ALABAMA STATE COMMITTEE OF PUBLIC HEALTH
ALABAMA DEPARTMENT OF PUBLIC HEALTH
BUREAU OF ENVIRONMENTAL AND HEALTH SERVICE STANDARDS
DIVISION OF LICENSURE AND CERTIFICATION
ADMINISTRATIVE CODE

CHAPTER 420-5-8
INDEPENDENT CLINICAL LABORATORIES

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420-5-8-.01 General.

(1) Legal Authority for Adoption of Rules. Under and by virtue of authority vested in it by the Legislature of Alabama, Code of Ala. 1975, Section 22-21-20, et seq., requiring independent clinical laboratories and health care institutions engaged in offering diagnostic services to be licensed by the Alabama State Board of Health, the State Board of Health does hereby adopt and promulgate the following Rules governing all independent clinical laboratories and all independent physiological laboratories and other related institutions in Alabama, except those operated under the supervision of the Department of Mental Health and those laboratories otherwise exempt by law from licensure. Sections 420-5-8.01, 420-5-8.02, 420-5-8.05, and 420-5-8.06 are applicable to independent physiological laboratories. All sections of these Rules, except section 420-5-8.05 are applicable to independent clinical laboratories.

(2) Definitions. (A list of selected terms often used in connection with these Rules):

(a) "AAC Rule" means Alabama Administrative Code Rule.

(b) "Accredited" means accreditation by a nationally recognized accrediting agency or association as determined by the U.S. Commissioner of Education or the Alabama Department of Public Health.

(c) "Advisory Board." See Section 22-21-27 of the Appendix to these Rules.

(d) "Biophysical Procedures" means procedures wherein specimens which have been removed from the human body are subjected to biophysical determinations.

(e) "Board" or "State Board of Health" means the Alabama State Board of Health.

(f) "Collection Station" means a facility where materials or specimens are withdrawn or collected from patients for subsequent delivery to a clinical laboratory for examination. Physicians' offices are exempted from this definition.

(g) "Director" means any qualified person responsible for administration of technical and scientific operations of a laboratory, including supervision of testing procedures and result reporting.

(h) "Independent Clinical Laboratory" means any laboratory which operates primarily independent of other health care facilities that are licensed by the Alabama State Board of Health, or hospital laboratories that receive and perform reference work from sources outside of the hospital, and performs diagnostic and medical laboratory procedures upon referral. Independent clinical laboratory shall include laboratories operated by blood banks, plasmapheresis banks, radioisotope facilities, specimen collection stations, and laboratories engaged in manufacturing diagnostic test reagents from human whole blood or whole blood derivatives. Federal and State laboratories shall be excluded from these Rules.

(i) "Independent Physiological Laboratory" means any facility or unit, mobile or otherwise, that provides diagnostic physiological services for humans, for example, pulmonary function tests, spirometer, EKG, Holter monitor, EEG, transtelephonic pacemaker analysis, oximetry, diagnostic hearing tests, echo-ultrasound, diagnostic ultra sound, doppler studies, and non-invasive peripheral vascular studies. Facilities that provide ionizing radiation or magnetic resonance imaging only are excluded from this definition. Private physician offices performing diagnostic physiological services exclusively for their patients are excluded from this definition.

(j) "License" means the document issued by the State Board of Health and signed by the State Health Officer. The license shall constitute the authority to receive patients and perform the services included within the scope of these Rules.

(k) "Licensee" means the corporate body or individual to whom the license is issued and upon whom rests the responsibility for compliance with these Rules.

(l) "Licensed Practitioner of the Healing Arts" means a person currently licensed to practice medicine and surgery in the State of Alabama.

(m) "May" indicates permission.

(n) “Mobile Unit” means a laboratory testing unit, either independent clinical or independent physiological, that moves from testing site to testing site, or has a temporary testing location. The mobile unit shall provide the State Board of Health with an Alabama permanent address and an address of the physical location of the home base. The mobile unit must submit to the Board a monthly schedule of hours of operation and of the locations the mobile unit will be performing the procedures.

(o) "Patient" means a person referred to the independent clinical laboratory by and upon the recommendation of a physician.

(p) "Physician" means a person currently licensed to practice medicine in Alabama under the provisions contained in current state statutes.

(q) "Plasmapheresis and Whole Blood Centers" mean facilities which provide a system for collection, processing or storage of human blood and/or its components. Plasmapheresis and whole blood donor centers operating within this state shall obtain a license from the Alabama Department of Public Health. Such plasmapheresis and whole blood donor centers shall be maintained in accordance with the AAC Rule 420-5-8.02, 420-5-8.03(1)(a)(1), 420-5-8.04(1)(a), 420-5-8.04(4), 420-5-8.04(5)(c), and 420-5-8.06.

(r) "Qualifying Adjectives," such as adequate, proper, safe, sufficient, satisfactory, suitable, and substantial mean the degree of propriety or compliance that is being maintained by other independent clinical laboratories in Alabama that currently hold a regular license issued by the State Board of Health.

(s) "Shall" indicates mandatory requirements.

(t) "Supervisor" means any qualified person who, under general supervision of a director, supervises technical personnel, performs tests requiring special scientific skills, and in the absence of the director, is held responsible for proper performance of all laboratory procedures and the reporting of results.

(u) "Technician" means any qualified person who functions under the direct supervision of a director, supervisor, or technologist and performs only those clinical laboratory

procedures which require limited skill, responsibility, and a minimal exercise of independent judgment.

(v) "Technologist" means any qualified person who performs tests which require the exercise of independent judgment and responsibility with supervision by the director or supervisor, in only those specialties or subspecialties in which the person is qualified by education, training, and experience.

(w) "These Rules" means Rules 420-5-8.01 through 420-5-8.06, Chapter 420-5-8, Independent Clinical Laboratories, Alabama Administrative Code.

(x) "Trainee" means any person who is employed to perform services with or without remuneration or for the direct or indirect benefit of a clinical laboratory or owner and is being trained for the category for which he has applied.

(3) Procedures Governing Adoption, Amendment, and Revision of Rules.

(a) Authority. The State Board of Health, with the advice and approval of the Advisory Board defined in Code of Ala. 1975, Section 22-21-27, has the legal authority to adopt reasonable rules governing the operation and conduct of independent clinical laboratories and independent physiological laboratories, and it may amend or rescind any rules previously adopted.

(b) Joint Hearings. All hearings shall be joint hearings set by the State Board of Health and the Advisory Board, at which time any interested member of the public may be heard.

(c) Procedures. In adopting, amending, or rescinding rules, the Board shall follow the provisions of the Alabama Administrative Procedure Act. The effective date of any rules adopted, amended or rescinded shall likewise be governed by the Administrative Procedure Act.

(4) Inspection.

(a) Inspections Required. Each independent clinical laboratory or independent physiological laboratory for which a license has been granted may be inspected by the State Board of Health, or by its authorized representatives at such intervals as the Board may direct.

(b) Information Shall Be Confidential. Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections, and plans of correction submitted in response to those statements of deficiencies, are subject to public disclosure. Information received through other means and reports, other than

statements of deficiencies, shall be deemed to be confidential and shall not be publicly disclosed except in response to a valid subpoena or court order or in proceedings involving the affected facility's license or proceedings involving the license of another facility operated by the same governing authority.

Author: L. O'Neal Green, Patricia E. Ivie, Rick Harris
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420-5-8-.02 The License.

(1) Types of License.

(a) Regular License. A regular license may be issued by the State Board of Health after the board has determined that the independent clinical or physiological laboratory is in substantial compliance with the Rules herein adopted.

(b) Probational license. The State Board of Health may, in its discretion and in lieu of license revocation, issue a probational license to a facility when inspection shows that the maintenance and operation of the facility are such that the independent clinical laboratory or independent physiological laboratory no longer substantially complies with the rules adopted herein. However, the Board may issue a probational license only after determining that the health and safety of patients are adequately protected despite non-compliance, and that the facility has submitted an adequate written plan to correct the non-compliance in a timely manner. Maximum length of time for probational status is one year.

(c) Downgrade or Revocation of License. The State Board of Health is authorized to downgrade or revoke a license for any of the following reasons:

1. Violation of any of the provisions of these Rules.

2. Permitting, aiding or abetting the commission of any illegal act in such institution.

3. Conduct or practices deemed by the State Board of Health to be detrimental to the welfare of the patients.

(2) Application.

(a) Application. An application for license or renewal of license shall be made on forms provided by the State Board of

Health and shall contain such information as the Board my require.

(b) Fee. Each application for license shall be accompanied by a fee as mandated by statute. No fee shall be refunded. Fees shall be paid by cash, check or money order made payable to the Alabama Department of Public Health.

(3) Licensing.

(a) Issuance of License. The license shall be issued by the State Board of Health. It shall set forth the name and physical location in Alabama of the independent clinical laboratory or independent physiological laboratory.

(b) Separate Licenses. A separate license shall be required for each independent clinical laboratory or independent physiological laboratory when more than one independent clinical laboratory or independent physiological laboratory is operated under the same management; however, separate licenses are not required for separate buildings on the same grounds used by the same independent clinical laboratory or independent physiological laboratory.

(4) Right of Review. Whenever a license is denied or revoked, the applicant or licensee will be afforded an opportunity for a hearing in accordance with the requirements for contested case proceedings under the Alabama Administrative Procedures Act, Code of Ala. 1975, §41-22-17, and Chapter 420-1-3 of the Alabama Administrative Code.

(a) Research Projects. Any licensee who is, or contemplates being, engaged in a bona fide research program which may be in conflict with one or more specific provision(s) of these Rules, may make application for waiver of the specific provisions in conflict. Application for waiver shall be made in writing to the Licensure Advisory Board who shall, upon completion of its investigation, send its findings, conclusions, and recommendations to the State Board of Health for final action.

(b) Reissuing of License. See Section 22-21-25 of Appendix.

(5) Disclosure of Information. Disclosure of Information received by State Board of Health. Official reports, such as statements of deficiencies generated by the State Board of Health as a result of on-site inspections, and plans of correction submitted in response to those statements of deficiencies, are subject to public disclosure. Information received through other means and reports, other than statements of deficiencies, shall be deemed to be confidential and shall not be publicly disclosed except in response to a valid subpoena or court order or in proceedings involving the affected facility's license or proceedings involving

the license of another facility operated by the same governing authority.
Author: L. O'Neal Green, Patricia E. Ivie, Rick Harris
Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.
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420-5-8-.03 Personnel Qualifications.

(1) Director.

(a) A director shall meet one of the following requirements:

1. Is a physician licensed to practice medicine in Alabama with at least two years of pertinent laboratory experience.

2. Holds an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject, and

(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, or other national accrediting boards with equivalent standards accepted by the State Health Department in one of the laboratory specialties and may direct only that division or subspecialty for which he is certified, or

(ii) Has four or more years of general clinical laboratory training and experience, of which at least two years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory, under a director at the doctoral level, of a hospital, a health department, a university or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health.

(2) Supervisor.

(a) A supervisor shall meet one of the following requirements:

1. Is a physician licensed to practice medicine in Alabama and has had at least two years of pertinent laboratory experience; or

2. Has earned a doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject and has had at least two

years experience in one of the laboratory specialties in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

3. Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and has had at least four years of pertinent laboratory experience of which not less than two years has been spent working in one of the laboratory specialties in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

4. Holds a bachelor's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and has had at least six years of pertinent laboratory experience of which not less than two years has been spent working in one of the laboratory specialties in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

5. Successful completion of three years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university with a chemical, physical, or biological science as a major subject and meets the requirements of a technologist under AAC Rule 420-5-8.03(3) and has at least six years of experience in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health.

6. Achieve a satisfactory grade on a proficiency examination for technologists approved by the United States Secretary of Health and Human Services and have six years of full-time laboratory experience obtained after passing the examination.

(b) An exception in AAC Rule 420-5-8.03(2) may be made when emergencies arise outside regularly scheduled hours of duty, an individual who qualifies as a supervisor is not required to be on the premises provided that the technologist performing tests is qualified to perform such tests, the supervisor who is responsible for the results of the work reviews them during the next duty period, and a record is maintained to reflect the actual review.

(3) Technologist.

(a) A technologist shall meet one of the following requirements:

1. Successful completion of a full course of study which meets academic requirements for a bachelor's degree in medical technology from an accredited college or university; or

2. Successful completion of three years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university which meets the requirements for entrance into and the successful completion of a course of training of at least 12 months in a school of medical technology approved by the Council on Medical Education and Hospitals of the American Medical Association; or

3. Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical, or biological sciences and at least one year of pertinent laboratory experience or training covering the specialties or subspecialties in which tests are performed, provided the combination has given the individual the equivalent in those specialties or subspecialties of the education and training described in AAC Rule 420-5-8.03(3)(a)1, and 2.

4. Successful completion of three years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university with a chemical, physical, or biological science as a major subject and at least one year of experience in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

5. Achieve a satisfactory grade on a proficiency examination approved by the United States Secretary of Health and Human Services.

(4) Technician.

(a) A technician shall meet one of the following requirements:

1. Successful completion of two years of academic study (a minimum of 60 semester hours or equivalent) in an accredited college or university and have an associate's degree in Medical Technology; or

2. Graduation from high school and subsequent to graduation has had two years of experience as a technician trainee in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health; or

3. Graduation from high school and successful completion of an official military laboratory procedures course of at least 12 calendar months of study and has had at least one year of experience as a technician trainee in a clinical laboratory of a hospital, a health department, a university, or a medical research institution or in a clinical laboratory providing equivalent training accepted by the Alabama Department of Public Health.

(b) No clinical laboratory technician performs procedures in the absence of a qualified clinical laboratory technologist, supervisor, or director.

(5) Supervisor, Cytotechnologist. If the laboratory performs only anatomical procedures, a cytotechnologist meeting qualifications under AAC Rule 420-5-8.03(6) and having four years of experience as a cytotechnologist may supervise other cytotechnologists and histotechnicians.

(6) Cytotechnologist.

(a) Cytotechnologists shall meet one of the following requirements:

1. Has successfully completed two years in an accredited college or university with at least 12 semester hours in science, 8 hours in biology, and

(i) has had 12 months of training in a school of cytotechnology accredited by an accrediting agency and approved by the State, or

(ii) has received six months of formal training in a school of cytotechnology accredited by an accrediting agency and six months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal six months of training, or

2. Prior to January 1, 1969, has:

(i) been graduated from high school,

(ii) completed six months of training in cytotechnology in a laboratory directed by a

pathologist or other physician recognized as a specialist in cytology, and

(iii) completed two years of full-time supervised experience in cytotechnology, or

3. Achieved a satisfactory grade in a proficiency examination approved by the United States Secretary of Health and Human Services; however, after December 31, 1977, initial certification as a cytotechnologist must be in accordance with AAC Rule 420-5-8.03(6)(a)1, or 2.

(7) Technician Trainee.

(a) A "technician trainee" shall mean an employee who is a high school graduate or equivalent, who is gaining the required two years of clinical laboratory on-the-job experience to qualify as a technician, and who is participating in a structured training program approved by the State Health Department and designed to provide the trainee with a broad range of laboratory procedures of progressive technical difficulty.

(b) A technician trainee performs only repetitive procedures which require a minimal exercise of independent judgment and may perform such procedures only under the personal and direct supervision of a qualified supervisor or technologist.

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420-5-8-.04 Management.

(1) Personnel.

(a) The laboratory shall be under the direction of a director and shall provide the number of other qualified personnel commensurate with the volume and type of tests performed.

(b) The laboratory shall perform only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director, supervisors, or persons engaged to perform tests are qualified.

(c) The laboratory may perform laboratory procedures and tests in all specialties provided that the director or supervisor is a pathologist certified or eligible for certification in both anatomical and clinical pathology by the American Board of Pathology or American Osteopathic Board of Pathology.

(d) In circumstances where AAC Rule 420-5-8.04(1)(c) is not met, the following criteria shall be used to establish qualifications of laboratory personnel to perform each specialty:

1. Microbiology, including serology - The laboratory engages the services of an individual who holds an earned doctoral degree or master's degree in microbiology from an accredited institution or is a licensed practitioner of the healing arts with two years of experience in microbiology.

2. Hematology - The laboratory engages the services of an individual who holds a master's or bachelor's degree in biology, immunology or microbiology from an accredited institution and has had at least four years experience in hematology or is a licensed practitioner of the healing arts with pertinent experience.

3. Immunohematology - The laboratory engages the services of a licensed physician with specific experience in this field or an individual with a master's or bachelor's degree in biology, immunology or microbiology from an accredited institution and has four years of experience in immunohematology.

4. Chemistry - The laboratory engages the services of an individual who holds an earned doctoral degree or master's degree in chemistry or biochemistry from an accredited institution or is a licensed practitioner of the healing arts with two years experience in clinical chemistry.

5. Histopathology - The laboratory engages the services of a licensed practitioner in the healing arts who is certified in anatomic pathology or is eligible for certification by the American Board of Pathology or the American Board of Osteopathic Pathology or possesses qualifications which are equivalent to those required for certification by these Boards.

6. Cytotechnology - The laboratory engages the services of a licensed practitioner of the healing arts who is certified in anatomic pathology or is eligible for certification by the American Board of Pathology or the American Osteopathic Board of Pathology or is certified by the American Society of Cytology to practice cytopathology or who possesses qualifications which are equivalent to those required for certification by these Boards.

(2) Operation.

(a) Equipment shall be provided and maintained for the proper performance of the specialties and volume of service offered.

(b) The laboratory shall be in compliance with all state and local laws and regulations including those relating to construction and sanitary conditions and also including the handling and disposal of specimens.

(3) Administration and Organization.

(a) The director shall serve the laboratory full time or on a regular part-time basis and shall be readily available for personal or telephone consultations.

(b) If the director is not in attendance throughout normal periods of operation, at least one clinical laboratory supervisor shall be available and on the premises.

(c) The licensee shall be responsible for the proper maintenance and conduct of the laboratory.

(4) Procedures and Equipment.

(a) All technical procedures employed in the laboratory shall be the standard procedures which are generally accepted by leading authorities in microbiology, serology, chemistry, hematology, immunohematology, biophysics, cytotechnology, and histopathology as applicable or are equivalents approved by the Alabama Department of Public Health.

(b) There shall be quality control procedures in effect, including the use of reference and control sera and other biological samples, calibrating standards, and control charts.

(c) All equipment shall be in good working order, routinely checked and calibrated, and documentation of checks and calibrations shall be maintained.

(d) Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall be cleaned and sterilized prior to each use. Each sterilizing cycle shall contain an indicator device which assures proper sterilization.

(e) A specimen received by a laboratory shall not be tested or reported if:

1. The apparent condition of the specimen indicates that it is unsatisfactory for testing or that it is inappropriate for the test requested.

2. It has been collected, labeled, preserved, or otherwise handled in such a manner that it has become unsatisfactory or unreliable as a test specimen.

3. It is perishable and the time lapse between the collection of the specimen and its receipt by the laboratory is of such duration that the test finding may no longer be reliable.

4. When a specimen is not tested for any of the reasons specified in AAC Rule 420-5-8.04(4)(e), the laboratory shall promptly notify the sender and give the reason therefore.

(f) Notebooks or manuals containing appropriate current laboratory methods shall be maintained.

(5) Records and Reports.

(a) All changes in clinical laboratory personnel shall be reported to the Alabama Department of Public Health initially and annually at time of licensing.

(b) Modifications of facilities or services affecting the operation of the laboratory shall be reported to the Alabama Department of Public Health annually at the time of licensing.

(c) The laboratory shall participate in one or more of the proficiency testing programs offered by state or private organizations approved by the Alabama Department of Public Health. The results of such programs shall be made available to the Alabama Department of Public Health for review upon request. Proficiency testing is not required for CLIA waived tests as published by the U.S. Food and Drug Administration at http://www.fda.gov.

(d) Records shall be maintained on each specimen received for testing and shall contain the following information:

1. Laboratory number or other identification of the specimen.

2. Name and other identification of the person from whom the specimen was taken.

3. Name and address of the licensed practitioner of the healing arts or other authorized person or clinical laboratory that submitted the specimen.

4. Date the specimen was collected.

5. Condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed, turbid).

6. Date the specimen was received.

7. Date the specimen was tested.

8. Type of test performed.

9. Complete information as to the disposition of the specimen when it has been referred to another laboratory for examination.

10. Result of test and date of reporting.

(e) The laboratory director is responsible for laboratory reports and the following records shall be maintained:

1. Tissue pathology reports utilizing acceptable terminology of a recognized system of disease nomenclature.

2. Duplicate copies of laboratory reports shall be filed in the laboratory or stored in a readily accessible location for at least two years.

3. Records and reports of examinations of all specimens shall be treated as confidential information.

(6) Collection Stations.

(a) Clinical laboratories operating collection stations within this state shall obtain a license from the Alabama Department of Public Health for each collection station. Such collection stations shall be maintained in accordance with the following requirements:

1. A refrigerator which maintains a temperature of 40-50 degrees F. shall be available on the premises for storage of specimens.

2. Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall be clean and sterile prior to use. Each sterilizing cycle shall contain an indicator device which assures proper sterilization.

3. Laboratory tests shall not be performed at collection stations.

4. Records shall be maintained indicating the daily accession of specimens containing the following information:

(i) Name and other identification of the person from whom specimen was obtained.

(ii) Name and address of the licensed practitioner of the healing arts or other authorized person or clinical laboratory who submitted the specimen.

(iii) Date the specimen was collected.

(iv) Date the specimen was received.

(v) Type of test requested.

(vi) Name and address of referring laboratory or authorized person.

(b) Procedure manuals relating to the procedures performed by the collection station shall be maintained in laboratories and collection stations.

(7) Plasmapheresis and Whole Blood Donor Centers.

(a) Methods shall be provided for the selection of donors and for the collection, storage, processing and transfusion, which shall ensure as far as possible that: 1) the donation is not detrimental to the donor, and, 2) the recipient of the donated human blood or any of its components is protected from exposure to infectious diseases known to be transmissible by blood.

(b) Written policies and procedures shall conform to the current edition of the American Association of Blood Banks' Standards for Blood Banks and Transfusion Services. Copies of this reference may be purchased from: American Association of Blood Banks, 1117 North 19th Street, Suite 600, Arlington, Virginia 22209, telephone number 1-703-528-8200, or may be inspected at the office of the Alabama Department of Public Health, Division of Licensure and Certification, Laboratory Section, Montgomery, Alabama.

(c) Personnel Requirements.

1. Director shall meet at least the requirements specified in AAC Rule 420-5-8.03(1)(a)(1) and shall be responsible at all times for all phases of operation.

2. Donor Selection (Screening Area).

(i) This area shall be staffed with at least one person with no lesser qualifications than that of a Licensed Practical Nurse (LPN), Clinical Laboratory Technician (MLT), or equivalent level of training or experience (approved by the Alabama Department of Public Health). Said qualified person shall be assigned the responsibility for supervision of all activities of the donor screening area (including

such laboratory procedures as total serum protein, urine dipstick tests, hemoglobin and hematocrit testing).

(ii) Every person employed in the screening area shall receive ongoing continuing or in-service education to enable him to recognize abnormalities that could make it detrimental to the donor to donate (i.e., problem with blood pressure, pulse, etc.) and to conduct careful evaluations of donor suitability in accordance with the outline for donor selection published by the American Association of Blood Banks. Documentation of the continuing or in-service education for each donor screening employee shall be available for review by the Alabama Department of Public Health.

3. Phlebotomy Area.

(i) Phlebotomists shall be persons who have a minimum of one month's training in a plasmapheresis or blood donor center.

(ii) A phlebotomist shall be employed for the care of each four (or fraction of four) donors being processed at one time.

(iii) The phlebotomy area shall be supervised by a person with no lesser qualifications than that of a Licensed Practical Nurse (LPN), Clinical Laboratory Technician (MLT), or equivalent level of training and/or experience (approved by the Alabama Department of Public Health). Said supervisor shall be certified in cardiopulmonary resuscitation (CPR) annually. It is permissible for one qualified person to supervise both the donor screening area and the phlebotomy area.

4. Plasmapheresis or Whole Blood Donor Testing Centers. Plasmapheresis or Whole Blood Donor Centers that perform any laboratory procedures other than screening procedures such as total serum protein, urine dipstick, hemoglobin and hematocrit testing, must comply with all provisions of the Alabama Administrative Code (AAC), Chapter 420-5-8, Rules of the Alabama State Board of Health for Independent Clinical Laboratories and Independent Physiological Laboratories.

5. Other Personnel. Aides, clerks, volunteer workers, etc., may be employed in the center but shall not perform technical duties.

(d) Proficiency Testing Requirements. The center shall participate in one or more of the proficiency testing programs approved by the Alabama Department of Public Health. The results of such programs shall be made available to the Alabama Department of Public Health for review.

(e) Quality Control Requirements. Quality control requirements shall be in accordance with AAC 420-5-8.04(4)(b).

(f) Documentation of Reactions.

1. The facility shall maintain a records system documenting all reactions.

2. Adequate reporting and recording forms shall be available and utilized.

Author: L. O'Neal Green, Patricia E. Ivie, Rick Harris, W. T. Geary, Jr., M.D.
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420-5-8-.05 Requirements For Independent Physiological Laboratories.

(1) Each independent physiological laboratory must have a governing body responsible for the management, control and operation of the facility. Said governing body is responsible for employing a qualified person to serve as the laboratory's medical director. Any change in the appointment of the laboratory's medical director must be promptly reported to the State Board of Health. Correspondence and inquiries from the State Board of Health will be directed to the medical director, and the medical director is responsible for responding to same.

(2) Each independent physiological laboratory is required to maintain a permanent facility in Alabama where its records are kept. Any changes in the location of this facility must be submitted to this office for approval, prior to relocating.

(3) Each independent physiological laboratory shall employ or have under contract a physician who serves as the medical director of the laboratory. Said medical director must be a physician licensed to practice in Alabama. The medical director's duties are as follows:

(a) The medical director must provide written certification that each of the employees of the laboratory who perform diagnostic testing or services are appropriately trained and

qualified to perform same. Such written certification, along with a current record showing each employee's training and qualifications is required to be maintained on site by the facility. The medical director is required to make a separate written certification for each employee on an annual basis. If an employee is not sufficiently trained or qualified to perform the duties assigned to that employee, then the medical director must not provide written certification for that employee and the laboratory must not permit the employee to perform such duties.

(b) Interpretation of the diagnostic physiological testing results must be performed by the medical director or other licensed physician. See paragraph (4) below for additional requirements for specific types of tests.

(c) The medical director is responsible for periodic verification that the equipment utilized by the laboratory is functioning properly and producing reliable and accurate results.

(d) The medical director is responsible for ensuring that the employees performing diagnostic physiological testing and services receive proper instruction or additional training when needed to maintain or acquire skills to adequately perform their duties, and is responsible for notifying the director of the laboratory when there are problems with personnel or equipment that require correction in order to maintain reliable and adequate testing results and services.

(4) Before performing carotid artery, abdominal aorta, ankle brachial vascular, or any other testing utilizing Doppler technology and ultrasonography on a patient, an independent physiological laboratory must comply with subsection (a) or (b).

(a) Receive a written order from a physician, licensed in Alabama, that specifies the name of the patient to be tested and the reason(s) the physician believes the patient should have the test(s). If the physician ordering the test(s) is the patient’s regular attending physician, the results shall be returned to that physician for appropriate follow-up. If the physician ordering the test(s) is an employee or agent of the independent physiological laboratory, then the physician shall consult with the patient to explain the results and shall either conduct or arrange for follow-up tests, consultations, and/or procedures as medically necessary.

(b) For screening examinations to be performed in the absence of a written order from a physician, licensed in Alabama, that specifies the name of the patient to be screened and the reason(s) the physician believes the patient should have the screening examination, an independent physiological laboratory shall apply for and receive permanent written approval from

the State Board of Health to conduct screening examinations. Any independent physiological laboratory approved under this subsection shall:

1. file annual reports with the Alabama State Department of Public Health containing the following information:

(i) the number of patients screened in Alabama during that year;

(ii) the number of patients screened during that year with results that indicated the need for follow-up care from a primary care physician;

(iii) the number of patients screened during that year with results that indicated the need for immediate follow-up care from a primary care physician; and

(iv) the number of patients in each above category who schedule a follow-up visit with a physician.

2. help any patient identify and contact a primary care physician, if such assistance is requested by the patient;

3. follow-up by telephone or letter with any patient whose results indicated the need for follow-up care from a primary care physician and advise the patient to contact a primary care physician; and

4. require that any screening examination performed is reviewed by a physician licensed in the state of Alabama and board certified in one or more of the following areas: cardiothoracic surgery, cardiology, vascular surgery, neurology, radiology, or in internal medicine with special training in vascular medicine.

(5) The laboratory must develop and follow a written procedure for adequate measures to prevent the spread of infection. Blood-letting or invasive devices capable of transmitting infection from one person to another shall be cleaned and sterilized prior to each use.

(6) Failure to permit inspection of the physiological laboratory and its records by representatives of the State Board of Health is a violation of these Rules.

Author: Rick Harris
Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.
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420-5-8-.06 Building Requirements.

(1) Local Restrictions. The location and construction of all independent laboratories shall comply with local building and fire ordinances.

(2) Water Supply. If at all possible, all water shall be obtained from a public water supply. If it is impossible to connect to a public water system, the private water supply shall be approved by the State Board of Health. Provisions shall be made for demineralized water. An adequate number of sinks and lavatories shall be provided to meet the needs of the laboratory. All water fixtures shall be equipped with vacuum breakers to preclude back-siphonage from any sink, lavatory, water closet or other item of equipment.

(3) Disposal of Liquid And Human Wastes.

(a) There shall be installed within the building a properly designed waste disposal system, connecting to all fixtures to which water under pressure is supplied.

(b) All liquid and human waste, including floor wash water and liquid waste from refrigerators, shall be disposed through tapped drains into a public sewer system in localities where such systems are available.

(c) In localities where a public sanitary sewer is not available, liquid and human waste shall be disposed through trapped drains into a sewage disposal system approved by the local county health department and/or the State Board of Health. The sewage disposal system shall be of adequate size and capacity based on the number of personnel and patients using these facilities.

(4) Disposal Of Flammable And Hazardous Materials. Disposal of all flammable and laboratory waste materials shall be in accordance with the requirements of the National Fire Protection Association's handbook number 56C. Instructions contained in this publication shall be extracted and developed into procedure manuals that shall be available to all laboratory personnel. Procedures shall be established and enforced for the safe handling of all potentially infectious cultures and specimens and for the disposal of terminal disinfection of such materials, supplies or equipment.

(5) Housekeeping Facilities And Services.

(a) Housekeeping facilities and services are required to be maintained to ensure comfortable and sanitary conditions.

(b) The physical plant shall be kept in a good state of repair, neat and attractive; and safety shall be the first consideration.

(6) Temperature To Be Maintained. Temperature within the laboratory shall be maintained at a level consistent with comfortable working conditions and in keeping with special requirements for the performance of any particular procedure.

(7) Communication. A telephone and extensions shall be provided to ensure internal and external communication.

(8) Exits. The laboratory shall be provided with at least two exits remote from each other, leading directly to the outside or to an unobstructed passageway to the outside. Exits from the laboratory or any area used by patients shall be equipped with doors sufficient in width to accommodate wheelchairs. Exit doors shall open in the direction of exit travel.

(9) Storage Of Flammable Materials, Reagents and Gases. Storage of the items noted in this section shall be in accordance with the requirements of handbook number 56C of the National Fire Protection Association.

(10) Fire Extinguishers And Personnel Safety Devices.

(a) Fire extinguishers shall be provided in accordance with handbook number 56C of the National Fire Protection Association or as determined by the State Fire Control Authority.

(b) Emergency showers and eye baths or equivalent devices shall be provided in accordance with the requirements of handbook number 56C of the National Fire Protection Association.

(11) Fire Plan. A fire plan including fire evacuation routes shall be posted in conspicuous places. Fire drills shall be held at least semi-annually with all personnel participating and written reports of the effectiveness of these drills kept in writing.

(12) Lighting. Sufficient lighting shall be provided in all areas of the laboratory in keeping with the requirements for particular tests. Lighting of other areas shall be adequate to ensure safety for personnel and/or patients. Illuminated exit lights and direction signs shall be provided for each required exit.

Author: Patricia E. Ivie
Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.
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