle accelerators, process applications to license the use of radioactive material(s), and investigate accidents, incidents and overexposure as may be required to assure the safe use of particle accelerators or radioactive materials.

3. To conduct environmental monitoring around nuclear facilities which have a reasonable potential for releasing radioactive material into the environment.

4. To develop emergency plans for responding to any radiological emergency in accordance with Memoranda of Understanding and other Agencies.

5. To respond to, and pursuant to written delegations, issue orders necessary to protect the public health and safety during radiation emergencies, incidents or accidents.

6. To conduct limited training in the safe use of radiation.

7. To answer public inquiries, investigate complaints, and provide limited quantities of general information to the public.

8. To receive, process, and coordinate with other agencies requests for orders for the routing of radioactive material shipments.

9. To determine the compliance of a person's use of radiation as the result of an inspection, investigation, or review of submitted information. This is subject to review and appeal as provided for in this Rule.

10. To issue orders directing compliance with these rules, and when not contested issue orders to suspend, revoke, or modify a license or registration, or sources of radiation.

11. To develop contracts for programs compatible with the Act.

12. To issue orders relating to the routing of radioactive materials as provided for in this Rule.

13. To maintain an index and file of all decisions, opinions, and declaratory rulings issued by the Agency; by subject matter. Copies of these orders are available in the Division of Radiation Control's Office for public review and copying at 25¢ per page.

14. To maintain a file of all licenses, registrations, inspections, investigations and related correspondence for public inspection and copying at 25¢ per page. Certain files may be temporarily unavailable when being used by the Staff or pending determination of compliance or enforcement action. Further, information as determined pursuant to §22-14-6(d) Code of Ala. 1975, shall not be available for public review or copying.

15. To maintain a list of all forms, statements of policy, instructions, guides, and interpretations available for public review and copying.

16. To maintain copies of all memoranda of understanding or contracts between the Agency and other agencies relating to the radiation program in Alabama, for public inspection and for copying at 25¢ per page.

17. To issue orders suspending a license if the inspection fees are not paid within 45 days of billing the licensee as provided for in the Act.

18. To notify a licensee of any proposed civil penalty as may be determined in accordance to Appendix A of this Rule 420-3-26-.13. Note, the licensee may appeal or provide mitigating information for consideration before a final order is issued.

(b) Applications for Licenses, Registration, or Notice of Registration.

1. All applications for a radioactive materials license shall meet the applicable requirements of Rule 420-3-26-.02 of these rules before being approved. To assist applicants in preparing their applications, the Agency has prepared instructions and guides which are available on request. In addition, any application for the commercial burial of low-1evel radioactive wastes must conform with the Agency policy statement, copies of which are available on request. Amendment requests may be submitted by letter but must otherwise meet the requirements of an application prior to approval.

2. All applications for a Notice of Registration shall meet the applicable requirements of Rule 420-3-26-.08 of these rules before being approved. Amendment requests may be submitted by letter but must otherwise meet the requirement of an application prior to approval.

3. All applications to register x-ray equipment shall meet the requirements of Rule 420-3-26-.05 of these rules prior to approval. Amendment requests may be by letter but must otherwise meet the requirements for an application prior to approval.

4. Any application may be approved in part, for those proposed activities for which adequate information was supplied. Those proposed portions for which inadequate information was supplied may be approved upon receipt of additional, sufficient information without a reapplication.

5. Any person's application or amendment request which is denied may request a hearing within 30 days of the denial of the application or amendment request in accordance with the hearing procedures of this Rule.

6. Any application or amendment request will be considered abandoned, upon failure of the applicant to supply any additional reasonable information requested to determine whether the application meets the requirements of these rules within 90 days of the written request for supplemental information. This section does not apply if the applicant files for a hearing pursuant to 5 above.

7. Except for the activities listed in 420-3-26-.02 (10)(q)4, if the Agency fails to respond to an application by either issuing the appropriate license, amendment, or Notice of Registration; by requesting additional supplemental information; or by denying the request within 90 days of Agency receiving the supplemental information in writing, or the application, if supplemental information was not requested; the applicant may file a petition with the Agency requiring the approval of the request. Such petition only needs to show that the Agency has received, in

writing, all of the information requested from the applicant and at least 90 days has elapsed without a request for information and no action has been taken by the Agency. The petition will be granted unless the Agency can show that prior to the filing of the petition,

(i) the Agency requested in writing sent to the last known address of the applicant, additional information which has not been received,

(ii) the Agency denied the application, or

(iii) the construction, testing, or technical studies have not been completed by the Agency.

(3) Hearings.

(a) Rule Making.

1. In conformance with Section 5 of the Administrative Procedures Act (Act 81-855), the Agency shall adopt its rules and regulations. Any notice regarding the adoption, repeal or amendment of such rules shall include:

(i) The terms or substance of the proposed action.

(ii) A description of the subject and issues involved if not included in (i).

(iii) The address where written comments or statements may be delivered and the last time and date for delivering such statements.

(iv) The date, time, and place for oral statements to be made and any conditions pertaining thereto.

(v) Who the hearing officer will be if other than the Division Director or Agency Director.

2. Petitions for Rulemaking.

(i) Any interested person may petition the Agency to issue, amend, or rescind any rule. The petition should be addressed to the Director, Division of Radiation Control, Alabama Department of Public Health, Montgomery, AL 36130.

(ii) Each petition filed under this section shall:

(I) Set forth a general solution to the problem or the substance or text of any proposed rule, or amendment or specify the rule which is to be revoked or amended;

(II) State clearly and concisely the petitioner's grounds for and interest in the action requested;

(III) Include a statement in support of the petition which shall set forth the specific issues involved, the petitioner's views or arguments with respect to those issues, relevant technical, scientific or other data involved which is reasonably available to the petitioner, and such other pertinent information as the petitioner deems necessary to support the action sought. In support of its petition, the petitioner should note any specific cases of which the petitioner is aware where the current rule is unduly burdensome, deficient, or needs to be strengthened.

(iii) If it is determined that the petition includes that information required by paragraph (ii) of this section and is complete and is probably needed, the Director of Division of Radiation Control or his designee through the Agency Secretary will cause a notice of the petition to be published in the Alabama Administrative Monthly in accordance with the rule making provisions of this Rule, within 60 days.

(iv) If it is determined by the Director of Division of Radiation Control that the petition does not include the information required by paragraph (ii) of this section, or is incomplete or is not needed to protect the health and safety or not authorized by law, the petitioner will be notified of that determination and the respects in which the petition is deficient and will be accorded an opportunity to submit additional data to correct any deficiency within 90 days of the notification to the petitioner of any deficiency, the petition may be returned to the petitioner without prejudice.

(v) No hearing or rulemaking will be held on the petition unless the Director of the Division of Radiation Control determines that sufficient reason exists, he will initiate rulemaking proceedings as provided in this Rule. In any other case he will deny the petition and will notify the petitioner with a simple statement of denial. The petitioner may appeal the denial pursuant to the appeal provisions of this Rule.

(b) Appeals.

1. All orders, determinations, or denials of the Director, Division of Radiation Control, or of any local Health Departments are appealable to the State Health Officer. All initial determinations, orders, or denials of the State Officer as Agency Director are appealable as described in this section. In addition, this Rule provides for certain informal procedures to resolve contested cases.

2. Any request to appeal an order, determination, or denial shall be filed within 30 days of receiving written notice of such order, determination or denial. Such request should be addressed to:

State Health Officer
Alabama Department of Public Health
Montgomery, Alabama 36130-1701

All appeals should:

(i) For each exception, separately numbered; state concisely, without supporting argument the single error of fact or law which is being asserted in that exception and identify with particularly the portion of the decision, determination, order or denial to which the exception is addressed. A brief in support of the exception(s) should accompany the exception(s). Within 10 days of receiving the request, the Division Staff, and any other party, shall file their response to the petition.

(ii) All documents filed under this section shall be accompanied by a certificate reflecting service upon all parties to the proceeding.

3. Within 5 business days of receiving the Staff's response the State Health Officer shall issue an order designating:

(i) The Hearing Officer and any members of a Hearing Board (such as the Radiation Advisory Board of Health);

(ii) The date, time, and place for the start of the hearing;

(iii) The issues to be resolved;

(iv) And other matters appropriate for such an order, such as contained in Section 12(2) of the Alabama Administrative Procedures Act.

4. The Hearing Officer, or Hearing Board, as appropriate, shall submit their recommendations to the State Health Officer, together with the record of the proceeding as described in Section 12(b) of the Alabama Administrative Procedures Act within 10 business days of the close of the hearing.

5. The State Health Officer after reviewing the r9ecord and the recommendations shall issue an order upholding, denying or modifying the matter being appealed within 5 business days of receiving the recommendations described in paragraph (4) above. This order will be the final order of the Agency unless the State Committee of Public Health, sua sponte, elects to review the order within 30 days of its issuance.

(c) Conduct of Hearings.

1. All adjudicatory hearings shall be conducted in accordance with 10 CFR Part 2 §§2.705; 2.706; 2.707; 2.711; 2.712; except (f); 2.713; 2.714; 2.715; 2.716; 2.718 except (b), (h), (i),(k),(l), and (m); 2.719; 2.730; 2.731; 2.732; 2.733; 2.740; 2.741 except

(e); 2.742; 2.743; 2.750; except (c); 2.753; and 2.757 as in effect July 1, 1989. All references to the Commission, Atomic Safety and Licensing Board, and Presiding Officer, are to be replaced with the Hearing Officer.

2. Documents shall be filed with the State Health Officer or the Hearing Officer in adjudication subject to this Rule, either by (1) delivery to the office of the State Health Officer, in the State Office Building, 501 Dexter Avenue, Montgomery, or (2) U.S. Mail to the State Health Officer, Alabama Department of Public Health, Montgomery, Alabama 36130-1701.

3. All documents offered for filing shall be accompanied by proof of service upon all parties to the proceeding or their attorney of record, the Hearing Officer and Hearing Board members if any.

4. Filing by U.S. Mail will be deemed to be complete as of the time of deposit in the mail with sufficient postage.

5. Parties to all adjudicatory hearings shall consist of the petitioner or appellant, the Division of Radiation Control and such others as may be admitted by the Hearing Officer.

6. Rulemaking and investigatory hearings shall be conducted in accordance with the procedures outlined in the order established in the hearing. The Hearing Officer has the authority to conduct the hearing in an orderly manner and may require the consolidation of statements and close or adjourn the hearing to another day or time in the event the hearing becomes disorderly. In these hearings the Hearing Officer, Hearing Board members, and the Division of Radiological Health may ask questions of witnesses. If appropriate, they may be placed under oath.

(4) Guidance Documents of Division of Radiation Control. From time to time the Division of Radiation Control may prepare instructions, guidance documents, suggested procedures, etc., to assist persons in complying with these rules. These documents are to provide assistance and are not binding on the Board of Health. Further, other methods may be acceptable and will be approved if the rules are otherwise met. The Board of Health's policy for minimum acceptable training, experience and equipment is to be the same as the U.S. Nuclear Regulatory Commission.

(5) The Routing of Radioactive Material Shipments.

(a) Applications for designating a route shall contain sufficient information to make the assessment and determination required by 49 CFR 171.8 in effect July 1, 1989. Copies of this regulation and the associated U.S. Department of Transportation guide "Guidelines for Selecting preferred Highway Routes for Large Quantity Shipments of Radioactive Materials" are available from the Agency.

(b) Upon receiving a routing request (10 copies) with adequate information to make the necessary assessment and determination, when designated by proper delegation of the Agency Director, the Director, Division of Radiation Control shall notify the Alabama Departments of Public Safety, Highway and Emergency Management and any counties and municipalities along the proposed alternate routes of the request.

(c) The Agency Director or the Director, Division of Radiation Control shall also cause a notice to be published in a newspaper of general circulation near the routes under consideration. Such notice shall provide for an investigation hearing to be conducted by the Agency Director or the Director, Division of Radiation Control as the Hearing Officer. Such notice shall provide for receiving written comments and shall indicate the date which comments will be received. This date may be modified at the hearing if appropriate.

(d) Within 30 days of the end written comment period, the Agency Director or the Director, Division of Radiation Control will issue an order with his decision. This order shall briefly detail the basis for the decision. This is appealable as any other initial order by the Agency Director or order or decision of the Director, Division of Radiation Control.

(6) Criteria for Determining Enforcement Action.

(a) A major continuing goal of the Agency is to assure that ionizing radiation source facilities are constructed and operated with the necessary degree of safety and reliability. Similarly, it is the responsibility of the Agency to assure a corresponding degree of management controls and safety in the licensed materials processes and programs.

The nuclear industry generally recognizes the necessity for improvements in safety as well as the economic advantages that are derived by extending the management techniques and philosophy of safety to the operations of plants and processes. It is essential that all registrants and licensees meet these high standards.

While broad sanctions are available to the Agency in the event they are necessary, the objectives of safety and reliability should generally be achievable through augmented internal management programs.

Results of Agency inspections and investigations of licensed activities have shown that registrants and licensees have not in all cases complied with regulatory requirements and it has been necessary to take specific enforcement actions commensurate with the violations. This document sets out the criteria for enforcement actions to be taken with respect to future violations of license conditions relating to health and safety, in accordance with the Alabama Regulations for Control of Radiation and Act 582,

Regular Session 1963, Title 22, Chapter 14, Code of Ala. 1975, as amended.

The enforcement actions available to the Agency in the exercise of its regulatory responsibilities may be divided into the following four basic types which are applicable to specific enforcement situations:

1. Noncompliance Letters.

This is a letter describing the proposed violations and request to reply within usually thirty (30) days. In his reply, the registrant or licensee may:

(i) Deny any or all violations.

(ii) Indicate what corrective measures have been instituted and their effect.

(iii) Indicate proposed corrective actions and the date when compliance will be achieved.

2. Written Notices of Violations.

Enforcement actions may be written notices to registrants or licensees, citing the proposed violations observed during investigations, inspections, or inquiries. This is a formal notice and requires at least a written response.

3. Civil Penalties.

The Agency has authority to assess a civil penalty of radioactive material licensees in cases where the noncompliance is serious or repeated. Appendix A details how and when the civil penalties are determined and how they may be reduced.

4. Orders to Cease and Desist; and Orders for Suspension, Modification or Revocation of a License or to Suspend the Activities of a Registrant.

The Agency has authority to issue orders to "cease and desist," and orders to suspend, modify, or revoke licenses. Such orders are preceded by certain procedural requirements including a written notice of violation to the licensee or registrant providing him with an opportunity to respond as to the corrective measures being taken. In the event the licensee or registrant fails to respond to the notice or to demonstrate that satisfactory corrective action is being taken, an order to show cause may be issued requiring the licensee or registrant to show why the particular order (either of revocation, or modification or suspension) should not be made effective. In those instances where the health, safety, or interest of employees to the public so requires or willful violation of the agency's rules is involved, the notice provision

may be dispensed with and, in addition, the particular order may be made immediately effective pending further order. In addition to proceeding by way of order, the Agency may also, pursuant to §22-14-12, request the Attorney General to obtain an injunction or other court order to enjoin licensees or registrants from violating the Act or any rules or order issued thereunder.

APPENDIX A

GENERAL STATEMENT OF POLICY AND PROCEDURE FOR ENFORCEMENT ACTIONS

The following statement of general policy and procedure explains the enforcement policy and procedures of the Agency and its staff in initiating enforcement actions. This statement is applicable to enforcement in matters involving the public health and safety, and the environment.

(1) Introduction and Purpose. The purpose of the Agency enforcement program is to promote and protect the radiological health and safety of the public, including employees' health and safety, and the environment by:

(a) Ensuring compliance with Agency rules and license conditions or registration commitments;

(b) Obtaining prompt correction of violations and adverse quality conditions which may affect safety;

(c) Deterring future violations and occurrences of conditions adverse to environmental quality; and

(d) Encouraging improvement of licensee or registrant and by example, that of industry, including the prompt identification and reporting of potential safety problems.

Consistent with the purpose of this program, prompt and vigorous enforcement action will be taken when dealing with licensees or registrants who do not achieve the necessary meticulous attention to detail and the high standard of compliance which the Agency expects. Each enforcement action is dependent on the circumstances of the case and requires the exercise of discretion after consideration of these policies and procedures. In no case, however, will licensees or registrants who cannot achieve and maintain adequate levels of protection be permitted to conduct licensed or registered activities.

(2) Procedural Framework. Rule 420-3-26-.13 of these rules sets forth the procedures the Agency uses in exercising its enforcement authority. This rule sets forth the procedures for issuing notices of violation.

The procedure to be used in assessing civil penalties is set forth in 420-3-26-.13(2). This rule provides that the Agency Director or Radiation Control Division Director initiates the civil penalty process by issuing a notice of violation and proposed imposition of a civil penalty. The licensee is provided an opportunity to contest in writing, the proposed imposition of a civil penalty. After evaluation of the licensee's response, the Director may mitigate, remit, or impose the civil penalty. An opportunity is provided for a hearing if a civil penalty is imposed.

The procedure for issuing an order to show cause why a license should not be modified, suspended, or revoked or why such other action should not be taken is set forth in Rule 420-3-26-.13. The mechanism for modifying a license or registration by order is set forth in the same rule. These sections provide an opportunity for a hearing to the affected licensee. However, the Agency is authorized to make orders immediately effective if the public health, safety or interest so requires.

(3) Severity of Violation. Regulatory requirements[31] have varying degrees of safety, safeguards, or environmental significance. Therefore, the relative importance of each violation must be identified as the first step in the enforcement process.

Consequently, violations are categorized in terms of five levels of severity to show their relative importance within each of the following five activity areas:

(a) Health Physics;

(b) Transportation;

(c) Radioactive Materials Operations;

(d) Miscellaneous Matters; and

(e) Emergency Preparedness.

Licensed or registered activities not directly covered by one of the above listed areas, e.g., reciprocity license or

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[31] The term "requirement" as used in this Appendix means a legally binding requirement such as a statute, rule, regulation, license condition, technical specification, or order.

registered activities, will be placed in the activity area most suitable in light of the particular violation involved. Within each activity area, Severity Level I has been assigned to violations that are the most significant and Severity Level V violations are the least significant. Severity Level I and II

violations are of very significant regulatory concern. In general, violations that are included in these severity categories involve actual or high potential impact on the public or an individual. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern; i.e., if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.

Comparisons of significance between activity areas are inappropriate. For example, the immediacy of any hazard to the public associated with Severity Level I violations in nuclear medicine is not directly comparable to that associated with Severity Level I violations in industrial radiography.

While examples are provided in Supplements I through V for determining the appropriate severity level for violations in each of the five activity areas, the examples are neither exhaustive nor controlling. These examples do not create new requirements. Each is designed to illustrate the significance which the Agency places on a particular type of violations of Agency requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement.

In each case, the severity of a violation will be characterized at the level best suited to the significance of the particular violation. In some cases, violations may be evaluated in the aggregate and a single severity level assigned for a group of violations.

The severity level of a violation may be increased if the circumstances surrounding the matter involve careless disregard of requirements, deception, or other indications of willfulness. The term "willfulness" as used here embraces a spectrum of violations ranging from deliberate intent to violate or falsify, to and including careless disregard for requirements. Willfulness does not include acts which do not rise to the level of careless disregard, i.e., inadvertent clerical errors in a document submitted to the Agency. In determining the specific severity level of a violation involving willfulness, consideration will be given to such factors as the position of the person involved in the violation (e.g., first-line supervisor or senior manager), the significance of any underlying violation, the intent of the violator (i.e., negligence not amounting to careless disregard, careless disregard, or deliberateness), and the economic advantage, if any, gained as a result of the violation. The relative weight given to each of these factors in arriving at the appropriate severity level will be dependent on the circumstances of the violation.

The Agency expects licensees or registrants to provide full, complete, timely, and accurate information and reports. Accordingly, unless otherwise categorized in the Supplements, the

severity level of a violation involving the failure to make a required report to the Agency will be based upon the significance of and the circumstances surrounding the matter that should have been reported. A licensee or registrant will not normally be cited for a failure to report a condition or event unless the licensee or registrant was actually aware of the condition or event which it failed to report. However, the severity level of an untimely report, in contrast to no report, may be reduced depending on the circumstances surrounding the matter.

(4) Enforcement Conferences. Whenever the Agency has learned of the existence of a potential violation for which a civil penalty or other escalated enforcement action may be warranted, the Agency will normally hold an enforcement conference with the licensee or registrant prior to taking enforcement action. The Agency may also elect to hold an enforcement conference for other violations, e.g., Severity Level IV violation which, if repeated, could lead to escalated enforcement action. The purpose of the enforcement conference is to:

1. discuss the violations or nonconformance, the significance of each and causes, and the licensee's or registrant's corrective actions;

2. determine whether there are any aggravating or mitigating circumstances; and

3. obtain other information which will help determine the appropriate enforcement action.

In addition, during the enforcement conference, the licensee or registrant will be given an opportunity to explain to the Agency what corrective actions (if any) were taken or will be taken following discovery of the potential violation or nonconformance. Licensees or registrants will be told when a meeting is an enforcement conference. Enforcement conferences will not normally be announced to the public.

When needed to protect the public health and safety, escalated enforcement action, such as the issuance of an immediately effective order modifying, suspending, terminating, or revoking a license or registration, will be taken prior to the enforcement conference. In such cases, an enforcement conference may be held after the escalated enforcement action is taken.

(5) Enforcement Actions. This section describes the enforcement sanctions available to the Agency and specifies the conditions under which each may be used. The basic sanctions are notices of violation, civil penalties, and orders of various types. Additionally, related administrative mechanisms such as bulletins and confirmatory action letters, notices of nonconformance and notices of deviation are used to supplement the enforcement program. In selecting the enforcement sanctions to be applied, the

Agency will consider enforcement actions taken by other Federal or State regulatory bodies having concurrent jurisdiction, such as in transportation matters. With very limited exceptions, whenever a violation of Agency requirements is identified, enforcement action is taken. The nature and extent of the enforcement action is intended to reflect the seriousness of the violation involved. For the vast majority of violations, action by the Radiation Control Division Director is appropriate in the form of a Notice of Violation requiring a formal response from the recipient describing corrective actions. The relatively small number of cases involving elevated enforcement action receives substantial attention by the public, and may have significant impact on the licensee's or registrant's operation. These elevated enforcement actions include civil penalties; orders modifying, suspending, terminating, or revoking licenses or registrations; or orders to cease and desist from designated activities.

(a) Notice of Violation. A notice of violation is a written notice setting forth one or more violations of a legally binding requirement. The notice normally requires the recipient to provide a written statement describing:

1. corrective steps which have been taken and the results achieved;

2. corrective steps which will be taken to prevent recurrence; and

3. the date when full compliance will be achieved.

The Agency may require responses to notices of violation to be under oath. Normally, responses under oath will be required only in connection with civil penalties and orders.

The Agency uses the notice of violation as the standard method for formalizing the existence of a violation. A notice of violation is normally the only enforcement action taken, except in cases where the criteria for civil penalties and orders, as set forth in Sections (5)(b) and (5)(c) respectively, are met. In such cases, the notice of violation will be issued in conjunction with the elevated actions.

Licensees or registrants are not ordinarily cited for violations resulting from matters not within their control, such as equipment failures that were not avoidable by reasonable licensee or registrant quality assurance measures or management controls. Generally, however, licensees or registrants are held responsible for the acts of their employees. Accordingly, this policy should not be construed to excuse personnel errors.

(b) Civil Penalty. A civil penalty applies only to radioactive material licensees and is a monetary penalty that may be imposed for violation of:

1. certain specified licensing provisions of the Section 22-14, Code of Ala. 1975, as amended, or supplementary Agency rule or orders;

2. any requirement for which a license may be revoked.

Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations.

Civil penalties are imposed absent mitigating circumstances for Severity Level I and II violations, are considered for Severity Level III violations, and may be imposed for Severity Level IV violations that are similar
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to previous violations for which the licensee failed to take effective corrective action.

In applying this guidance for Severity Level IV violations, the Agency normally considers civil penalties only for similar Severity Level IV violations that occur after the date of the last inspection or within two years, whichever period is greater.

Civil penalties will normally be assessed for any willful violation of any Agency requirement including those at any severity level.

The Agency imposes different levels of penalties for different severity level violations and different classes of licensees. Tables 1A and 1B show the base civil penalties for various fuel cycle, and materials programs. The structure of these tables generally takes into account the gravity of the violation as a primary consideration and the ability to pay as a secondary consideration. Generally, operations involving greater potential consequences to the public and licensee employees receive higher civil penalties. Regarding the secondary factor of ability of various classes of licensees to pay the civil penalties, it is not the Agency's intention that the economic impact of a civil penalty be such that it puts a licensee out of business (orders, rather than civil penalties, are used when the intent is to terminate licensed activities) or adversely affects a licensee's ability to safely conduct licensed activities. The deterrent effect of civil penalties is best served when the amounts of such penalties take into account a licensee's "ability to pay." In determining the amounts of civil penalties for licensees for whom the tables do not reflect the ability to pay, the Agency will consider as necessary an increase or decrease on a case-by-case basis.

The Agency attaches great importance to comprehensive licensee programs for detection, correction, and reporting of problems that may constitute, or lead to, violation of regulatory requirements. This is emphasized by giving credit for effective licensee audit programs when licensees find, correct, and report problems

expeditiously and effectively. To encourage licensee self-identification and correction of

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32 The word "similar" as used in this Rule, refers to those violations which could have been reasonably expected to have been prevented by the licensee's corrective action.

violations and to avoid potential concealment of problems of safety significance, application of the adjustment factors set forth below may result in no civil penalty being assessed for violations which are identified, reported (if required), and effectively corrected by the licensee.

On the other hand, ineffective licensee programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant Agency identified violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the Agency intends to apply its full enforcement authority where such action is warranted, including issuing appropriate orders and assessing civil penalties for continuing violations on a per day basis, up to the statutory limit of $10,000[331] per violation, per day. In this regard, while management involvement, direct or indirect, in a violation may lead to an increase in the civil penalty, the lack of such involvement may not be used to mitigate a civil penalty.

Allowance of mitigation could encourage lack of management involvement in licensed activities and a decrease in protection of the public health and safety.

The Agency reviews each proposed civil penalty case on its own merits and adjusts the base civil penalty values upward or downward appropriately. Tables 1A and 1B identify the base civil penalty values for different severity levels, activity areas, and classes of licensees. After considering all relevant circumstances adjustments to these values may be made for the factors described in the following table.

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33 $1,000 for qualifying small businesses and nonprofit entities.

TABLE 1A. - BASE CIVIL PENALTIES[1]

Plant	Transportation

	operations const., health physics and EP	**Greater than type A quantity**[2]	**Type A quantity or less**[3]
a. Industrial	$10,000	$10,000	$5,000
Processors[4]	10,000	5,000	2,000
b. Mills & Uranium Conversion Facilities	10,000	5,000	2,000
c. Industrial Users of Material[5]	10,000	5,000	2,000
d. Waste Disposal Licensees	5,000	2,500	1,000
e. Academic or Medical Institutions	1,000	2,500	1,000
f. Other Material Licensees			

1. Prompt Identification and Reporting. Reduction of up to 50% of the base civil penalty may be given when a licensee identifies the violation and promptly reports the

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[1] For qualifying small businesses and nonprofit entities use one-tenth the values listed in the table. Civil penalties only apply to radioactive material licensees.

[2] Includes high level waste, unirradiated fissile material, and any other quantities requiring Type B packaging.

[3] Includes low specific activity waste (LSA), low level waste, Type A packages, and excepted quantities and articles.

[4] Large firms engaged in manufacturing or distribution of byproduct, source, or special nuclear material.

[5] Includes industrial radiographers, nuclear pharmacies, and other industrial users.

violation to the Agency. In weighing this factor, consideration will be given to, among other things, the length of time the violation existed prior to discovery, the opportunity available to discover the violation, the ease of discovery and the promptness and completeness of any required report. No consideration will be given to this factor if the licensee does not take immediate action to correct the problem upon discovery.

2. Corrective Action to Prevent Recurrence.

Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed. Unusually prompt and extensive corrective action may result in reducing the proposed civil penalty as much as 50% of the base value shown in Table 1. On the other hand, the civil penalty may be increased as much as 50% of the base value if initiation of corrective action is not prompt or if the corrective action is only minimally acceptable. In weighing this factor, consideration will be given to, among other things, the timeliness of the corrective action, degree of licensee initiative, and comprehensiveness of the corrective action--such as whether the action is focused narrowly to the specific violation or broadly to the general area of concern.

3. Past Performance. Reduction by as much as 100% of the base civil penalty shown in Table 1 may be given for prior good performance in the general area of concern. On the other hand, the base civil penalty may be increased as much as 100% for prior poor performance in the general area of concern.

In weighing this factor, consideration will be given to, among other things, the effectiveness of previous corrective action for similar problems, overall performance such as prior enforcement history including Severity Level IV and V violations in the area of concern. For example, failure to implement previous corrective

action for prior similar problems may result in an increase in the civil penalty.

4. Prior Notice of Similar Events. The base civil penalty may be increased as much as 50% for cases where the licensee had prior knowledge of a problem as a result of a licensee audit, or specific Agency or industry notification, and had failed to take effective preventive steps.

5. Multiple Occurrences. The base civil penalty may be increased as much as 50% where multiple examples of a particular violation are identified during the inspection period.

The above factors are additive. However, in no instance will a civil penalty for any one violation exceed $10,000 per day.

The duration of a violation may also be considered in assessing a civil penalty. A greater civil penalty may be imposed if a violation continues for more than a day. For example:

(i) If a licensee is aware of the existence of a condition which results in an ongoing violation and fails to initiate corrective action, each day the condition existed may be considered as a separate violation and as such subject to a separate additional civil penalty.

(ii) If a licensee is unaware of a condition resulting in a continuing violation, but clearly should have been aware of the condition or had an opportunity to correct the condition but failed to do so, a separate violation and attendant civil penalty may be considered for each day that the licensee clearly should have been aware of the condition or had an opportunity to correct the condition, but failed to do so.

(iii) Alternatively, whether or not a licensee is aware or should have been aware of a violation that continues for more than one day, the civil penalty imposed for one violation may be increased to reflect the added significance resulting from the duration of the violation.

The Tables and the mitigating factors determine the civil penalties which may be assessed for each violation. However, the focus is on the fundamental underlying causes of a problem for which enforcement action appears to be warranted, the cumulative total for all violations which contributed to or were unavoidable consequences of that problem may be based on the amount shown in the table for a problem of that Severity Level, as adjusted. If an evaluation of such multiple violations shows that more than one fundamental problem is involved, each of which, if viewed independently, could lead to civil penalty action by itself, then separate civil penalties may be assessed for each such fundamental problem. In addition, the failure to make a required report of an event requiring such reporting is considered a separate problem

and will normally be assessed a separate civil penalty, if the licensee is aware of the matter that should have been reported.

TABLE 1B. - BASE CIVIL PENALTIES Applies only to Radioactive Material Licensees

Severity Levelin Table 1A)	**Base civil penalty amount (percent of amount listed**
I	100
II	80
III	50
IV	15
V	5

(c) Orders. An order is a written Agency directive to modify, suspend, terminate, or revoke a license or registration; to cease and desist from a given practice or activity; or to take such other action as may be proper (see 420-3-26-.13). Orders may also be issued in lieu of, or in addition to, civil penalties, as appropriate. Orders may be issued as set forth below.

1. License or Registration Modification Orders are issued when some change in a licensee's or registrant's equipment, procedures, or management controls is necessary.

2. Suspension Orders may be used:

(i) To remove a threat to the public health and safety, or the environment;

(ii) To stop facility construction when;

(I) further work could preclude or significantly hinder the identification or correction of an improperly constructed safety-related system or component, or

(II) the licensee's or registrant's quality assurance program implementation is not adequate to provide confidence that construction activities are being properly carried out;

(iii) When the licensee or registrant has not responded adequately to other enforcement action;

(iv) When the licensee or registrant interferes with the conduct of an inspection or investigation; or

(v) For any reason not mentioned above for which license revocation or registration termination is legally authorized.

Suspensions may apply to all or part of the licensed or registered activity. Ordinarily, a licensed or registered activity is not suspended (nor is a suspension prolonged) for failure to comply with requirements where such failure is not willful and adequate corrective action has been taken.

3. Revocation Orders may be used:

(i) When a licensee or registrant is unable or unwilling to comply with Agency requirements,

(ii) When a licensee or registrant refuses to correct a violation,

(iii) When a licensee or registrant does not respond to a notice of violation where a response was required,

(iv) When a licensee refuses to pay a fee or civil penalty required by Act 82-328, as amended, or

(v) For any other reason for which revocation is authorized under these rules (e.g., any condition which would warrant refusal of a license or registration on an original application).

4. Cease and Desist Orders are typically used to stop an unauthorized activity that has continued after notification by the Agency that such activity is unauthorized.

Orders are made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing on the order is afforded. For cases in which the Agency believes a basis could reasonably exist for not taking the action as proposed, the licensee or registrant will ordinarily be afforded an opportunity to show cause why the order should not be issued in the proposed manner.

(d) Escalation of Enforcement Sanctions. The Agency considers violations of Severity Levels I, II, or III to be serious. If serious violations occur, the Agency will, where necessary, issue orders in conjunction with civil penalties to achieve immediate corrective actions and to deter further recurrence of serious violations. The Agency carefully considers the circumstances of each case in selecting and applying the sanction(s) appropriate to

the case in accordance with the criteria described in Sections (5)(b) and (5)(c) above.

Examples or enforcement actions that could be taken for similar Severity Level I, II, or III violations are set forth in Table 2. The actual progression to be used in a particular case will depend on the circumstances. However, enforcement sanctions will normally escalate for recurring similar violations.

Normally the progression of enforcement actions for similar violations will be based on violations under a single license or registration. When more than one facility is covered by a single license or registration, the normal progression will be based on similar violations at an individual facility and not on similar violations under the same license. However, it should be noted that under some circumstances, e.g., where there is common control over some facet of facility operations, similar violations may be charged even though the second violation occurred at a different facility or under a different license or registration. For example, a survey violation at Unit 2 of a multiunit plant that repeats an earlier violation at Unit 1 might be considered similar.

TABLE 2. - EXAMPLES OF PROGRESSION OF ESCALATED ENFORCEMENT ACTIONS FOR SIMILAR VIOLATIONS IN THE SAME ACTIVITY AREA

UNDER THE SAME LICENSE OR REGISTRATION[a]

	Number of similar violations from the date of the last inspection or within the previous two years (whichever period is greater)		
Severity violation	**1st**	**2nd**	**3rd**
I	(a + b)	(a + b + c)	(d)
II	(a)	(a + b)	(a + b + c)
III		(a)	(a + b)

(e) Enforcement Actions Involving Individuals.

Enforcement actions involving individuals, including licensed users or physicians or registered users, are significant personnel actions, which will be closely controlled and judiciously applied. An enforcement action will normally be taken only when there is little doubt that the individual fully understood, or should have understood, his or her responsibility: knew, or should have known, the required actions: and knowingly, or with careless disregard (i.e., with more than mere negligence), failed to take required actions which have actual or potential safety significance. Most transgressions of individuals at the level of Severity Level III, IV or V violations will be handled by citing only the facility licensee or registrant.

More serious violations, including those involving the integrity of an individual (e.g., lying to the Agency), concerning matters within the scope of the individual's responsibilities, will be considered for enforcement action against the individual. Action against the individual, however, will not be taken if the improper action by the individual was

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[a] Civil penalty, applies only to radioactive material licensees.

[b] Suspension of affected operations until the Radiological Health Branch Director is satisfied that there is reasonable assurance that the licensee or registrant can operate in compliance with the applicable requirements; or modification of the license or registration, as appropriate.

[c] Show cause for modification or revocation of the license or registration, as appropriate.

[d] Further action, as appropriate.

caused by management failures. The following examples of situations illustrate this concept:

1. Inadvertent individual mistakes resulting from inadequate training or guidance provided by the facility licensee or registrant.

2. Inadvertently missing an insignificant procedural requirement when the action is routine, fairly uncomplicated, and there is no unusual circumstance indicating that the procedures should be referred to and followed step-by-step.

3. Compliance with an express direction of management, such as the Shift Supervisor or Plant Manager, resulted in a violation unless the individual did not express his or her concern or objection to the direction.

4. Individual error directly resulting from following the technical advice of an expert unless the advice was clearly unreasonable and the licensed individual should have recognized it as such.

5. Violations resulting from inadequate procedures unless the individual used a faulty procedure knowing it was faulty and had not attempted to get the procedure corrected.

Examples of situations which could result in enforcement actions against individuals include, but are not limited to, violations which involve:

1. Recognizing a violation of procedural requirements and willfully not taking corrective action.

2. Willfully performing unauthorized bypassing or required safety systems.

3. Willfully defeating alarms which have safety significance.

4. Unauthorized abandoning of controls.

5. Inattention to duty such as sleeping or being intoxicated while on duty.

6. Willfully taking actions that violate License or Technical Specification Limiting Conditions for operation or registration commitments.

7. Falsifying records required for Agency regulations or by the facility licensee or registrant.

8. Willfully failing to take "immediate actions" of emergency procedures.

9. Willfully withholding safety significant information rather than making such information known to appropriate supervisory or technical personnel.

Any proposed enforcement action against individuals must be done by the Radiation Control Division Director. The opportunity for an Enforcement Conference with the individual will usually be provided.

Examples of sanctions that may be appropriate against Agency licensed or registered operators are:

1. Issuance of a letter of reprimand to be placed in the operator's license file or registration file,

2. Issuance of a Notice of Violation, and

3. Suspension for a specified period, modification, or revocation of the license or registration authorization.

The sanctions are listed in escalating order of significance.[34] The particular sanction to be used should be determined on a case-by-case basis.

In the case of an unlicensed individual, an Order modifying the facility license to require the removal of the individual from all radioactive material related activities for a specified period of time or indefinitely may be appropriate.

(f) Reopening Closed Enforcement Actions. If significant new information is received or obtained by the

Agency which indicates that an enforcement sanction was incorrectly applied, consideration may be given, dependent on the circumstances, to reopening a closed enforcement action to increase or decrease the severity of a sanction or to correct the record. Reopening decisions will be made on a case-by-case

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34 Except for individuals subject to civil penalties because they are person as defined by Section 22-14 et seq., Code of Ala. 1975, as amended, and are licensed as the named licensee on the licensing document.

basis, are expected to occur rarely, and require the specific approval of the Radiation Control Division Director.

(g) Exercise of Discretion.

1. Because the Agency wants to encourage and support licensee or registrant initiative for self-identification and correction of problems, the Agency will not generally issue a notice of violation for a violation that meets all of the following criteria:

(i) It was identified by the licensee or registrant;

(ii) It fits in Severity Level IV or V;

(iii) It was reported, if required;

(iv) It was or will be corrected, including to prevent recurrence, within a reasonable time; and

(v) It was not a violation that could reasonably be expected to have been prevented by the licensee's or registrant's corrective action for a previous violation.

2. The Agency may also refrain from issuing a Notice of Violation or a proposed civil penalty for violations that meet all of the following criteria:

(i)(I) The Agency has taken significant enforcement action based upon a major safety event contributing to an extended shutdown of a licensee's or registrant's operations or the licensee or registrant is forced into an extended shutdown or work stoppage related to generally poor performance over a long period;

(II) The licensee or registrant has developed and is aggressively implementing during the shutdown a comprehensive program for problem identification and correction; and

(III) Agency concurrence is needed by the licensee or registrant prior to restart.

(ii) Non-willful violations are identified by the licensee or registrant (as opposed to the Agency) as the result of its comprehensive program, or the violations are identified as a result of an employee allegation to the licensee. If the Agency identifies the violation, the Agency should determine whether enforcement action is necessary to achieve remedial action.

(iii) The violations are based upon activities of the licensee or registrant prior to the events leading to the shutdown, and

(iv) The non-willful violations would normally not be categorized as higher than Severity Level III violations under the Agency's Enforcement Policy.

Notwithstanding the above, a civil penalty may be proposed in a case where multiple Severity Level III violations are discovered. This action would be taken when judgment warrants it on the circumstances of the individual case.

(h) Related Administrative Actions. In addition to the formal enforcement mechanisms of notices of violation, civil penalties, and orders, the Agency also uses administrative mechanisms, such as bulletins, information notices, generic letters, notices of deviation, notices of nonconformance and confirmatory action letters to supplement its enforcement program. The Agency expects licenses to adhere to any obligations and commitments resulting from these processes and will not hesitate to issue appropriate orders to licensees or registrants to make sure that such commitments are met.

1. Bulletins, Information Notices and Generic Letters are written notifications to groups of licensees or registrants identifying specific problems and recommending specific actions.

2. Notices of Deviation are written notices describing a licensee's or registrant's failure to satisfy a commitment where the commitment involved has not been made a legally binding requirement. A notice of deviation requests a licensee or registrant to provide a written explanation or statement describing corrective steps taken (or planned), the results achieved, and the date when corrective action will be completed.

3. Confirmatory Action Letters are letters confirming a licensee's agreement to take certain actions to remove significant concerns about health and safety, or the environment.

4. Notices of Nonconformance are written notices describing nonlicensee's or registrant's failures to meet commitments which have not been made legally binding requirements by the Agency. An example is a commitment made in a procurement contract with a licensee or registrant. Notices of Nonconformance request nonlicensees or registrants to provide written explanations or statements describing corrective steps (taken or planned), the results achieved, the dates when corrective actions will be completed, and measures taken to preclude recurrence.

(6) Referrals to the Attorney General. Alleged or suspected criminal violations of Section 22-14 et seq., Code of Ala. 1975, as amended, are referred to the Attorney General for investigation. Such referral does not preclude the Agency from taking other enforcement action under this General Statement of Policy. However, such actions will be coordinated with the Attorney General to the extent practicable.

(7) Inaccurate and Incomplete Information. A violation of the regulations on submitting incomplete and inaccurate information, whether or not considered a material false statement, can result in the full range of enforcement sanctions. The labeling of a communication failure as a material false statement will be made on a case-by-case basis and will be reserved for egregious violations. Violations involving inaccurate or incomplete information or the failure to provide significant information identified by a licensee or registrant normally will be categorized based on the guidance herein in (3) of this Appendix, "Severity of Violations," and in Supplement IV.

The Agency recognizes that oral information may in some situations be inherently less reliable than written submittals because of the absence of an opportunity for reflection and management review. However, the Agency must be able to rely on oral communications from licensee officials concerning significant information. A licensor registrantee or registrant official for purposes of application of the Enforcement Policy means a first line supervisor or above as well as a licensed individual or registered

activity, radiation safety officer, or a person listed on a license or registration as an authorized user of licensed material or registered equipment or activity. Therefore, in determining whether to take enforcement action for an oral statement, consideration may be given to such factors as:

(a) the degree of knowledge that the communicator should have had, regarding the matter, in view of his or her position, training, and experience;

(b) the opportunity and time available prior to the communication to assure the accuracy or completeness of the information;

(c) the degree of intent or negligence, if any, involved;

(d) the formality of the communication;

(e) the reasonableness of Agency reliance on the information;

(f) the importance of the information which was wrong or not provided; and

(g) the reasonableness of the explanation for not providing complete and accurate information.

Absent at least careless disregard, an incomplete or inaccurate unsworn oral statement normally will not be subject to enforcement action unless it involves significant information provided by a licensee or registrant official. However, enforcement action may be taken for an unintentionally incomplete or inaccurate oral statement provided to the Agency by a licensee or registrant official or others on behalf of a licensee or registrant, if a record was made of the oral informantor, and provided to the licensee or registrant thereby permitting an opportunity to correct the oral informantor, such as if a transcript of the communication or meeting summary containing the error was made available to the licensee or registrant and was not subsequently corrected in a timely manner.

When a licensee or registrant has corrected inaccurate or incomplete information, the decision to issue a citation for the initial inaccurate or incomplete information normally will be dependent on the circumstances, including the case of detection of the error, the timeliness of the correction, whether the

Agency or the licensee or registrant identified the problem with the communication, and whether the Agency relied on the information prior to the correction. Generally, if the matter was promptly identified and corrected by the licensee or registrant prior to reliance by the Agency, or before the Agency raised a question about the information, no enforcement action will be taken for the initial inaccurate or incomplete information. On the

other hand, if the misinformation is identified after the Agency relies on it, or after some question is raised regarding the accuracy of the information, then some enforcement action normally will be taken even if it is in fact corrected. However, if the initial submittal was accurate when made but later turns out to be erroneous because of newly discovered information or advance in technology, a citation normally would not be appropriate if, when the new information or advance in technology, a citation normally would not be appropriate if, when the new information became available, the initial submittal was corrected.

The failure to correct inaccurate or incomplete information which the licensee or registrant does not identify as significant normally will not constitute a separate violation. However, the circumstances surrounding the failure to correct may be considered relevant to the determination of enforcement action for the initial inaccurate or incomplete statement. For example, an unintentionally inaccurate or incomplete submission may be treated as a more severe matter if the licensee or registrant later determines that the initial submittal was in error and does not correct it or if there were clear opportunities to identify the error. If information not corrected was recognized by a licensee or registrant as significant, a separate citation may be made for the failure to provide significant information. In any event, in serious cases where the licensee's or registrant's actions in not correcting or providing information raise questions about its commitment to safety or its fundamental trustworthiness, the Agency may exercise its authority to issue orders modifying, suspending, or revoking the license or registration. The Agency recognizes that enforcement determinations must be made on a case-by-case basis taking into consideration the issues described above.

(8) Public Disclosure of Enforcement Actions. In accordance with 420-3-26-.01, all enforcement actions and licensee's or registrant's responses are publicly available for inspection. In addition, press releases are generally prepared for civil penalties and orders. In the case of orders and civil penalties related to violations at Severity Levels I, II, or III, press releases are prepared at the time of the order or the proposed imposition of the civil penalty. Press releases are not normally prepared for Notices of Violation.

(9) Responsibilities. The Director, Division of Radiation Control, as the principal enforcement officer of the Agency, has been delegated the authority to issue notices of violations, civil penalties, and orders. In recognition that the regulation of radiation related activities in many cases does not lend itself to a mechanistic treatment, the Director, Radiological Health Branch must exercise judgment and discretion in determining the severity levels of the violations and the appropriate enforcement sanctions, including the decision to impose a civil penalty and the amount of such penalty, after considering the general

principles of this statement of policy and the technical significance of the violations and the surrounding circumstances.

The State Committee of Public Health will be provided written notification of all enforcement actions involving civil penalties or orders.

SUPPLEMENT I - SEVERITY CATEGORIES

Health Physics 420-3-26-.03[35]

(1) Severity I. - Violations involving for example:

(a) Single exposure of a worker in excess of 25 rems of radiation to the whole body, 150 rems to the skin of the whole body, or 375 rems to the feet, ankles, hands, or forearms;

(b) Annual whole body exposure of a member of the public in excess of 2.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of ten times the limits of 420-3-26-.03(7);

(d) Disposal of licensed material in quantities or concentrations in excess of ten times the limits of 420-3-26-.03(18); or

(e) Exposure of a worker in restricted areas of ten times the limits of 420-3-26-.03(4).

(2) Severity II. - Violations involving for example:

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35 Personnel overexposures and associated violations, incurred during a life-saving effort, will be treated on a case-by-case basis.

(a) Single exposure of a worker in excess of 5 rems of radiation to the whole body, 30 rems to the skin of the whole body, or 75 rems to the feet, ankles, hands or forearms;

(b) Annual whole body exposure of a member of the public in excess of 0.5 rems of radiation;

(c) Release of radioactive material to an unrestricted area in excess of five times the limits of 420-3-26-.03(7);

(d) Failure to make an immediate notification as required by 420-3-26-.03(24)(a)1. and 420-3-26-.03(24)(a)2.;

(e) Disposal of licensed material in quantities or concentrations in excess of five times the limits of 420-3-26-.03(18); or

(f) Exposure of a worker in restricted areas in excess of five times the limits of 420-3-26-.03(4).

(3) Severity III. - Violations involving for example:

(a) Single exposure of a worker in excess of 3 rems of radiation to the whole body, 7.5 rems to the skin of the whole body, or 18.75 rems to the feet, ankles, hands or forearms;

(b) A radiation level in an unrestricted area such that an individual could receive greater than 100 millirem in a one hour period or 500 millirem in any seven consecutive days;

(c) Failure to make a 24-hour notification as required by 420-3-26-.03(24)(b)or an immediate notification required by 420-3-26-.03(24)(a);

(d) Substantial potential for an exposure or release in excess of Rule 420-3-26-.03 whether or not such exposure or release occurs (e.g., entry into high radiation areas in the vicinity of exposed radiographic sources, or operating x-ray equipment without having performed an adequate survey, operation of a radiation facility with a nonfunctioning interlock system);

(e) Release of radioactive material to an unrestricted area in excess of the limits of 420-3-26-.03(7);

(f) Improper disposal of licensed material not covered in Severity Level I or II;

(g) Exposure of a worker in restricted areas in excess of the limits of 420-3-26-.03(4);

(h) Release for unrestricted use of contaminated or radioactive material or equipment which poses a realistic potential for significant exposure to members of the public, or which reflects a programmatic (rather than isolated) weakness in the radiation control program;

(i) Cumulative worker exposure above regulatory limits when such cumulative exposure reflects a programmatic, rather than an isolated weakness in radiation protection;

(j) Conduct of licensee or registrant's activities by a technically unqualified person; or

(k) Significant failure to control licensed material or a registered activity.

(4) Severity IV. - Violations involving for example:

(a) Exposures in excess of the limits of 420-3-26-.03(2) not constituting Severity Level I, II, or III violations;

(b) A radiation level in an unrestricted area such that an individual could receive greater than 2 millirem in a one-hour period or 100 millirem in any seven consecutive days;

(c) Failure to make a 30-day notification required by 420-3-26-.03(25);

(d) Failure to make a follow-up written report as required by 420-3-26-.03(23)(b), and 420-3-26-.10(4); or

(e) Any other matter that has more than minor safety or environmental significance.

(5) Severity V. - Violations that have minor safety or environmental significance.

SUPPLEMENT II - SEVERITY CATEGORIES

Transportation[36]

(1) Severity I. - Violations of NRC transportation requirements involving for example:

(a) Annual whole body radiation exposure of a member of the public in excess of 0.5 rems of radiation; or

(b) Breach of package integrity resulting in surface contamination or external radiation levels in excess of ten times the U.S. Department of Transportation limits.

(2) Severity II. - Violations of Agency transportation requirements involving for example:

(a) Breach of package integrity resulting in surface contamination or external radiation levels in excess of U.S. Department of Transportation requirements;

(b) Surface contamination or external radiation levels in excess of five times U.S. Department of Transportation limits that did not result from a breach of package integrity; or

(c) Failure to make required initial notification associated with Severity Level I or II violations.

(3) Severity III. - Violations of Agency transportation requirements involving for example:

(a) Breach of package integrity;

(b) Surface contamination or external radiation levels in excess of, but less than a factor of five above U.S. Department of Transportation requirements, that did not result from a breach of package integrity;

(c) Any noncompliance with labeling, placarding, shipping paper, packaging, loading, or other requirements that could reasonably result in the following:

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36 Some transportation requirements are applied to more than one licensee involved in the same activity such as a shipper and a carrier. When a violation of such a requirement occurs, enforcement action will be directed against the responsible licensee which, under the circumstances of the case, may be one or more of the licensees involved.

1. Improper identification of the type, quantity, or form of material;

2. Failure of the carrier or recipient to exercise adequate controls; or

3. Substantial potential for personnel exposure or contamination, or improper transfer of material; or

(d) Failure to make required initial notification associated with Severity Level III violations.

(4) Severity IV. - Violations of Agency transportation requirements involving for example:

(a) Package selection or preparation requirements which do not result in a breach of package integrity or surface contamination or external radiation levels in excess of U.S. Department of Transportation requirements; or

(b) Other violations that have more than minor safety or environmental significance.

(5) Severity V. - Violations that have minor safety or environmental significance.

SUPPLEMENT III - SEVERITY CATEGORIES

Radioactive Materials Operations

(1) Severity I. - Violations involving for example:

(a) Radiation levels, contamination levels, or releases that exceed ten times the limits specified in the license;

(b) A system designed to prevent or mitigate a serious safety event not being operable when actually required to perform its design function; or

(2) Severity II. - Violations involving for example:

(a) Radiation levels, contamination levels, or releases that exceed five times the limits specified in the license; or

(b) A system designed to prevent or mitigate a serious safety event being inoperable.

(3) Severity III. - Violations involving for example:

(a) Failure to control access to licensed materials or registered operations for radiation purposes as specified by Agency requirements;

(b) Possession or use of unauthorized equipment or materials in the conduct of licensee or registrant activities which degrades safety;

(c) Use of radioactive material on humans where such use is not authorized;

(d) Conduct licensed or registered activities by a technically unqualified person;

(e) Radiation levels, contamination levels, or releases that exceed the limits specified in the license; or

(f) Medical therapeutic misadministrations.

(4) Severity IV. - Violations involving for example:

(a) Failure to maintain patients hospitalized who have cobalt-60, cesium-137, or iridium-192 implants or to conduct required leakage or contamination tests, or to use properly calibrated equipment;

(b) Other violations that have more than minor safety or environmental significance; or

(c) Failure to report medical diagnostic misadministrations.

(5) Severity V. - Violations that have minor safety or environmental significance.

SUPPLEMENT IV - SEVERITY CATEGORIES

Miscellaneous Matters

(1) Severity I. - Violations involving for example:

(a) Inaccurate or incomplete information[37] which is provided to the Agency;

1. deliberately with the knowledge of a licensee or registrant official that the information is incomplete or inaccurate, or

2. if the information, had or been complete and accurate at the time provided, likely would have resulted in regulatory action such as an immediate order required by the public health and safety.

(b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;

1. incomplete or inaccurate because of falsification by or with the knowledge of a licensee or registrant official, or

2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in regulatory action such as an immediate order required by public health and safety considerations;

(c) Information which the licensee or registrant has identified as having significant implications for public health and safety ("significant information identified by a licensee or registrant") and which is deliberately withheld from the Agency;

(d) Action by senior corporate management in violation of 420-3-26-.10(7)(c) or similar rule against an employee;

(2) Severity II. - Violations involving for example:

(a) Inaccurate or incomplete information which is provided to the Agency;

1. by a licensee or registrant official because of careless disregard for the completeness or accuracy of the information, or

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37 In applying the examples in this supplement regarding inaccurate or incomplete information and records, reference also should be made to the information in (6) of this Appendix.

2. if the information, had it been complete and accurate at the time provided, likely would have resulted in regulatory action such as a show cause order or a different regulatory position.

(b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;

1. incomplete or inaccurate because of careless disregard for the accuracy of the information on the part of a licensee or registrant official, or

2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in regulatory action such as a show cause order or a different regulatory position;

(c) "Significant information identified by a licensee or registrant" and not provided to the Agency because of careless disregard on the part of a licensee or registrant official; or

(d) Action by plant management above first-line supervision in violation of 420-3-26-.10(7)(c) or similar regulations against an employee;

(3) Severity III. - Violations involving for example:

(a) Incomplete or inaccurate information which is provided to the Agency;

1. because of inadequate actions on the part of licensee officials but not amounting to a Severity Level I or II violation, or

2. if the information, had it been complete and accurate at the time provided, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection of a formal request for information;

(b) Incomplete or inaccurate information which the Agency requires be kept by a licensee or registrant which is;

1. incomplete or inaccurate because of inadequate actions on the part of licensee or registrant officials but not amounting to a Severity Level I or II violation, or

2. if the information, had it been complete and accurate when reviewed by the Agency, likely would have resulted in a reconsideration of a regulatory position or substantial further inquiry such as an additional inspection or a formal request for information;

(c) Failure to provide "significant information identified by a licensee or registrant" to the Agency and not amounting to a Severity Level I or II violation; or
(d) Action by first-line supervision in violation of 420-3-26-.010(7)(c) or similar regulations against an employee.

(4) Severity IV. - Violations involving for example:

(a) Incomplete or inaccurate information of more than minor significance which is provided to the Agency but not amounting to a Severity Level I, II, or III violation;

(b) Information which the Agency requires be kept by a licensee or registrant and which is incomplete or inaccurate and of more than minor significance but not amounting to a Severity Level I, II, or III violation; or

(5) Severity V. - Violations involving for example:

(a) Incomplete or inaccurate information which is provided to the Agency and the incompleteness or inaccuracy is of minor significance, or

(b) Information which the Agency requires be kept by a licensee or registrant which is incomplete or inaccurate and the incompleteness or inaccuracy is of minor significance.

SUPPLEMENT V - SEVERITY CATEGORIES

Emergency Preparedness

(1) Severity I. - Violations involving for example:

In a general emergency, licensee failure to promptly

(a) correctly classify the event,

(b) make required notifications to responsible Federal, State, and local agencies, or

(c) respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff).

Severity II. - Violations involving for example:

(a) In a site area emergency, licensee failure to promptly

1. correctly classify the event,

2. make required notifications to responsible Federal, State, and local agencies, or

3. respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or

(b) Licensee failure to meet or implement more than one emergency planning standard involving assessment or notification.

(3) Severity III. - Violations involving for example:

(a) In an alert, licensee failure to promptly

1. correctly classify the event,

2. make required notifications to responsible Federal, State, and local agencies, or

3. respond to the event (e.g., assess actual or potential offsite consequences, activate emergency response facilities, and augment shift staff); or

(b) Licensee or registrant's failure to meet or implement emergency planning standard involving assessment or notification.

(4) Severity IV. - Violations involving for example:

Licensee or registrant's failure to meet or implement any emergency planning standard or requirement not directly related to assessment and notification.

(5)Severity V. - Violations that have minor safetyor environmental significance.

Author:
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-11, 22-14-12, 22-14-13, 41-22-4, 41-22-5, 41-22-6, 41-22-7, 41-22-9, 41-22-11, 41-22-12, 41-22-13, 41-22-14, 41-22-15, 41-22-16, 41-22-17, 41-22-18, 41-22-19.
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420-3-26-.14 Radiation Safety Requirements For Irradiators.

(1) Purpose and Scope.

(a) This rule contains requirements for the use of sealed sources containing radioactive material in irradiators used to irradiate objects or materials using gamma radiation. This rule also contains radiation safety requirements for operating irradiators. The requirements of this rule are in addition to other requirements of these rules. Nothing in this rule relieves the licensee from complying with other applicable federal, state and

local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

(b) The requirements in this rule apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at 1 meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this rule.

(c) The requirements in this rule do not apply to self-contained dry-source-storage irradiators in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel; medical radiology or teletherapy; radiography for the irradiation of materials for nondestructive testing purposes; gauging; or open-field, agricultural irradiations.

(2) Definitions.

(a) "Annually" means at intervals not to exceed one year.

(b) "Doubly encapsulated sealed source" means a sealed source in which the radioactive material is sealed within an inner capsule and that capsule is sealed within an outer capsule.

(c) "Irradiator" means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

(d) "Irradiator operator" means an individual who has successfully completed the training and testing described in 420-3-26-.14(17) and is authorized by the terms of the license to operate the irradiator without a supervisor present.

(e) "Irradiator operator supervisor" means an individual who meets the requirements for an irradiator operator and who physically oversees operation of the irradiator by an individual who is currently receiving training and testing described in 420-3-26-.14(17).

(f) "Panoramic dry-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

(g) "Panoramic irradiator" means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

(h) "Panoramic wet-source-storage irradiator" means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

(i) "Pool irradiator" means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

(k) "Product conveyor system" means a system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

(l) "Radiation room" means a shielded room in which irradiations take place. Underwater irradiators do not have radiation rooms.

(m) "Sealed source" (see definition in 420-3-26-.01(2) (a)95.).

(n) "Seismic area" means any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10%, as designated by the US Geological Survey.

(o) "Underwater irradiator" means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

(3) Start of Construction. The applicant may not begin construction of a new irradiator prior to the submission to the Agency of both an application for a license for the irradiator and any fee required by the applicable state requirement or statute. As used in this part, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparation, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the appropriate state statute, rules, regulations, and orders issued under the appropriate state statute.

(4) Applications for Exemptions. Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives from the requirements of this rule. The Agency will approve the proposed alternatives if the applicant provides

adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

(5) Request for Written Statements. Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Agency's request, submit a written statement to enable the Agency to determine whether the license should be modified, suspended, or revoked.

(6) Performance Criteria for Sealed Sources.

(a) Requirements for sealed sources installed in irradiators after July 1, 1996:

1. Must have been evaluated in accordance with 10 CFR 32.210.

2. Must be doubly encapsulated;

3. Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

4. Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

5. In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in 420-3-26-.14(6)(b) through (g).

(b) Temperature. The test source must be held at -40 C for 20 minutes, 600 C for one hour, and then be subjected to thermal shock test with a temperature drop from 600 C to 20 C within 15 seconds.

(c) Pressure. The test source must be twice subjected for at least five minutes to an absolute external pressure of 2 million newtons per square meter.

(d) Impact. A 2 kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.

(e) Vibration. The test source must be subjected three times for ten minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.

(f) Puncture. A 50 gram weight and pin, 0.3 centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.

(g) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is ten times the minimum cross-sectional dimension of the source.

(7) Access Control.

(a) Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position. Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier. It must not be possible to move the sources out of their shielded position if the door or barrier is open. Opening the door or barrier while the sources are exposed must cause the sources to return promptly to the shielded position. The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources. The control panel lock must be designed so that the key cannot be removed unless the sources have been returned to the shielded position. The doors and barriers must not prevent any individual in the radiation room from leaving.

(b) In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. The alarm must also alert at least one other individual who is on-site of the entry. That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

(c) A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels must activate the alarm described in 420-3-26-.14(7)(b). The monitor may be located in the entrance, normally referred to as the maze, but not in the direct radiation beam.

(d) Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their

shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

(e) Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to the fully shielded position.

(f) Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

(g) Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must have a sign bearing the radiation symbol and the words, "CAUTION (or DANGER) RADIOACTIVE MATERIAL." Panoramic irradiators must also have a sign stating "GRAVE DANGER, VERY HIGH RADIATION AREA", but the sign may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

(h) If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. The requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

(i) Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators or facility management shall have access to keys that operate the personnel access barrier. There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual who is not necessarily on-site but who is prepared to respond or summon assistance.

(10) Shielding.

(a) The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 mrem) per hour at any location 30 centimeters or more from the wall of the room when the sources are exposed. The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than 20 centimeters. Any area where the radiation dose rate exceeds 0.02 millisievert (2 mrem) per hour must be locked, roped off, or posted.

(b) The radiation dose at 30 centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 mrem) per hour when the sources are in the fully shielded position.

(c) The radiation dose rate at 1 meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 mrem) per hour and at 5 centimeters from the shield may not exceed 0.2 millisievert (20 mrem) per hour.

(9) Fire Protection.

(a) The radiation room at a panoramic irradiator must have heat and smoke detectors. The detectors must activate an audible alarm. The alarm must be capable of alerting a person who is prepared to summon assistance promptly. The sources must automatically become fully shielded if a fire is detected.

(b) The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

(10) Radiation Monitors.

(a) Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

(b) Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

(11) Control of Source Movement.

(a) The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the

key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

(b) The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

(c) The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

(d) Each control for a panoramic irradiator must be clearly marked as to its function.

(12) Irradiator Pools.

(a) For licenses initially issued after July 1, 1996, irradiator pools must either:

1. Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination. In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

(b) For licenses initially issued after July 1, 1996, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphon breakers to prevent the siphoning of pool water.

(c) A means must be provided to replenish water losses from the pool.

(d) A visible indicator must be provided in a clearly observable location to indicate if the pool water level is below the normal low water level or above the normal high water level.

(e) Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of 20 microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

(f) A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

(g) If long-handled tools or poles are used in irradiator pools, the radiation dose rate to the operator at the handling areas of the tools may not exceed 0.02 millisievert (2 mrem) per hour.

(13) Source Rack Protection. If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a carrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

(14) Power Failures.

(a) If electrical power at a panoramic irradiator is lost for longer than ten seconds, the sources must automatically return to the shielded position.

(b) The lock on the door of the radiation room of a panoramic irradiator must remain locked in the event of a power failure.

(c) During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

(15) Design Requirements. Irradiators whose construction begins after July 1, 1996, must meet the design requirements of this section.

(a) Shielding. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of 420-3-26-.14(8). If the irradiator will use more than 2 x 1017 becquerels (5 million Ci) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

(b) Foundations. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

(c) Pool integrity. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of 420-3-26-.14(12)(b), and that metal components are metallurgically compatible with other components in the pool.

(d) Water handling system. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of 420-3-26-.14(12)(e). The

system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

(e) Radiation monitors. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by 420-3-26-.14(10)(a). The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under 420-3-26-.14(21)(b)., the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

(f) Source rack. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables, or alternate means of support, will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

(g) Access control. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of 420-3-26-.14(7).

(h) Fire protection. For panoramic irradiators, the licensee shall verify that the number, locations, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

(i) Source return. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if power is lost for more than ten seconds.

(j) Seismic. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as the American Concrete Institute Standard ACI 318-89, "Building Code Requirements for Reinforced Concrete," Chapter 21,

"Special Provisions for Seismic Design," or local building codes, if current.

(k) Wiring. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

(16) Construction Monitoring and Acceptance Testing. The requirements of this section must be met for irradiators whose construction begins after July 1, 1996. The requirements must be met prior to loading sources.

(a) Shielding. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

(b) Foundations. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

(c) Pool integrity. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of 420-3-26- .14(12)(b).

(d) Water handling system. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

(e) Radiation monitors. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by 420-3-26-.14(10)(a). For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet 420-3-26-.14(21)(b). For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by 420-3-26- .14(10)(b).

(f) Source rack. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in 420-3-26-.14(13) are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves that rack from moving product carriers.

(g) Access control. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

(h) Fire protection. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

(i) Source return. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without power.

(j) Computer systems. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when the system is required to be operable.

(k) Wiring. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

(17) Training.

(a) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must be instructed in:

1. The fundamentals of radiation protection applied to irradiators. This must include the differences between external radiation and radioactive contamination, units of radiation dose, dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator;

2. The requirements of these rules and the applicable sections of Rule 420-3-26-.03 and Rule 420-3-26-.10 that are relevant to the irradiator;

3. The operation of the irradiator;

4. Those operating and emergency procedures listed in 420-3-26-.14(18) that the individual is responsible for performing; and

5. Case histories of accidents or problems involving irradiators.

(b) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

(c) Before an individual is permitted to act as an irradiator operator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

(d) The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

1. Changes in operating and emergency procedures since the last review, if any;

2. Changes in regulations and license conditions since the last review, if any;

3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

4. Relevant results of inspections of operator safety performance;

5. Relevant results of the facility's inspection and maintenance checks; and

6. A drill to practice an emergency or abnormal event procedure.

(e) The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that regulations, license conditions, and operating, safety, and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

(f) Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in 420- 3-26-.14(18) that they are expected to perform or comply with, and their proper response to alarms required in this part. Tests may be oral.

(g) Individuals who must be prepared to respond to alarms required by 420-3-26- .14(7)(b). and (i), 420-3-26-.14(9)(a), 420-3-26-.14(10)(a) and (b), and 420-3-26-.14(21)(b) shall be trained and tested on how to respond. Each individual shall be retested at least annually. Tests may be oral.

(18) Operating and Emergency Procedures.

(a) The licensee shall have and follow written operating procedures for:

1. Operation of the irradiator, including entering and leaving the radiation room;

2. Use of personnel dosimeters;

3. Surveying the shielding of panoramic irradiators;

4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

5. Leak testing of sources;

6. Inspection and maintenance checks required by 420-3-26-.14(22);

7. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

8. Inspection of movable shielding required by 420-3-26-.14(7)(h), if applicable.

(b) The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

1. Sources stuck in the unshielded position;

2. Personnel overexposures;

3. A radiation alarm from the product exit portal monitor or pool monitor;

4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

6. A prolonged loss of electrical power;

7. A fire alarm or explosion in the radiation room;

8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area;

9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

10. The jamming of automatic conveyor systems.

(c) The licensee may revise operating and emergency procedures without Agency approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility;

2. The revisions are consistent with the outline or summary of procedures submitted with the license application;

3. The revisions have been reviewed and approved by the radiation safety officer; and

4. The users or operators are instructed and tested on the revised procedures before they are put into use.

(19) Personnel Monitoring.

(a) Irradiator operators shall wear either a film badge or a thermoluminescent dosimeter (TLD) while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The film badge or TLD processor must be accredited by the National Voluntary Laboratory Accreditation Program for high energy photons in the normal and accident dose ranges [see 420-3-26-.03(17)(c)]. Each film badge or TLD must be assigned to and worn by only one individual. Film badges must be processed at least monthly, and TLDs must be processed at least quarterly.

(b) Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of the paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within ñ20% of the true radiation dose.

(20) Radiation Surveys.

(a) A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three years and before resuming operation after addition of

new sources or any modification to the radiation room shielding or structure that might increase dose rates.

(b) If the radiation levels specified in 420-3-26-.14(8) are exceeded, the facility must be modified to comply with the requirements in 420-3-26-.14(8).

(c) Portable radiation survey meters must be calibrated at least annually to an accuracy of ñ20% for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

(d) Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Table II, Column 2 or Table III of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage" of rule 420-3-26-.03.

(e) Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.5 microsievert (0.05 mrem) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.5 microsievert (0.05 mrem) per hour.

(21) Detection of Leaking Sources.

(a) Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six months using a leak test kit or method approved by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the six months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 æCi) of radioactive material and must be performed by a person approved by the Agency, the U. S. Nuclear Regulatory Commission, or an Agreement State, to perform the test.

(b) For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that leak test has been done within the six months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water.

If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours. If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set-point to a higher level if necessary to operate the pool water purification system to clear up contamination in the pool if specifically provided for in written emergency procedures.

(c) If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by an Agency, the Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by an Agency, the Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions. If a pool is contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table II, Column 2, Appendix B of 420-3-26- .03. See 420-3-26-.02(29) for reporting requirements.

(22) Inspection and Maintenance.

(a) The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

1. Operability of each aspect of the access control system required by 420-3-26-.14(7).

2. Functioning of the source position indicator required by 420-3-26-.14(11)(b).

3. Operability of the radiation monitor for radioactive contamination in pool water required by 420-3-26-.14(21)(b) using a radiation check source, if applicable.

4. Operability of the over-pool radiation monitor at underwater irradiators as required by 420-3-26-.14(10)(b).

5. Operability of the product exit monitor required by 420-3-26-. 14(10)(a).

6. Operability of the emergency source return control required by 420-3-26-.14(11)(c).

7. Visual inspection of leak-tightness of systems through which pool water circulates.

8. Operability of the heat and smoke detectors and extinguisher system required by 420-3-26-.14(9), without turning extinguishers on.

9. Operability of the means of pool water replenishment required by 420-3-26-.14(12)(c).

10. Operability of the indicators of high and low pool water levels required by 420-3-26-.14(12)(d).

11. Operability of the intrusion alarm required by 420-3-26-.14(7)(i), if applicable.

12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 420-3-26-.14(13).

14. Amount of water added to the pool to determine if the pool is leaking.

15. Electrical wiring on required safety systems for radiation damage.

16. Pool water conductivity measurements and analysis as required by 420-3-26-.14(23)(b).

(b) Malfunctions and defects found during inspection and maintenance checks must be repaired within time frames specified in the license or license application.

(23) Pool Water Purity.

(a) Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below 20 microsiemens per centimeter under normal circumstances. If pool water conductivity rises above 20 microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

(b) The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below 20 microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

(24) Attendance During Operation.

(a) Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present on site:

1. Whenever the irradiator is operated using an automatic product conveyor system; and

2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

(b) At a panoramic irradiator at which static irradiations with no movement of the product are occurring, a person who has received the training on how to respond to alarms described in 420-3-26-.14(17)(g) must be on site.

(c) At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in 420-3-26-.14(17)(f) and (g). Static irradiations may be performed without a person present at the facility.

(25) Entering and Leaving the Radiation Room.

(a) Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

(b) Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

1. Visually inspect the entire radiation room to verify that no one else is in it; and

2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

(c) During a power failure, the area around the pool of an underwater irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by 420-3-26-.14(10)(b) is operating with backup power.

(26) Irradiation of Explosive or Flammable Materials.

(a) Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

(b) Irradiation of more than small quantities of flammable material with a flash point below 140 F is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Agency. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

(27) Records and Retention Periods. The licensee shall maintain the following records at the irradiator for the periods specified.

(a) A copy of the license, the license conditions, documents incorporated into the license by reference, and amendments thereto until superseded by new documents or until the Agency terminates the license for documents not superseded.

(b) Records of each individual's training, tests, and safety reviews provided to meet the requirements of 420-3-26-.14(17)(a), (b), (c), (d), (f), and (g) until three years after the individual terminates work.

(c) Records of the annual evaluations of the safety performance of irradiator operators required by 420-3-26-.14(17)(e) for three years after the evaluation.

(d) A copy of the current operating and emergency procedures required by 420-3-26-.14(18) until superseded or the Agency terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by 420-3-26-.14(18)(c)3. retained for three years from the date of the change.

(e) Film badge and TLD results required by 420-3-26-.14(19) until the Agency terminates the license.

(f) Records of radiation surveys required by 420-3-26-.14(20) for three years from the date of the survey.

(g) Records of radiation survey meter calibrations required by 420-3-26-.14(20) and pool water conductivity meter calibrations required by 420-3-26-.14(23)(b) until three years from the date of calibration.

(h) Records of the results of leak tests required by 420-3-26-.14(21)(a) and the results of contamination checks required by 420-3-26-.14(21)(b) for three years from the date of each test.

(i) Records of inspection and maintenance checks required by 420-3-26-.14(22) for three years.

(j) Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three years after repairs are completed.

(k) Records of the receipt, transfer and disposal, of all licensed sealed sources as required by Rule 420-3-26-.01 and Rule 420-3-26-.03.

(l) Records on the design checks required by 420-3-26-.14(15) and the construction control checks as required by 420-3-26-.14(16) until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

(m) Records related to decommissioning of the irradiator as required by 420-3-26-.02(26)(i).

(28) Reports.

(a) In addition to the reporting requirements in other parts of these rules, the licensee shall report the following events if not reported under other sections of these rules:

1. Source stuck in an unshielded position.

2. Any fire or explosion in a radiation room.

3. Damage to the source racks.

4. Failure of the cable or drive mechanism used to move the source racks.

5. Inoperability of the access control system.

6. Detection of radiation source by the product exit monitor.

7. Detection of radioactive contamination attributable to licensed radioactive material.

8. Structural damage to the pool liner or walls.

9. Water loss or leakage from the source storage pool, greater than the irradiator pool design parameters submitted by the licensee or applicant.

10. Pool water conductivity exceeding 100 microsiemens per centimeter.

(b) The report must include a telephone report within 24 hours as described in 420-3-26-.02(29)(c)1. and a written report within 30 days as described in 420-3-26-.02(29)(c)2.
Author: David Turberville, Division of Radiation Control, Bureau of Health Care Standards, Alabama Department of Public Health.
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, 22-14-14, 22-2-1, 22-2-2, 22-2-5, 22-2-6.
History: **New Rule:** Filed March 20, 1998; effective April 24, 1998.

420-3-26-.15 **Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.**

(1) **Purpose.** This rule has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material listed in Appendix A to this rule. These requirements provide reasonable assurance of the security of Category 1 or Category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this rule authorizes possession of licensed material.

(2) **Scope.**

(a) This rule applies to any person who, under the provisions of 420-3-26-.15(7) through 420-3-26-.15(22), possesses or uses at any site, an aggregated Category 1 or Category 2 quantity of radioactive material.

(b) This rule applies to any person who, under the provisions of 420-3-26-.15(23) through 420-3-26-.15(28):

1. Transports or delivers to a carrier for transport in a single shipment, a Category 1 or Category 2 quantity of radioactive material; or

2. Imports or exports a Category 1 or Category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

(3) **Definitions.** As used in this rule:

(a) "Access control" means a system for allowing only approved individuals to have unescorted access to the security zone and for

ensuring that all other individuals are subject to escorted access.

(b) "Aggregated" means accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a Category 2 quantity of radioactive material.

(c) "Approved individual" means an individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with 420-3-26-.15(7) through 420-3-26-.15(13) and who has completed the training required by 420-3-26-.15(15)(c).

(d) "Background investigation" means the investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

(e) "Carrier" means a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

(f) "Category 1 quantity of radioactive material" means a quantity of radioactive material meeting or exceeding the Category 1 threshold in Table 1 of Appendix A to this rule. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

(g) "Category 2 quantity of radioactive material" means a quantity of radioactive material meeting or exceeding the Category 2 threshold but less than the Category 1 threshold in Table 1 of Appendix A to this rule. This is determined by calculating the ratio of the total activity of each radionuclide to the Category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a Category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

(h) "Diversion" means the unauthorized movement of radioactive material subject to this rule to a location different from the material’s authorized destination inside or outside of the site at which the material is used or stored.

(i) "Escorted access" means accompaniment while in a security zone by an approved individual who maintains continuous direct visual

surveillance at all times over an individual who is not approved for unescorted access.

(j) "Fingerprint orders" means the orders issued by the U.S. Nuclear Regulatory Commission (NRC) or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to Category 1 and Category 2 quantities of radioactive material or safeguards information-modified handling.

(k) "Local law enforcement agency (LLEA)" means a public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed Category 1 or Category 2 quantity of radioactive material is used, stored, or transported.

(l) "Mobile device" means a piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

(m) "Movement control center" means an operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies, and can request and coordinate appropriate aid.

(n) "No-later-than arrival time" means the date and time that the shipping licensee and receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than 6 hours after the estimated arrival time for shipments of Category 2 quantities of radioactive material.

(o) “Person” means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state or political subdivision or agency thereof, and any legal successor, representative, agent, or agency of the foregoing.

(p) "Reviewing official" means the individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the Category 1 or Category 2 quantities of radioactive materials that are possessed by the licensee.

(q) "Sabotage" means deliberate damage, with malevolent intent, to a Category 1 or Category 2 quantity of radioactive material, a

device that contains a Category 1 or Category 2 quantity of radioactive material, or the components of the security system.

(r) "Safe haven" means a readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

(s) "Security zone" means any temporary or permanent area determined and established by the licensee for the physical protection of Category 1 or Category 2 quantities of radioactive material.

(t) "State" means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(u) "Telemetric position monitoring system" means a data transfer system that captures information by instrumentation and/or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

(v) "Trustworthiness and reliability" are characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access to Category 1 or Category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

(w) "Unescorted access" means solitary access to an aggregated Category 1 or Category 2 quantity of radioactive material or the devices that contain the material.

(4) **Communications.** Except where otherwise specified or covered, all communications and reports concerning these rules may be sent as follows:

Office of Radiation Control
Alabama Department of Public Health
P. O. Box 303017
Montgomery, Alabama 36130-3017

(5) **Interpretations.** Except as specifically authorized by the Agency in writing, no interpretation of these rules by any officer or employee of the Agency other than a written interpretation by Agency legal counsel will be recognized as binding upon the Agency.

(6) **Specific Exemptions.**

(a) The Agency may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of these rules as it determines are authorized by law and will not endanger life or property or the physical protection of radioactive material, and are otherwise in the public interest.

(b) A licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material is exempt from the requirements of 420-3-26-.15(7) through 420-3-26-.15(28). Except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this rule. The licensee shall implement the following requirements to secure the radioactive waste:

1. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

2. Use a locked door or gate with monitored alarm at the access control point;

3. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

4. Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains Category 1 or Category 2 quantities of radioactive material.

Background Investigations and Access Authorization Program

(7) **Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Material.**

(a) General.

1. Each licensee that possesses an aggregated quantity of radioactive material at or above the Category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of this rule.

2. An applicant for a new license and each licensee that would become newly subject to the requirements of this rule upon application for modification of its license shall implement the requirements of this rule, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

3. Any licensee that has not previously implemented the Security Orders or been subject to the provisions of 420-3-26-.15(7) through 420-3-26-.15(13) shall implement the provisions of

420-3-26-.15(7) through 420-3-26-.15(13) before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

(b) General performance objective. The licensee's access authorization program must ensure that the individuals specified in 420-3-26-.15(7)(c)1 are trustworthy and reliable.

(c) Applicability.

1. Licensees shall subject the following individuals to an access authorization program in accordance with 420-3-26-.15(8):

(i) Any individual whose assigned duties require unescorted access to Category 1 or Category 2 quantities of radioactive material or to any device that contains the radioactive material; and

(ii) Reviewing officials.

2. Licensees need not subject the categories of individuals listed in 420-3-26-.15(11)(a)1 through 420-3-26-.15(11)(a)13 to the investigation elements of the access authorization program.

3. Licensees shall approve for unescorted access to Category 1 or Category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to Category 1 or Category 2 quantities of radioactive material.

4. Licensees may include individuals needing access to safeguards information-modified handling under10 CFR Part 73 in the access authorization program under 420-3-26-.15(7) through 420-3-26-.15(13).

(8) **Access Authorization Program Requirements.**

(a) Granting unescorted access authorization.

1. Licensees shall implement the requirements of this rule for granting initial or reinstated unescorted access authorization.

2. Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by 420-3-26-.15(15)(c) before being allowed unescorted access to Category 1 or Category 2 quantities of radioactive material.

(b) Reviewing officials.

1. Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to Category 1 or Category 2 quantities of radioactive materials possessed by the licensee.

2. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath and affirmation certifications to the Agency. The fingerprints of the named reviewing official must be taken by a law enforcement agency, federal or state agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a state to take fingerprints. The licensee shall re-certify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with 420-3-26-.15(9)(c).

3. Reviewing officials must be permitted to have unescorted access to Category 1 or Category 2 quantities of radioactive materials or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling.

4. Reviewing officials cannot approve other individuals to act as reviewing officials.

5. A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(i) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(ii) The individual is subject to a Category listed in 420-3-26-.15(11)(a).

(c) Informed consent.

1. Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of 420-3-26-.15(9)(b). A signed consent must be obtained prior to any reinvestigation.

2. The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

(i) If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that

were not in progress at the time the individual withdrew his or her consent; and

(ii) The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

(d) Personal history disclosure. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this rule is sufficient cause for denial or termination of unescorted access.

(e) Determination basis.

1. The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of this rule.

2. The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of this rule and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

3. The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

4. The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

5. Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

(f) Procedures. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the

notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

(g) Right to correct and complete information.

1. Prior to any final adverse determination, licensees shall provide each individual subject to this rule with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of 1 year from the date of the notification.

2. If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR Part 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data, and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

(h) Records.

1. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

2. The licensee shall retain a copy of the current access authorization program procedures as a record for 3 years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

3. The licensee shall retain the list of persons approved for unescorted access authorization for 3 years after the list is superseded or replaced.

(9) **Background Investigations.**

(a) Initial investigation. Before allowing an individual unescorted access to Category 1 or Category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. The scope of the investigation must encompass at least the 7 years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. The background investigation must include at a minimum:

1. Fingerprinting and an FBI identification and criminal history records check in accordance with 420-3-26-.15(10);

2. Verification of true identity. Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. A licensee shall review official e.g., identification documents (driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with 420-3-26-.15(12). Licensees shall certify in writing that the identification was properly reviewed, and shall maintain the certification and all related documents for review upon inspection;

3. Employment history verification. Licensees shall complete an employment history verification, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent 7 years before the date of application;

4. Verification of education. Licensees shall verify that the individual participated in the education process during the claimed period;

5. Character and reputation determination. Licensees shall complete reference checks to determine the character and

reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this rule must be limited to whether the individual has been and continues to be trustworthy and reliable;

6. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by e.g., the individual (seek references not supplied by the individual); and

7. If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source. .

(b) Grandfathering

1. Individuals who have been determined to be trustworthy and reliable for unescorted access to Category 1 or Category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

2. Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

(c) Reinvestigations. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to Category 1 or Category 2 quantities of radioactive material. The

reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with 420-3-26-.15(10). The reinvestigations must be completed within 10 years of the date on which these elements were last completed.

(10) **Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material.**

(a) General performance objective and requirements.

1. Except for those individuals listed in 420-3-26-.15(11) and those individuals grandfathered under 420-3-26-.15(9)(b), each licensee subject to the provisions of this rule shall fingerprint each individual who is to be permitted unescorted access to Category 1 or Category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to Category 1 or Category 2 quantities of radioactive materials for that individual.

2. The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record, and shall inform him or her of the procedures for revising the record or adding explanations to the record.

3. Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials if:

(i) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

(ii) The previous access was terminated under favorable conditions.

4. Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to Category 1 or Category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this rule, the Fingerprint Orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of 420-3-26-.15(12)(c).

5. Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

(b) Prohibitions.

1. Licensees may not base a final determination to deny an individual unescorted access authorization to Category 1 or Category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(i) An arrest more than 1 year old for which there is no information of the disposition of the case; or

(ii) An arrest that resulted in dismissal of the charge or an acquittal.

2. Licensees may not use information received from a criminal history records check obtained under this rule in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

(c) Procedures for processing of fingerprint checks.

1. For the purpose of complying with this rule, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, Rockville, Maryland 20852-2738, ATTN: Criminal History Program, Mail Stop T- 7D04M, one completed, legible standard fingerprint card (Fonn FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found https://nrc.gov/security/chp.html.

2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to "U.S. NRC." (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by e-mailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the

Licensee Criminal History Records Checks & Firearms Background Check information page at https://www.nrc.gov/security/chp.html and see the link for How do I determine how much to pay for the request?).

3. The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

(11) **Relief from Fingerprinting, Identification, and Criminal History Records Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials.**

(a) Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to Category 1 or Category 2 quantities of radioactive materials:

1. An employee of the NRC or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

2. A Member of Congress;

3. An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

4. The governor of a state or his or her designated state employee representative;

5. Federal, state, or local law enforcement personnel;

6. State Radiation Control Program Directors and State Homeland Security Advisors or their designated state employee representatives;

7. Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under Section 274.i. of the Atomic Energy Act;

8. Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

9. Emergency response personnel who are responding to an emergency;

10. Commercial vehicle drivers for road shipments of Category 1 and Category 2 quantities of radioactive material;

11. Package handlers at transportation facilities such as freight terminals and railroad yards;

12. Any individual who has an active federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that granted the federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material; and

13. Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to Category 1 or Category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

(b) Fingerprinting, and the identification and criminal history records checks required by Section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last 5 years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material. These programs include, but are not limited to:

1. National Agency Check;

2. Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;

3. Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;

4. Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR Part 73;

5. Hazardous Material security threat assessment for hazardous material endorsement to commercial driver’s license under 49 CFR Part 1572; and

6. Customs and Border Protection's Free and Secure Trade (FAST) Program.

(12) **Protection of Information.**

(a) Each licensee who obtains background information on an individual under this rule shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

(b) The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to Category 1 or Category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

(c) The personal information obtained on an individual from a background investigation may be provided to another licensee:

1. Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

2. The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

(d) The licensee shall make background investigation records obtained under this rule available for examination by an authorized representative of the Agency to determine compliance with the regulations and laws.

(e) The licensee shall retain all fingerprint and criminal history records on an individual (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, for 3 years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

(13) **Access Authorization Program Review.**

(a) Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this rule and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall

periodically (at least annually) review the access program content and implementation.

(b) The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(c) Review records must be maintained for 3 years.

Physical Protection Requirements During Use

(14) **Security Program.**

(a) Applicability.

1. Each licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this rule.

2. An applicant for a new license and each licensee that would become newly subject to the requirements of this rule upon application for modification of its license shall implement the requirements of this rule, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material.

3. Any licensee that has not previously implemented the Security Orders or been subject to 420-3-26-.15(14) through 420-3-26-.15(22) shall provide written notification to the Agency at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

(b) General performance objective. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

(c) Program features. Each licensee's security program must include the program features, as appropriate, described in 420-3-26-.15(15) through 420-3-26-.15(21).

(15) **General Security Program Requirements.**

(a) Security plan.

1. Each licensee identified in 420-3-26-.15(14)(a) shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this rule. The security plan must, at a minimum:

(i) Describe the measures and strategies used to implement the requirements of this rule; and

(ii) Identify the security resources, equipment, and technology used to satisfy the requirements of this rule.

2. The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

3. A licensee shall revise its security plan as necessary to ensure the effective implementation of Agency requirements. The licensee shall ensure that:

(i) The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

(ii) The affected individuals are instructed on the revised plan before the changes are implemented.

4. The licensee shall retain a copy of the current security plan as a record for 3 years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for 3 years after the record is superseded.

(b) Implementing procedures.

1. The licensee shall develop and maintain written procedures that document how the requirements of this rule and the security plan will be met.

2. The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall responsibility for the security program.

3. The licensee shall retain a copy of the current procedure as a record for 3 years after the procedure is no longer needed. Superseded portions of the procedure must be retained for 3 years after the record is superseded.

(c) Training.

1. Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned

duties and responsibilities effectively. The training must include instruction in:

(i) The licensee’s security program and procedures to secure Category 1 or Category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

(ii) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Agency requirements;

(iii) The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material; and

(iv) The appropriate response to security alarms.

2. In determining those individuals who shall be trained on the security program, the licensee shall consider each individual’s assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of Category 1 or Category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual’s potential involvement in the security of Category 1 or Category 2 quantities of radioactive material.

3. Refresher training must be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training must include:

(i) Review of the training requirements of 420-3-26-.15(15)(c) and any changes made to the security program since the last training;

(ii) Reports on any relevant security issues, problems, and lessons learned;

(iii) Relevant results of Agency inspections; and

(iv) Relevant results of the licensee’s program review and testing and maintenance.

4. The licensee shall maintain records of the initial and refresher training for 3 years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

(d) Protection of information.

1. Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and

unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

2. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

3. Before granting an individual access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

(i) Evaluate an individual’s need to know the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access; and

(ii) If the individual has not been authorized for unescorted access to Category 1 or Category 2quantities of radioactive material, safeguards information, or safeguards information-modified handling, the licensee must complete a background investigation to determine the individual’s trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in 420-3-26-.15(9)(a)2. through 420-3-26-.15(9)(a)7.

4. Licensees need not subject the following individuals to the background investigation elements for protection of information:

(i) The categories of individuals listed in 420-3-26-.15(11)(a)1. through 420-3-26-.15(11)(a)13.; or

(ii) Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in 420-3-26-.15(9)(a)2. through 420-3-26-.15(9)(a)7., has been provided by the security service provider.

5. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

6. Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access. When a licensee determines that a person no longer needs access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to

the information, the licensee shall remove the person from the approved list as soon as possible, but no later than 7 working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

7. When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

8. The licensee shall retain as a record for 3 years after the document is no longer needed:

(i) A copy of the information protection procedures; and

(ii) The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

(16) **LLEA Coordination.**

(a) A licensee subject to this rule shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

1. A description of the facilities and the Category 1 and Category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this rule; and

2. A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of material.

(b) The licensee shall notify the Agency within 3 business days if:

1. The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

2. The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

(c) The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for 3 years.

(d) The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation

adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

(17) **Security Zones.**

(a) Licensees shall ensure that all aggregated Category 1 and Category 2 quantities of radioactive material are used or stored within licensee established security zones. Security zones may be permanent or temporary.

(b) Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

(c) Security zones must, at a minimum, allow unescorted access only to approved individuals through:

1. Isolation of Category 1 and Category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the Category 1 or Category 2 quantities of radioactive material within a security zone; or

2. Direct control of the security zone by approved individuals at all times; or

3. A combination of continuous physical barriers and direct control.

(d) For Category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

(e) Individuals not approved for unescorted access to Category 1 or Category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

(18) **Monitoring, Detection, and Assessment.**

(a) Monitoring and detection.

1. Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the

event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

2. Monitoring and detection must be performed by:

(i) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

(ii) Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

(iii) A monitored video surveillance system; or

(iv) Direct visual surveillance by approved individuals located within the security zone; or

(v) Direct visual surveillance by a licensee designated individual located outside the security zone.

3. A licensee subject to this rule shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

(i) For Category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

(I) Electronic sensors linked to an alarm; or

(II) Continuous monitored video surveillance; or

(III) Direct visual surveillance.

(ii) For Category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

(b) Assessment. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

(c) Personnel communications and data transmission.For personnel and automated or electronic systems supporting the licensee’s monitoring, detection, and assessment systems, licensees shall:

1. Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

2. Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems. .

(d) Response Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

(19) **Maintenance and Testing.**

(a) Each licensee subject to this rule shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this rule must be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no manufacturer's suggested frequency, the testing must be performed at least annually, not to exceed 12 months.

(b) The licensee shall maintain records on the maintenance and testing activities for 3 years.

(20) **Requirements for Mobile Devices.** Each licensee that possesses mobile devices containing Category 1 or Category 2 quantities of radioactive material must:

(a) Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

(b) For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

(21) **Security Program Review.**

(a) Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this rule and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall, not to exceed 12 months, review the security program content and implementation.

(b) The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

(c) The licensee shall maintain the review documentation for 3 years.

(22) **Reporting of Events.**

(a) The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a Category 1 or Category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Agency by telephone. In no case shall the notification to the Agency be later than 4 hours after the discovery of any attempted or actual theft, sabotage, or diversion.

(b) The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than 4 hours after notifying the LLEA, the licensee shall notify the Agency.

(c) The initial telephonic notification required by 420-3-26-.15(22)(a) must be followed within a period of 30 days by a written report submitted to the Agency. The report must include sufficient information for Agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

Physical Protection in Transit

(23) **Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material.** A licensee transferring a Category 1 or Category 2 quantity of radioactive

material to a licensee of the Agency, NRC, or an Agreement State shall meet the license verification provisions listed below instead of those listed in 420-3-26-.02(18)(e) of these rules:

(a) Any licensee transferring Category 1 quantities of radioactive material to a licensee of the Agency, NRC, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(b) Any licensee transferring Category 2 quantities of radioactive material to a licensee of the Agency, NRC, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

(c) In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a Category 1 shipment the authorized address. The licensee shall keep a copy of the certification. The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

(d) The transferor shall keep a copy of the verification documentation as a record for 3 years.

(24) **Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit.**

(a) For shipments of Category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in 420-3-26-.15(25)(a) and (e); 420-3-26-.15(26); 420-3-26-.15(27)(a)1., (b)1. and (c); and 420-3-26-.15(28)(a), (c), (e), (g), and (h).

(b) For shipments of Category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in 420-3-26-.15(25)(b) through (e); 420-3-26-.15(27)(a)2., (a)3., (b)2., and (c); and 420-3-26-.15(28)(b), (d), (f), (g), and (h). For those shipments of Category 2 quantities of radioactive material that meet the criteria of 10 CFR Part 71.97(b), the shipping licensee shall also comply with the advance notification provisions of 10 CFR Part 71.97.

(c) The shipping licensee shall be responsible for meeting the requirements of this rule unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this rule.

(d) Each licensee that imports or exports Category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in 420-3-26-.15(25)(a)2. and (e); 420-3-26-.15(26); 420-3-26-.15(27)(a)1., (b)1., and (c); and 420-3-26-.15(28)(a), (c), (e), (g), and (h) for the domestic portion of the shipment.

(e) Each licensee that imports or exports Category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in 420-3-26-.15(27)(a)2., (a)3., and (b)2.; and 420-3-26-.15(28)(b), (d), (f), (g) and (h) for the domestic portion of the shipment.

(25) **Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material.**

(a) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 1 quantity of radioactive material outside the confines of the licensee’s facility or other place of use or storage shall:

1. Preplan and coordinate shipment arrival and departure times with the receiving licensee;

2. Preplan and coordinate shipment information with the governor or the governor’s designee of any state through which the shipment will pass to:

(i) Discuss the state’s intention to provide law enforcement escorts; and

(ii) Identify safe havens; and

3. Document the preplanning and coordination activities.

(b) Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 2 quantity of radioactive material outside the confines of the licensee’s

facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

(c) Each licensee who receives a shipment of a Category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

(d) Each licensee, who transports or plans to transport a shipment of a Category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to 420-3-26-.15(25)(b), shall promptly notify the receiving licensee of the new no-later-than arrival time.

(e) The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for 3 years.

(26) **Advance Notification of Shipment of Category 1 Quantities of Radioactive Material.** As specified in 420-3-26-.15(26)(a) and (b), each licensee shall provide advanced notification to the Agency and to the governor of a state, or the governor’s designee, of the shipment of licensed material in a Category 1 quantity, through or across the boundary of the state, before the transport, or delivery to a carrier for transport of the licensed material outside the confines of the licensee’s facility or other place of use or storage.

(a) Procedures for submitting advance notification.

1. The notification must be made to the Agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governors' designees, is available on the NRC website at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Director, Division of Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

2. A notification delivered by mail must be postmarked at least 7 days before transport of the shipment commences at the shipping facility.

3. A notification delivered by any means other than mail must reach the Agency at least 4 days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least 4 days before transport of a shipment within or through the state.

(b) Information to be furnished in advance notification of shipment. Each advance notification of shipment of Category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the Category 1 radioactive material;

2. The license numbers of the shipper and receiver;

3. A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

4. The point of origin of the shipment and the estimated time and date that shipment will commence;

5. The estimated time and date that the shipment is expected to enter each state along the route;

6. The estimated time and date of arrival of the shipment at the destination; and

7. A point of contact, with a telephone number, for current shipment information.

(c) Revision notice.

1. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the state or the governor’s designee and to the Agency.

2. A licensee shall promptly notify the governor of the state or the governor’s designee of any changes to the information provided in accordance with paragraphs 420-3-26-.15(26)(b) and (c)1. The licensee shall also immediately notify the Agency of any such changes.

(d) Cancellation notice. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each state or to the governor’s designee previously notified and to the Agency. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

(e) Records. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for 3 years.

(f) Protection of information. State officials, state employees, and other individuals, whether or not licensees of the Agency, NRC, or another Agreement State, who receive schedule information of the kind specified in 420-3-26-15.(26)(b) shall protect that information against unauthorized disclosure as specified in 420-3-26-.15(15)(d).

(27) **Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment.**

(a) Shipments by road

1. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a Category 1 quantity of radioactive material shall:

(i) Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

(ii) Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

(iii) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(iv) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

(v) Develop written normal and contingency procedures to address:

I. Notifications to the communication center and law enforcement agencies;

II. Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

III. Loss of communications; and

IV. Responses to an actual or attempted theft or diversion of a shipment.

(vi) Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

2. Each licensee that transports Category 2 quantities of radioactive material shall maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

3. Each licensee who delivers to a carrier for transport, in a single shipment, a Category 2 quantity of radioactive material shall:

(i) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(ii) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(iii) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(b) Shipments by rail.

1. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a Category 1 quantity of radioactive material shall:

(i) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in

response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

(ii) Ensure that periodic reports to the communications center are made at preset intervals.

2. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a Category 2 quantity of radioactive material shall:

(i) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and/or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

(ii) Use carriers that maintain constant control and/or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(iii) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

(c) Investigations. Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a Category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of Category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

(28) **Reporting of Events.**

(a) The shipping licensee shall notify the appropriate LLEA and the Agency within 1 hour of its determination that a shipment of Category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment’s last confirmed location. During the investigation required by 420-3-26-.15(27)(c), the shipping licensee will provide agreed upon updates to the Agency on the status of the investigation.

(b) The shipping licensee shall notify the Agency within 4 hours of its determination that a shipment of Category 2 quantities of

radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Agency.

(c) The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a Category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the Agency upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of Category 1 quantities of radioactive material.

(d) The shipping licensee shall notify the Agency as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a Category 2 quantity of radioactive material.

(e) The shipping licensee shall notify the Agency and the LLEA as soon as possible upon recovery of any lost or missing Category 1 quantities of radioactive material.

(f) The shipping licensee shall notify the Agency as soon as possible upon recovery of any lost or missing Category 2 quantities of radioactive material.

(g) The initial telephonic notification required by 420-3-26-.15(28)(a) through (d) must be followed within a period of 30 days by a written report submitted to the Agency. A written report is not required for notifications on suspicious activities required by 420-3-26-.15(28)(c) and (d). The report must set forth the following information:

1. A description of the licensed material involved, including kind, quantity, and chemical and physical form;

2. A description of the circumstances under which the loss or theft occurred;

3. A statement of disposition, or probable disposition, of the licensed material involved;

4. Actions that have been taken, or will be taken, to recover the material; and

5. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

(h) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or

theft within 30 days after the licensee learns of such information.

Records

(29) **Form of Records.** Each record required by this rule must be legible throughout the retention period specified by each Agency rule. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

(30) **Record Retention.** Licensees shall maintain the records that are required by these rules for the period specified by the appropriate rule. If a retention period is not otherwise specified, these records must be retained until the Agency terminates the facility's license. All records related to this rule may be destroyed upon Agency termination of the facility license.

Enforcement

(31) **Inspections.**

(a) Each licensee shall afford to the Agency at all reasonable times opportunity to inspect Category 1 or Category 2 quantities of radioactive material and the premises and facilities wherein the radioactive material is used, produced, or stored.

(b) Each licensee shall make available to the Agency for inspection, upon reasonable notice, records kept by the licensee pertaining to its receipt, possession, use, acquisition, import, export, or transfer of Category 1 or Category 2 quantities of radioactive material.

(32) **Violations.** An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

Appendix A

Category 1 and Category 2 Radioactive Materials Table 1—Category 1 and Category 2 Threshold

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241.....	60	1,620	0.6	16.2
Americium-241/Be....	60	1,620	0.6	16.2
Californium-252.....	20	540	0.2	5.40
Cobalt-60.....	30	810	0.3	8.10
Curium-244.....	50	1,350	0.5	13.5
Cesium-137.....	100	2,700	1	27.0
Gadolinium-153.....	1,000	27,000	10	270
Iridium-192.....	80	2,160	0.8	241.6
Plutonium-238.....	60	1,620	0.6	16.2
Plutonium-239/Be....	60	1,620	0.6	16.2
Promethium-147.....	40,000	1,080,000	400	10,800
Radium-226.....	40	1,080	0.4	10.8
Selenium-75.....	200	5,400	2	54.0
Strontium-90.....	1,000	27,000	10	270
Thulium-170.....	20,000	540,000	200	5,400
Ytterbium-169.....	300	8,100	3	81.0

Note: *Calculations Concerning Multiple Sources or Multiple Radionuclides* The ''sum of fractions'' methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this rule.

I. If multiple sources of the same radionuclide and/or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the Category 1 or Category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this rule apply.

II. First determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed

in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1 R_2 = total activity for radionuclide 2

R_N = total activity for radionuclide n

AR_1 = activity threshold for radionuclide 1

AR_2 = activity threshold for radionuclide 2

AR_N = activity threshold for radionuclide n

$$\sum_{1}^{n}\left[\frac{R_1}{AR_1}+\frac{R_2}{AR_2}+\frac{R_n}{AR_n}\right]\geq 1.0$$

Author: David Allen Turberville
Statutory Authority: Code of Ala. 1975, §§22-14-4, 22-14-6, 22-14-7, 22-14-8, 22-14-9, 22-14-11, 22-14-12, 22-14-13, 22-14-14, 22-2-1, 22-2-2, 22-2-5, 22-2-6.
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