

APA-1

TRANSMITTAL SHEET FOR NOTICE
OF INTENDED ACTION

Control: 335

Department or Agency: Alabama Department of Environmental Management Land
Division - Medical Waste Program

Rule No.: Chapter 335-17-1

Rule Title: General Provisions

Intended Action Amend

Would the absence of the proposed rule significantly harm or
endanger the public health, welfare, or safety? Yes

Is there a reasonable relationship between the state's police
power and the protection of the public health, safety, or welfare? Yes

Is there another, less restrictive method of regulation available
that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly
increasing the costs of any goods or services involved? No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm
that might result from the absence of the proposed rule? NA

Are all facets of the rule-making process designed solely for the
purpose of, and so they have, as their primary effect, the
protection of the public? Yes

Does the proposed action relate to or affect in any manner any
litigation which the agency is a party to concerning the subject
matter of the proposed rule? No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be
accompanied by a fiscal note prepared in accordance with subsection (f) of Section
41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance
with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it
conforms to all applicable filing requirements of the Administrative Procedure
Division of the Legislative Services Agency.

Signature of certifying officer

Jeffery W. Kitchens
Jeffery W. Kitchens

Date

Tuesday, March 18, 2025

REC'D & FILED
MAR 18, 2025
LEGISLATIVE SVC AGENCY

APA-2

ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
LAND DIVISION – MEDICAL WASTE PROGRAM

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Environmental Management

RULE NO. & TITLE: Chapter 335-17-1 General Provisions

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:

Revisions are being proposed to 335-17-1 to update, revise, and clarify definitions and remove outdated language.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:

Comments may be submitted in writing or orally at a public hearing to be held at 2:00 p.m., May 6, 2025, in the ADEM Main Hearing Room, 1400 Coliseum Boulevard, Montgomery, Alabama 36110. Attendance at the hearing is not necessary to present such data, views, arguments, or comments. All comments should be received by 5:00 p.m., May 6, 2025. Written submissions and other inquiries should be directed to: ADEM Hearing Officer, Office of General Counsel, Alabama Department of Environmental Management, P.O. Box 301463, Montgomery, AL 36130-1463 (street address: 1400 Coliseum Boulevard, Montgomery, AL 36110-2400) or by e-mail at hearing.officer@adem.alabama.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Tuesday, May 6, 2025

CONTACT PERSON AT AGENCY:

Lynn T. Roper, 334-271-7728

Jeffery W. Kitchens

Jeffery W. Kitchens

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

**ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT- LAND DIVISION -
MEDICAL WASTE PROGRAM
ADMINISTRATIVE CODE**

**CHAPTER 335-17-1
GENERAL PROVISIONS**

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335-17-1-.01 Purpose.

The purpose of ~~ADEM Administrative Code~~ 335-17 is to establish minimum criteria for the storage, transportation, treatment and disposal of medical wastes under authority of the Alabama Solid Wastes and Recyclable Materials Management Act, Code of ~~Ala.~~Alabama 1975, Section 22-27-1, et seq. ~~335-17 is to comprise all regulations of ADEM dealing with medical waste management.~~

Author: James L. Bryant. Ashley S. Powell.

Statutory Authority: Code of Ala. 1975, §§22-27-9, 22-27-12.

History: New Rule: Filed December 12, 2011; effective January 16, 2012. Amended: Published ; effective .

335-17-1-.02 Definitions.

For the purpose of these rules and regulations, the following words and phrases shall have the meanings ascribed to them in this Rule and as ascribed by law unless the context of the regulations indicate differently.

(1) Act - the "Solid Wastes and Recyclable Materials Management Act", Act No. 151, Regular Session 2008 (formerly the "Solid Waste Disposal Act, Act No. 771 Regular Session, 1969, as amended by Act No. 2247 Regular Session, 1971) Code of Ala.Alabama 1975, §22-27-1 et. seq. ~~the Alabama Solid Wastes and Recyclable Materials Management Act, Code of Ala. 1975, Section 22-27-1, et seq.~~

(2) Animal Waste - carcasses and body parts of animals exposed to human infectious agents as a result of the animal being used for the production and/or testing of biologicals and pharmaceuticals or in research. Bulk blood, blood components and potentially infectious body fluids from these animals shall be treated/handled in the same manner as handled as specified in (b) for human blood and body fluids. All materials discarded from surgical procedures involving these animals which are grossly contaminated with bulk blood, blood components, or body fluids shall be treated as specified for surgical waste.

(3) Bladeable - the physical condition of a sludge or similar waste. Physical conditions include, but are not limited to, the absence of free liquids and of a consistency that can be easily managed by heavy equipment normally utilized at a landfill unit.

(4) Blood and Body Fluids - all human bulk blood, bulk blood components (serum and plasma, for example), and bulk laboratory specimens of blood, tissue, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. Precautions do not apply to feces, nasal secretions, sputum, sweat, tears, urine or vomitus unless they contain visible blood. Free-flowing material or items saturated to the point of dripping liquids containing visible blood or blood components ~~would~~shall be treated/handled as bulk blood and bulk blood components.

(5) Commercial Medical Waste Treatment Facility - a facility, other than an incinerator, used to treat more than 220 pounds of medical waste per month.

(6) Container - any portable device in which a material is stored, transported, treated, disposed of or otherwise handled. The term container, when describing the packaging requirements, does not include items that are classified as medical waste.

(7) Contingency Plan - a document setting out an organized, planned and coordinated course of action to be followed in case of a fire, explosion or release of medical waste which could threaten human health or the environment.

(8) Decontamination - a process of reducing or eliminating the presence of harmful substances, such as infectious agents, so as to reduce the likelihood of disease transmission from those substances.

(9) Department or ADEM - the Alabama Department of Environmental Management as established by Code of Ala. Alabama 1975, §22-22A-4.

(10) Director - the Director of the Alabama Department of Environmental Management, appointed pursuant to Code of Ala. Alabama 1975, §22-22A-4, or his or her designee.

~~(11) Facility - all contiguous land, structures and other appurtenances used for the processing, treatment, storage or disposal of medical waste.~~

~~(12) Facility Structures - any buildings and sheds or utility or drainage lines on the facility.~~

~~(13)~~ Free Liquids - liquids which readily separate from the solid portion of a waste under ambient temperature and pressure as determined by the Paint Filter Test referenced in USEPA Publication SW-846, Method 9095.

~~(14)~~ (12) Generation - the act or process of producing medical waste. Medical waste shall be considered to be generated at the point that waste materials are first discarded or collected.

~~(15)~~ (13) Health Department - an approved county or district health department, including the State Health Department as defined by Code of Alabama 1975, §22-1-1, as amended, and the affected state and county health department.

~~(16)~~ (14) Health Officer - the State Health Officer for the State of Alabama as set out in Code of Alabama 1975, §22-2-8, as provided by law or affected county health officer or his or her designee.

~~(17)~~ (15) Incinerator or Combustion Unit - a device designed to burn that portion of medical waste which will be consumed at temperatures generally ranging 1600 degrees Fahrenheit or over. The unburned residue from an incinerator, including metal, glass, and the like shall be called ashes.

~~(18)~~ (16) Infectious Agent - any organism (such as a virus or a bacterium) that is capable of causing disease or adverse health impacts in humans by invasion and multiplication in body tissues, fluids or secretions.

~~(19)~~ (17) International Biological Hazard Symbol - the symbol that conforms to the design shown in 29 Code of Federal Regulations 1910.1030(g)(1)(i)(B).

~~(20)~~ (18) Medical Waste - A solid waste or combination of solid wastes which because of its infectious characteristics may either cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible or incapacitating reversible illness, or pose a substantial present hazard or potential hazard to human health or the environment when improperly treated, stored, transported, disposed, or otherwise managed.

~~(21)~~ (19) Medical Waste Facility - all contiguous land and structures, other appurtenances, and improvements on the land used for treating, destroying, or storing of medical waste. A facility may consist of several treatment, destruction, or storage units.

~~(22)~~ (20) Medical Waste Generator - a medical facility or person who produces or generates medical waste. The term includes, but is not limited to hospitals, nursing or convalescent facilities, intermediate care facilities, clinics, dialysis clinics, blood banks, dental offices, surgical clinics, medical buildings, health maintenance organizations, home health agencies, physicians offices, laboratories, emergency medical services, veterinary clinics, research and manufacturing facilities, and funeral homes. In the case where more than one person (e.g., doctors with separate medical practices) is located in the same building, each individual business entity is a separate generator. In no case shall a person be classified as a medical waste generator if those wastes are generated from a single-family residential dwelling by someone other than a health care professional.

~~(23)~~ (21) Medical Waste Storage - the containment of medical waste at the generating facility or some alternative place for a temporary or extended period of time at the end of which the waste is treated or stored elsewhere. Placing waste in a container at the point of generation such as a patient's room, operating room, or laboratory would not be considered as storage.

~~(24)~~ (22) Medical Waste Storage Facility - a permitted facility or part thereof at which medical waste is placed in storage. The permitted storage facility includes loading docks and parking areas where shipments of medical waste are held during the normal course of transportation.

~~(25)~~ (23) Medical Waste Transportation - the movement of untreated medical waste after leaving the generator's building to any intermediate transfer points, and finally to the medical waste treatment facility before it can be

disposed of in a landfill unit. The mode of transport may be by air, highway, rail, or water.

~~(26)~~ (24) Medical Waste Transporter - a person engaged in the off-site transportation of medical waste. A medical waste generator who generates less than 220 pounds (100 kilograms) of medical waste per month and transports his/her own waste is exempt from the transporter requirements.

~~(27)~~ (25) Medical Waste Transport Vehicle - a motor vehicle, barge, airplane or rail car used for the transportation of medical waste by any mode. Each cargo-carrying body (trailer, railroad car, etc.) is a separate transport vehicle. A vehicle used to transport less than 220 pounds of medical waste per month is exempt.

~~(28)~~ (26) Medical Waste Treatment - any process, including incineration or steam sterilization, which changes the character or composition of medical waste in order for decontamination to take place. Additional treatment measures may include melting, shredding, grinding, tearing, or breaking, so that it is no longer generally recognizable as medical waste.

~~(29)~~ (27) Medical Waste Treatment Facility - a location at which medical waste is subjected to treatment.

~~(30)~~ (28) Microbiological Waste - discarded cultures and stocks of human infectious agents and associated microbiologicals; human and animal cell cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; waste from the production of biologicals; discarded live and attenuated vaccines; culture dishes and devices used to transfer, inoculate and mix cultures. Only those animal vaccines which are potentially infectious to humans (e.g. Strain 19 Brucellosis Vaccine, Feline Pneumonitis Vaccine, contagious Eczema Vaccine for Sheep, Newcastle Disease Vaccine, Anthrax Spore Vaccine, and Venezuelan Equine Encephalitis Vaccine) shall be considered microbiological waste.

~~(31)~~ (29) Municipal Solid Waste Landfill (MSWLF) - a discrete area of land or an excavation that receives household waste and that is not a land application unit, surface impoundment, injection well, or waste pile. A municipal solid waste landfill may also receive other types of solid wastes, such as commercial solid waste, nonhazardous sludge, ~~conditionally exempt~~ very small quantity generator waste, industrial solid waste, construction/demolition waste, and rubbish. A

municipal solid waste landfill is a sanitary landfill. Such a landfill may be publicly or privately owned.

~~(32)~~ (30) Off-site - not a part of what is defined as on-site.

~~(33)~~ (31) On-site - the same or geographically contiguous property which may be divided by public or private right-of-way. Non-contiguous properties owned by the same person or entity connected by a right-of-way which he controls and to which the public does not have access, is also considered on-site property.

~~(34)~~ (32) Owner - the person(s) who owns a facility or part of a facility.

~~(35)~~ (33) Pathological Waste - all discarded human tissues, organs, and body parts which are removed during surgery, obstetrical procedures, autopsy, laboratory, embalming, or other medical procedures, or traumatic amputation. Extracted teeth are not included in this definition.

~~(36)~~ (34) Permit - written authorization granted to a person by the Department to operate a medical waste facility or to transport medical waste.

~~(37)~~ (35) Permittee - any person possessing a valid permit issued by the Department to manage or transport medical waste. This person is responsible for the overall operation of a medical waste facility or transportation facility.

~~(38)~~ (36) Person - any individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state, any interstate body, or any other private or public legal entity.

~~(39)~~ (37) Responsible Person - the person having direct supervision over and responsibility for the operation of a medical waste facility.

(38) Renal Dialysis Waste - all liquid waste from renal dialysis contaminated with peritoneal fluid or with human blood visible to the human eye. Solid renal dialysis waste is considered medical waste if it is saturated, having the potential to drip or splash regulated blood or body fluids.

~~(40)~~ (39) Sanitary Sewer - any device or system used in the treatment of municipal sewage or industrial waste of a liquid nature. This includes sewers, pipes or other conveyances only if they convey wastewater to a facility providing treatment.

~~(41)~~ (40) Sharps - any used or unused discarded article that may cause punctures or cuts and which has been or is intended for use in animal or human medical care, medical research, or in laboratories utilizing microorganisms. Such waste includes, but is not limited to, hypodermic needles, IV tubing with needles attached, scalpel blades, and syringes (with~~-or-without~~ a needle attached). Items listed above that have been removed from their original sterile containers are included in this definition. Glassware, blood vials, pipettes, and similar items are to be handled as sharps if they are contaminated with blood or body fluids.

~~(42)~~ (41) Special Waste - those wastes requiring specific processing, handling or disposal techniques as determined necessary by the Department which are different from the techniques normally utilized for handling or disposal. Examples of such waste types may include, but are not limited to: mining waste; fly ash; bottom ash; sludges; friable asbestos; industrial waste; liquid waste; large dead animals or large quantities of dead animals and residue, medical waste, foundry waste, petroleum contaminated wastes, municipal solid waste ash, or contaminated soil and water from the cleanup of a spill.

~~(43)~~ (42) Spill - the unplanned, accidental or unpermitted discharge, deposit, injection, leaking, pumping, pouring, emitting, dumping, placing or releasing of solid or medical waste, or materials which when spilled become solid or medical waste, into or on the land, the air or the water.

~~(44)~~ (43) State - the State of Alabama.

~~(45)~~ (44) Surgical Waste - all materials discarded from surgical procedures which are contaminated with human bulk blood, blood components, or body fluids, including but not limited to, disposable gowns, dressings, sponges, lavage tubes, drainage sets, underpads, and surgical gloves. Discarded surgical material is considered medical waste if it is saturated, having the potential to drip or splash regulated blood or body fluids. Extracted teeth are not included in this definition.

Author: James L. Bryant, Ashley S. Powell

Statutory Authority: Code of Ala. 1975, §§22-27-9, 22-27-12.

History: New Rule: Filed December 12, 2011; effective January 16, 2012. **Amended:** Published December 31, 2024; effective February 14, 2025. **Amended:** Published ; effective.

335-17-1-.03 Communications.

All official communications, reports, and correspondence concerning this Division shall be addressed to the ADEM, Land Division, 1400 Coliseum Boulevard, Montgomery, Alabama 36110-2059 or Post Office Box 301463, Montgomery, Alabama 36130-1463.

Author: James L. Bryant

Statutory Authority: Code of Ala. 1975, §§22-27-9, 22-27-12.

History: New Rule: Filed December 12, 2011; effective January 16, 2012.

335-17-1-.04 Penalty For Violations.

No person shall violate any of the provisions of these rules and regulations. Violation of these rules and regulations shall be deemed to be a violation of the Act, Code of ~~Ala.~~Alabama 1975, §§22-27-7 and 22-27-11, and shall be punishable as provided therein or by other applicable penalties which may be more stringent.

Author: James L. Bryant. Ashley S. Powell.

Statutory Authority: Code of Ala. 1975, §§22-27-9, 22-27-12.

History: New Rule: Filed December 12, 2011; effective January 16, 2012. Amended: Published ; effective .

335-17-1-.05 Appeals.

Any person aggrieved by any ruling of the Department with respect to these regulations, has the right of appeal in accordance with procedures established in ~~Division~~335-2 of the ADEM Administrative Code.

Author: James L. Bryant. Ashley S. Powell.

Statutory Authority: Code of Ala. 1975, §§22-27-9, 22-27-12.

History: New Rule: Filed December 12, 2011; effective January 16, 2012. Amended: Published ; effective .

335-17-1-.06 Severability.

The Chapters, Rules, paragraphs and provisions of this Division are severable. Should any portion thereof be ruled unconstitutional or unenforceable by any court, the said ruling

shall not affect any other provisions of this Division not ruled upon.

Author: James L. Bryant

Statutory Authority: Code of Ala. 1975, §§22-27-9, 22-27-12.

History: New Rule: Filed December 12, 2011; effective January 16, 2012.

335-17-1-.07 Reserved.

Author: James L. Bryant. Ashley S. Powell

Statutory Authority: Code of Ala. 1975, §§22-27-9, 22-27-12.

History: New Rule: Filed December 12, 2011; effective January 16, 2012. **Amended:** Published December 31, 2024; effective February 14, 2025.

335-17-1-.08 General.

All medical waste shall be managed in a manner consistent with the requirements of this Division.

Author: James L. Bryant

Statutory Authority: Code of Ala. 1975, §§22-27-9, 22-27-12.

History: New Rule: Filed December 12, 2011; effective January 16, 2012.