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ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT LAND DIVISION - MEDICAL WASTE PROGRAM

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CHAPTER 335-17-1 GENERAL PROVISIONS

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335-17-1-.01 Purpose.

The purpose of 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 Alabama 1975, Section 22-27-1, et seq.

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 June 30, 2025; effective August 14, 2025.

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 Alabama 1975, §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 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 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 $\underline{\text{Code of Alabama}}$ 1975, \$22-22A-4.
- (10) Director the Director of the Alabama Department of Environmental Management, appointed pursuant to <u>Code of</u> Alabama 1975, §22-22A-4, or his or her designee.
- (11) 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.
- (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.
- (13) Health Department an approved county or district health department, including the State Health Department as defined by Code of Alabama 1975, <a href="\$\\$22-1-1, as amended, and the affected state and county health department.
- (14) Health Officer the State Health Officer for the State of Alabama as set out in $\underline{\text{Code of Alabama 1975}}$, \$22-2-8, as provided by law or affected county health officer or his or her designee.
- (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.
- (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.
- (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).
- (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.

- (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.
- (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.
- (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.
- (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.
- (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.
- (24) Medical Waste Transporter a person engaged in the offsite 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.
- (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.
- (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.
- (27) Medical Waste Treatment Facility a location at which medical waste is subjected to treatment.
- (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.
- (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, 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.
- (30) Off-site not a part of what is defined as on-site.
- (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.

- (32) Owner the person(s) who owns a facility or part of a facility.
- (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.
- (34) Permit written authorization granted to a person by the Department to operate a medical waste facility or to transport medical waste.
- (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.
- (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.
- (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.
- (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.
- (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 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.

- (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.
- (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.
- (43) State the State of Alabama.
- (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 June 30, 2025; effective August 14, 2025.

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 Alabama 1975, S\$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 June 30, 2025; effective August 14, 2025.

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 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 June 30, 2025; effective August 14, 2025.

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

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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.

CHAPTER 335-17-2 MEDICAL WASTE GENERATORS

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335-17-2-.01 Generators

335-17-2-.01 Generators.

- (1) A facility which generates medical waste shall register with the Department according to the requirements found at 335-17-8.
- (2) Generators of medical waste shall prepare, maintain and update as necessary a written plan to ensure proper management of medical waste. This plan must be made available to the Department upon request. This plan shall address the following as applicable to the generators:
- (a) The type of medical waste generated;
- (b) Proper collection, packaging and labeling procedures of untreated and treated medical waste intended for off-site transportation should meet the requirements found at 335-17-3;
- (c) Treatment method to be utilized on-site;
- (d) Transporter to be utilized for the transport of any untreated medical waste off-site;
- 1. Name of transporter, address and telephone number of a responsible person; and
- 2. ADEM permit number;
- (e) Storage facilities utilized off-site;
- 1. Name of storage facility, address and telephone number of a responsible person for all off-site storage facilities; and
- 2. ADEM permit number for all off-site facilities.
- (f) All treatment/processing facilities utilized;

- 1. Name, address and telephone number of all treatment/processing facilities; and
- 2. ADEM permit number for all off-site facilities.
- (g) All disposal facilities utilized if on-site treatment occurs;
- 1. Name of disposal facility as it appears on their permit;
- 2. Permittee of disposal facility; and
- 3. ADEM permit number.
- (h) Frequency medical waste is removed off-site from medical waste generator's facility.
- (i) <u>Training of employees</u>. Facility personnel whose duties have a direct effect on medical waste management and/or medical waste accumulation, whether by direct contact with medical waste or through medical waste management activities, shall receive appropriate training.
- (3) Medical waste shall be maintained in a non-putrescent state during accumulation.
- (4) Accumulation of untreated medical waste shall meet the following criteria:
- (a) Accumulation as used in this rule shall begin after a shipping container is prepared for shipment to a storage or treatment facility.
- (b) Accumulation of medical waste by generators who generate 220 pounds or more per month of medical waste shall not exceed thirty (30) calendar days from the accumulation date as described in 335-17-2-.01(4) (a). Generators who generate less than 220 pounds per month of medical waste may accumulate medical waste for up to six (6) months.
- (c) Accumulation areas shall be conspicuously identified with signs which contain either the phrase "Medical Waste,", "Infectious Waste", "Biohazardous", or display the International Biological Hazard Symbol.
- (d) Surfaces of accumulation areas which may come into contact with untreated medical waste shall be constructed of smooth, easily cleanable materials that are impervious to liquids.
- (e) Accumulation areas shall be operated in such a manner to minimize entry by rodents or vectors.

- (5) Medical waste, such as liquids which are amenable to disposal by sanitary sewer, may be discharged subject to the following conditions:
- (a) Sanitary sewer system must provide secondary treatment;
- (b) Solid and liquid waste removed from systems which do not provide secondary treatment (e.g., holding tanks) must be further processed in a sanitary sewer system that provides secondary treatment. Prior approval for sewer systems not regulated by the Water Division of the Department must be obtained from the Local Health Officer.
- (c) Sanitary sewer system shall be operated in such a manner that medical waste will not bypass the treatment facility during normal operating conditions.

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

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CHAPTER 335-17-3 COLLECTION OF MEDICAL WASTE

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335-17-3-.01 Collections Of Untreated Medical Waste.

Collection of untreated medical waste intended for transport offsite shall be packaged and maintained in the following manner:

- (1) The outermost layer of packaging for medical waste shall be packaged in containers which have either a red background color or utilize red lettering with contrasting background color and conspicuously labeled with either the words "Infectious" or "Medical Waste" or "Biohazardous" and/or contain the International Biological Hazard Symbol.
- (a) The wording shall be either printed on the container or securely attached by label on two or more sides. The wording on the label and the International Biological Hazard Symbol must be easily readable and in good condition. The wording and symbol, if utilized, must be in a contrasting color to the background color.
- (2) Containers shall be impermeable to moisture and shall be of sufficient strength to prevent ripping, tearing, or bursting under normal conditions of use.
- (3) Sharps shall be placed directly into leak proof, spill proof, rigid, puncture-resistant containers and sealed to prevent loss of contents under normal handling procedures. These containers shall be clearly labeled as described in 335-17-3-.01(1), unless placed in rigid shipping containers that meet this requirement.
- (4) Small containers used to collect untreated medical waste should be placed inside larger containers to better facilitate storage, transportation, or disposal. Small containers that will be placed into larger shipping containers shall meet the following requirements:

- (a) Containers used for sharps shall meet the requirements in 335-17-3-.01(3).
- (b) All other containers shall utilize either a red background color or red lettering or Symbol which contrast with adjacent colors.
- (c) Wording and the use of the International Biological Hazard Symbol shall be utilized in accordance with 335-17-3-.01(1).
- (5) The outermost layer of packaging must be properly identified with the following information. This information shall be securely attached or permanently printed and shall be clearly legible.
- (a) The name and address;
- (b) The date the waste was packaged in its outermost container;
- (c) One of the following words or phrases used in conjunction with the International Biological Hazard Symbol: "Medical Waste" or "Biohazardous" or "Infectious."
- (6) Containers of medical waste must remain intact without signs of leakage or spillage until treatment.
- (7) Containers of medical waste shall be handled in a manner that does not affect the integrity of the packaging.
- (8) Disposable single use containers used for the storage and transportation of untreated medical waste shall be rigid, leak resistant, spill resistant, puncture resistant, burst resistant, and tear resistant under normal conditions of handling and use. Reusable containers shall meet the preceding requirements in addition to being constructed of smooth, easily cleanable, impermeable materials and resistant to corrosion. If a fiberboard container is used, it shall meet the standards of 49 CFR §173.197 of the Code of Federal Regulations. All containers must be sealed prior to shipment.
- (9) Containers utilized for collection, storage and transportation shall be constructed of materials that are compatible with the treatment method to be utilized.
- (a) Single-use containers destined for incinerators shall be burnable.
- (b) Containers destined for steam sterilizers shall allow the waste to be treated at required temperature and pressure.

- (c) Reusable containers shall be decontaminated after each use with an approved treatment method.
- (d) Reusable containers shall not be used for other purposes unless the following conditions are met:
- 1. Containers shall be decontaminated by a method approved by the Department;
- 2. All labeling, symbols or other identifications normally used to identify medical waste shall be removed.

Author: James L. Bryant, Ashley S. Powell
Statutory Authority: Code of Ala. 1975, \$\$22-27-9, 22-27-12.

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335-17-3-.02 Collections Of Treated Medical Waste.

The collection of treated medical waste intended for transport off-site shall comply with the following requirements:

- (1) Treated medical waste shall be managed in accordance with applicable requirements for solid waste management.
- (2) Containers not meeting the requirements of 335-17-6-.01 shall not be placed into a container used for shipment of treated medical waste.
- (3) Containerized treated medical waste may be mixed with other solid waste for transportation to an approved disposal facility in vehicles where compaction of the waste will take place.
- (4) Treated medical waste shall be delivered to an approved municipal solid waste landfill for disposal.
- (5) Written certification that all treatment requirements contained in 335-17-6-.01 have been met, shall be provided to the permittee of the disposal facility utilized at least on an annual basis or as specified by the Department or the permittee of the disposal facility being utilized. When written certification is required on a per load basis, transporters shall deliver the certification, signed by the person who treated the waste, to the permittee or his designee of the disposal facility utilized at

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the time of disposal. Appropriate documentation to confirm this certification may be required from the treatment facility.

(6) Pursuant to the provisions of <u>Code of Alabama 1975</u>, \$22-22A-4(i), additional regulations addressing the storage of solid waste remain within the function of the State Health Department pursuant to <u>Code of Alabama 1975</u>, \$22-22A-5, \$22-22A-8, and \$22-27-9.

Author: James L. Bryant. Ashley S. Powell
Statutory Authority: Code of Ala. 1975, \$\$22-27-9, 22-27-12.

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CHAPTER 335-17-4 STORAGE OF MEDICAL WASTE

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335-17-4-.01 Storage Of Untreated Medical Waste.

Persons engaged in the permitted storage of untreated medical waste shall comply with the following:

- (1) No person shall operate or maintain a facility for storage of untreated medical waste without having first obtained an Alabama Medical Waste Storage Permit with the requirements defined in 335-17-4 and 335-17-8. Accumulation areas that are an integral part of the generator's facility will not be required to obtain a permit.
- (2) Storage facilities shall be fully enclosed.
- (3) Designated storage facilities shall not be utilized for other purposes.
- (4) Surfaces of storage facilities which may come into contact with medical waste shall be constructed of smooth, easily cleanable materials that are impervious to liquids.
- (5) Storage facilities must be conspicuously identified with signs which contain either the phrase "Medical Waste," "Infectious Waste," "Biohazardous," or display the International Biological Hazard Symbol.
- (6) Storage facilities must be adequately secured to prevent entry of unauthorized persons.
- (7) Storage facilities must be operated in such a manner to minimize entry by rodents and vectors.
- (8) The operation of storage facilities must minimize or prevent objectionable odors as determined by the Department from migrating off-site.

- (9) If a container is damaged, leaking, spilling or improperly labeled, the storage facility may accept the container provided the damaged container is overpacked into another container or is properly labeled in accordance with the requirements of 335-17-3-.01(1).
- (10) Persons manually handling untreated medical waste at the storage facility shall wear impermeable gloves and protective clothing to minimize exposure.
- (11) The permittee or his designee shall allow inspection of the storage facility by Department Personnel during normal working hours.
- (12) The permittee shall maintain records as required by the Department for a period of three (3) years. Records shall, at a minimum, include the following:
- (a) The legal names and physical addresses of all generators and transporters who utilize the storage facility, together with the names and telephone numbers of the contact persons for each generator and transporter facility.
- (b) The quantity of medical waste received from each generator or transporter per month. The quantity may be recorded in tons, pounds, cubic yards, cubic feet, or gallons.
- (c) The date the waste was accepted from the generator or transporter for storage and the date it was removed from the storage facility.
- (d) The name and telephone number of the contact person for the transporter removing the waste to another facility together with the transporter name and permit number.
- (e) The quantity of medical waste removed from the storage facility per month. The quantity may be recorded in tons, pounds, cubic yards, cubic feet, or gallons.
- (f) Training records for current personnel shall be kept until closure of the facility. Training records on former employees shall be kept for at least three (3) years from the date the employee last worked at the facility. Employee training records may accompany personnel transferred within the same company.
- (13) The owner or operator of each storage facility shall prepare, maintain, and update as necessary, a Medical Waste Management Plan for the medical waste handled and stored at their facility.

- (a) The Medical Waste Management Plan shall describe:
- 1. The types of medical waste handled;
- 2. Unloading, handling, and storage procedures that will be followed;
- 3. Treatment facilities that will be utilized;
- 4. Employee Training. Facility personnel whose duties have a direct effect on medical waste management, whether by direct contact with the medical waste or through medical waste management activities, shall receive training.
- 5. Name of the individual responsible for the storage facility;
- 6. Receiving and recordkeeping procedure;
- 7. Emergency preparedness and response plan; and
- 8. Spill contingency plan.
- (b) The Medical Waste Management Plan must be kept at the permittee's principal place of business;
- (c) The Medical Waste Management Plan must be made available to the Department upon request.
- (14) Medical waste shall not be held for more than thirty (30) days at the storage facility without refrigeration at temperatures less than 45 degrees Fahrenheit. Refrigerated medical waste may be held at the storage facility for no longer than one (1) year after the date on which the facility received the waste. Medical waste at the storage facility shall be managed to prevent it from becoming putrescible at any time.
- (15) Notification of closure of the facility.
- (a) Prior to closure. A medical waste storage facility which closes or ceases to store medical waste, shall notify the Department in writing no less than thirty (30) days prior to the expected date of beginning relocation or closure activities. The storage facility shall be thoroughly cleaned and disinfected once closure and/or relocation has been completed.
- (b) After closure. Within thirty (30) days after completion of closure or the cessation of medical waste storage, the medical waste storage facility must provide documentation, which includes certification signed by the owner or operator, to the Department demonstrating that all regulated medical waste was transported

335-17-4-.02

off-site to a permitted medical waste storage or treatment facility.

Author: James L. Bryant. Ashley S. Powell

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335-17-4-.02 Storage Of Treated Medical Waste.

- (1) Containerized treated medical waste that meets the requirements of 335-17-6-.01 may be mixed with other solid waste for storage prior to transportation to an approved disposal facility.
- (2) When written certification is required on a per load basis, storage facilities shall provide transporters the certification from the treatment facility, to be delivered to the permittee or the designee of the disposal facility utilized at the time of delivery.
- (3) Pursuant to the provisions of <u>Code of Alabama 1975</u>, \$22-22A-4(i), additional regulations addressing the storage of solid waste remain within the function of the State Health Department pursuant to <u>Code of Alabama 1975</u>, \$22-22A-5, \$22-22A-8, and \$22-27-9.

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 June 30, 2025; effective August 14, 2025.

CHAPTER 335-17-5 TRANSPORTATION OF MEDICAL WASTE

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335-17-5-.01 Transportation Of Untreated Medical Waste.

The transportation of untreated medical waste shall comply with the following requirements.

- (1) A non-rail transporter shall not transport untreated medical waste without having received an Alabama Medical Waste Transporter Permit in compliance with requirements in accordance with 335-17-5 and 335-17-8.
- (2) No medical waste transporter shall accept untreated medical waste which contains hazardous waste or radioactive waste, for transportation to a medical waste treatment facility.
- (3) No medical waste transporter shall transport untreated medical waste in the same transport vehicle with other solid waste unless all the waste in the vehicle is managed as untreated medical waste.
- (4) No medical waste transporter shall accept any container of untreated medical waste for transport which shows visible signs of leakage or spillage, or which is not properly sealed and labeled.
- (5) No medical waste transporter shall compact untreated medical waste in a transport vehicle.
- (6) No medical waste transporter shall allow untreated medical waste to escape from a transport vehicle into the environment. All vehicles utilized must be enclosed.
- (7) No medical waste transporter shall deliver untreated medical waste to an unpermitted storage, treatment, or disposal facility

- in Alabama. All out-of-state shipments should be coordinated with the appropriate regulatory authority of the receiving State.
- (8) Persons manually loading or unloading containers of untreated medical waste from a medical waste transport vehicle must wear impermeable gloves and protective clothing to help minimize exposure.
- (9) Surfaces of medical waste transport vehicles which may come into contact with medical waste must be constructed of durable, easily cleanable materials.
- (10) Surfaces of medical waste transport vehicles which have been in contact with untreated medical waste shall be decontaminated.
- (11) All medical waste transport vehicles shall be identified with the following information.
- (a) The business name of the permitted transporter;
- (b) The telephone number of a contact person for the transporter;
- (c) One or more of the following phrases or symbols: "Medical Waste" or "Infectious Waste" or the International Biological Hazard Symbol; and
- (d) The ADEM permit number.
- (12) Each medical waste transporter shall allow the following at reasonable times and locations:
- (a) The inspection of vehicles by Department Personnel; and
- (b) The inspection of all documents required by this Division.
- (13) All medical waste transport vehicles shall be fully enclosed and secured when unattended.
- (14) A spill cleanup kit shall be kept in all transport vehicles.
- (15) All medical waste transporters shall notify the Department immediately by telephone at (334) 271-7700, if a spill of medical waste occurs. A written report addressing how the spill occurred, what impact if any it had on the environment, any injury to individuals, method of clean-up, and final disposition of the waste. In addition, the transporter must address what steps will be taken in the future to minimize a similar occurrence. This report shall be filed with the Department within seven (7) calendar days from the date the spill occurred.

- (16) All medical waste transporters shall maintain records for a period of at least three (3) years regarding the following:
- (a) The quantity of untreated medical waste transported from each generator or storage facility per month. The quantity may be recorded in tons, pounds, cubic yards, cubic feet, or gallons.
- (b) The name and location of any storage facilities utilized by the transporter prior to delivery to a treatment facility and the period of time the waste remained in storage.
- (c) The date the waste was accepted from the generator or storage facility, and the date it was delivered to a treatment facility or another storage facility.
- (d) Training records for current personnel shall be kept until closure of the company. Training records on former employees shall be kept for at least three (3) years from the date the employee last worked at the company. Employee training records may accompany personnel transferred within the same company.
- (17) Transportation of medical waste and/or subsequent storage prior to treatment shall be accomplished within fourteen (14) days.
- (18) Each medical waste transporter shall prepare, maintain, and update as necessary, a Medical Waste Management Plan for the medical waste they handle.
- (a) The Medical Waste Management Plan must address to the extent the information is applicable to the transporter:
- 1. The types of medical waste handled;
- 2. Transportation procedures;
- 3. Storage, treatment and disposal facilities that will be utilized;
- 4. Employee Training. Facility personnel whose duties have a direct effect on medical waste management, whether by direct contact with the medical waste or through medical waste management activities, shall receive appropriate medical waste management training.
- 5. The name of the individual responsible for the transportation and management of medical waste.
- (b) The Medical Waste Management Plan must be kept at the permittee's principal place of business.

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- (c) The Medical Waste Management Plan must be made available to the Department upon request.
- (19) All medical waste transporters shall notify the Department immediately by telephone at (334) 271-7700 when untreated medical waste has been or is anticipated to be out of compliance with the requirement as contained in paragraph 335-17-5-.01(17) while in their possession. A written report addressing why the waste was kept longer than fourteen (14) days, and what impact, if any, it had on the environment, how the occurrence was corrected, and what steps will be taken in the future to minimize a similar occurrence. This report shall be filed with the Department within seven (7) calendar days from the date noncompliance was noted.

 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 June 30, 2025; effective

335-17-5-.02 Transportation Of Treated Medical Waste.

Medical waste which has been treated shall meet the following requirements when transported off-site for disposal.

- (1) Transporters shall deliver the waste to an approved municipal solid waste landfill for disposal.
- (2) Treated medical waste that meets the requirements of 335-17-6-.01 may be mixed with other solid waste for transportation to a disposal facility in vehicles where compaction of the waste will take place.
- (3) When written certification is required on a per load basis as defined by the Department or the permittee of the disposal facility, transporters shall deliver the certification, provided by the person who treated the waste, to the permittee or his designee of the disposal facility utilized. Certifications required on a less frequent basis shall be provided by the treatment facility directly to the disposal facility permittee.
- (4) Pursuant to the provisions of $\underline{\text{Code of Alabama 1975}}$, \$22-22A-4(i), additional regulations addressing the transportation of solid waste remain within the function of the State Health Department pursuant to $\underline{\text{Code of Alabama 1975}}$, \$22-22A-5, \$22-22A-8, and \$22-27-9.

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 June 30, 2025; effective August 14, 2025.

CHAPTER 335-17-6 TREATMENT OF MEDICAL WASTE

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335-17-6-.01 Treatment Measures

335-17-6-.01 Treatment Measures.

- (1) Medical waste intended for transport to a permitted municipal solid waste disposal facility shall be treated on-site or at an appropriate permitted alternative location prior to disposal. When written certification is required by the Department or the permittee of the disposal facility to be utilized on a per load basis, the person treating the medical waste shall provide to the transporter the certification. The certification must state that all regulated medical waste has been treated prior to placing the waste in a designated location for transport to an approved disposal facility. When written certification is required on a less frequent basis as noted above, the responsible person for the treatment facility shall provide the certification to the permittee or his designee of the disposal facility to be utilized.
- (2) No person shall operate a facility for the treatment of medical waste without having first obtained an Alabama Medical Waste Treatment Permit in compliance with the requirements in 335-17-6 and 335-17-8. Medical waste incinerators that are permitted pursuant to the authority of the Department's Air Pollution Control Program or the air pollution control programs administered by the Jefferson County Department of Health, the City of Huntsville Department of Natural Resources and Environmental Management or EPA Region 4 are exempt from the permitting requirements of 335-17-6 and 335-17-8.
- (3) Each medical waste treatment facility (excluding incinerators) shall prepare, maintain, and update as necessary, a Medical Waste Management Plan for the treatment of medical waste. The Medical Waste Management Plan shall address to the extent that the information applies to the treatment facility:
- (a) The types of medical waste to be treated;

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- (b) Unloading and handling procedures;
- (c) Safety procedures;
- (d) Emergency preparedness and response plan;
- (e) Spill contingency plan;
- (f) Receiving and recordkeeping procedures;
- (g) Quality assurance plans for treatment methods;
- (h) Employee training. Facility personnel whose duties have a direct effect on medical waste management, whether by direct contact with the medical waste or through medical waste management activities, shall receive appropriate medical waste management training.
- (4) Storage requirements for untreated medical waste located at a medical waste treatment facility shall comply with 335-17-4-.01(2)-(10).
- (5) Medical waste shall be treated within thirty (30) days of receipt at the permitted treatment facility. Medical waste shall be maintained in a non-putrescent state.
- (6) All permitted treatment facilities are required to submit an annual report to the Department by February 28 of the following year, covering the preceding full calendar year. This report shall include the following:
- (a) A complete list of transporters along with ADEM permit numbers that delivered medical waste to the facility during the preceding calendar year;
- (b) The amount of waste treated.
- (7) The medical waste treatment facility shall maintain records as required by the Department for a period of three (3) years. Records shall contain the following as minimum requirements:
- (a) The legal names and physical addresses of all generators and transporters who utilize the treatment facility along with the names and telephone numbers of the contact persons at the generators' and transporters' facilities.
- (b) Written logs or other means of documentation related to the operation, testing, and maintenance of the treatment units.

- (c) Training records for personnel shall be kept until closure of the facility. Training records for former employees shall be kept for at least three (3) years from the date the employee last worked at the facility. Employee training records may accompany personnel transferred within the same company.
- (8) Notification for closure of the facility.
- (a) Prior to closure. A medical waste treatment facility which closes or ceases to treat medical waste, shall notify the Department in writing no less than thirty (30) days prior to the expected date of beginning closure activities. The treatment facility shall be thoroughly cleaned and disinfected after waste removal is complete.
- (b) After closure. Within thirty (30) days after completion of closure or the cessation of medical waste treatment, the medical waste treatment facility must provide documentation to the Department demonstrating that all regulated medical waste was either treated on-site and properly disposed or was transported off-site to a permitted medical waste storage or treatment facility.
- (9) <u>Incinerators</u>. Persons owning or operating an incinerator (combustion unit) shall comply with the ADEM requirements in 335-3 regarding air pollution control. In addition:
- (a) Storage requirements for untreated medical waste located at the incinerator facility shall comply with 335-17-4-.01(2)-(10).
- (b) Storage requirements for the ash residue collected at the incinerator facility shall comply with 335-17-4-.02.
- (c) Transportation of the ash or other treated waste shall comply with 335-17-5-.02.
- (d) All anatomical medical waste, including recognizable human tissue, organs, body parts, and infected animals, shall be rendered unrecognizable during incineration or further processed prior to disposal. Additional processing may include grinding or shredding to render the waste unrecognizable.
- (e) Disposal of ash and other solid waste generated at an incinerator or combustion unit used to treat medical waste shall comply with 335-13-4-.21(c) and 335-13-4-.26(5).
- (10) <u>Steam Sterilizers</u>. Medical waste may be treated by steam sterilizers (autoclaves) as outlined in the following requirements:

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- (a) Medical waste containing hazardous chemicals, or radioactive waste are not approved for this method of treatment.
- (b) Anatomical medical waste, including recognizable human tissue, organs, body parts, and infected animals, shall be further processed after the steam sterilization process to render the waste unrecognizable.
- 1. The additional processing methods for recognizable anatomical tissue, organs, and body parts includes, but is not limited to incineration and/or grinding. The method selected must render the waste unrecognizable prior to shipment to a disposal facility.
- (c) Loose sharps shall be further processed to render the waste safe for subsequent handling and disposal.
- 1. The additional processing methods for loose sharps includes, but is not limited to, grinding, incineration, or packaging in puncture proof containers that enable transport and disposal without leakage or spillage.
- (d) Steam sterilizers shall be equipped to continuously monitor and record temperature and pressure during the entire length of each cycle. Sterilizers not so equipped shall affix a temperature sensitive tape to each bag or container or obtain approval from the Department for an appropriate alternative method of ensuring complete treatment.
- 1. Each bag or container shall be exposed to a minimum temperature of 250 degrees Fahrenheit and at least fifteen (15) pounds of pressure for thirty (30) minutes. Processing requirements may be altered if proper decontamination is assured by appropriate testing, and approval is received from the Department for an appropriate alternative method of ensuring complete treatment.
- 2. Each sterilizer shall be evaluated for effectiveness under full loading by an approved method at least once for each forty (40) hours of combined operation. Biological indicators such as spores of "Geobacillus stearothemophilus" may be utilized with Departmental approval.
- (e) A written log or other means of documentation as approved by the Department shall be maintained for each steam sterilization unit and shall contain the following:
- 1. The date, time (including duration), and operator for each cycle;

- 2. Approximate weight or volume of medical waste treated during each cycle;
- 3. The temperature and pressure maintained during each cycle;
- 4. Method utilized for confirmation of temperature and pressure; and
- 5. Dates and results of calibration and maintenance.
- (f) Packaging of medical waste which has been treated by steam sterilization shall comply with the requirements contained in 335-17-3-.02.
- (g) Owners or operators of steam sterilizers shall not place untreated regulated medical waste in areas or containers designated for pickup and delivery to a solid waste disposal facility.
- (h) Sterilizers utilized for medical waste treatment shall not be utilized for sterilization of equipment, food, or other related items.
- (11) Pyrolysis. Persons owning or operating a pyrolysis unit shall comply with the ADEM requirements in 335-3 regarding air pollution control, the air pollution control programs administered by the Jefferson County Department of Health, or the City of Huntsville Department of Natural Resources and Environmental Management, as appropriate.
- (a) Storage requirements for untreated medical waste located at the pyrolysis facility shall comply with 335-17-4-.01(2)-(10).
- (b) Storage requirements for the pyrolysis residue collected at the pyrolysis facility shall comply with 335-17-4-.02.
- (c) Transportation of the pyrolysis residue or treated waste shall comply with 335-17-5-.02.
- (d) All anatomical medical waste, including recognizable human tissue, organs, body parts, and infected animals, shall be rendered unrecognizable during pyrolysis or further processed prior to disposal. Additional processing may include grinding or shredding to render the waste unrecognizable.
- (e) Disposal of pyrolysis waste and other solid waste generated at a pyrolysis unit used to treat medical waste shall comply with 335-13-4-.21 and 335-13-4-.26(1)(b).

- (12) Other treatment methods may be approved by the Department which are consistent with the requirements of 335-17. A person shall make a request in writing for approval of an alternative treatment method and shall address the following minimum requirements:
- (a) Storage requirements for untreated medical waste shall comply with 335-17-4-.01(2)-(10).
- (b) Storage requirements for treated medical waste shall comply with 335-17-4-.02.
- (c) Transportation of untreated medical waste shall comply with 335-17-5-.01.
- (d) Transportation of treated medical waste shall comply with 335-17-5-.02.
- (e) Specific types of medical waste and projected volumes shall be stated.
- (f) A demonstration that the alternative treatment method provides protection for the public and the environment equal to that provided by methods contained in 335-17-6-.01(9)-(11).
- (g) A demonstration of the effectiveness of the proposed treatment method.

[Note: All appropriate fees specified in 335-1-6 shall be paid and a completed Form 323 submitted before the Department initiates review of the proposed alternative treatment method.] 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 June 30, 2025; effective August 14, 2025.

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CHAPTER 335-17-7 DISPOSAL OF MEDICAL WASTE

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335-17-7-.01 Disposal Of Untreated Medical Waste.

Disposal of untreated medical waste is not allowed in the State of Alabama.

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

Statutory Authority: <u>Code of Ala. 1975</u>, §§22-27-9, 22-27-12. History: New Rule: Filed December 12, 2011; effective January 16, 2012. Amended: Published June 30, 2025; effective August 14, 2025.

335-17-7-.02 Disposal Of Treated Medical Waste.

- (1) Disposal of treated medical waste must be in accordance with 335-13. Treated medical waste must be processed and packaged to meet the requirements of 335-17-6-.01 before disposal.
- (2) Treated medical waste sent for disposal shall be accompanied by:
- (a) Written certification from the medical waste treater certifying that the medical waste has been properly treated in accordance with 335-17-6-.01.
- 1. The minimum frequency for providing this certification shall be annually. The treater shall be responsible for providing this certification.
- 2. The disposal facility or the Department may require more frequent certification.
- (i) Certifications provided on a per-load basis shall be made available to the disposal facility or the designee prior to unloading.

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- (ii) Certifications required more frequently than yearly, but less frequently than a per-load basis, shall be provided as required by the disposal facility or the Department.
- (3) Requirements for disposal in an approved solid waste disposal facility shall include the following:
- (a) Each permittee of a solid waste disposal facility shall maintain records in a format approved by the Department for each transporter of medical waste who utilizes their facility.
- (b) All records shall be maintained by the permittee for at least three (3) years and shall be available upon request for review by the Department.
- (c) No untreated medical waste shall be accepted for disposal.
- 1. Packaging, as required in 335-17-3-.02, shall not be accepted for disposal without a variance, as outlined in 335-17-9, being granted by the Department.
- 2. Containers showing signs of leakage or spillage shall not be accepted.
- (d) Medical waste properly treated shall be placed directly in the active face for putrescibles and managed accordingly.

 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 June 30, 2025; effective August 14, 2025.

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

CHAPTER 335-17-8 REGISTRATION AND PERMITS

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335-17-8-.01 Registration Requirements.

(1) Generators.

- (a) Any facility or person that meets the definition of a medical waste generator as defined in 335-17-1-.02 shall register with the Department within thirty (30) days of the commencement of operation.
- (b) Application for the medical waste generator registration shall be submitted electronically to the Department utilizing ADEM Form 410.

Author: James L. Bryant. Ashley S. Powell. Clethes Stallworth 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 June 30, 2025; effective August 14, 2025.

335-17-8-.02 Requirements for a Permit.

(1) As part of submitting an application for an initial issuance of a medical waste storage or treatment permit, the prospective permittee shall provide to the Department documentation of host

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government approval, as provided in the Code of Alabama 1975, $\S\S$ 22-27-48 and 48.1.

- (2) Storage Facilities: Any medical waste storage facility, as defined in 335-17-1-.02, shall apply for and obtain a medical waste storage permit prior to storing medical waste.
- (3) Transporters: Any medical waste transporter, as defined in 335-17-1-.02, shall apply for and obtain a medical waste transporter permit prior to transporting medical waste.
- (4) Treatment Facilities: Any medical waste treatment facility, as defined in 335-17-1-.02, shall apply for and obtain a medical waste treatment permit prior to treating medical waste.

Author: James L. Bryant. Ashley S. Powell. Clethes Stallworth. Statutory Authority: Code of Ala. 1975, §\$22-27-9, 22-27-12, 22-27-48, 22-27-48.1.

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335-17-8-.03 Permit Applications.

- (1) Any person who requires a permit pursuant to 335-17 shall complete, sign, and submit to the Department an application for each permit required under 335-17-8-.02.
- (a) <u>Storage Facilities</u>: Application for the medical waste storage permit shall be submitted electronically to the Department utilizing ADEM Form 413.
- (b) <u>Transporters</u>: Application for the medical waste transporter permit shall be submitted electronically to the Department utilizing ADEM Form 411.
- (c) <u>Treatment Facilities</u>: Application for the medical waste treatment permit shall be submitted electronically to the Department utilizing ADEM Form 412.

Note: Prior to or concurrently with the submission of an application for a new storage or treatment facility permit, documentation of host governmental approval as provided in $\underline{\text{Code}}$ of Alabama 1975, §§ 22-27-48 and 22-27-48.1 must be provided to the Department.

Author: James L. Bryant. Ashley S. Powell. Clethes Stallworth. Statutory Authority: Code of Ala. 1975, §\$22-27-9, 22-27-12, 22-27-48, 22-27-48.1.

History: New Rule: Filed December 12, 2011; effective January
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August 14, 2025.

335-17-8-.04 Issuance of Permits.

- (1) When the Department determines that an application is complete, it shall make a determination to issue or to deny a permit for the operations and activities described in the application. The Department shall notify the applicant of this determination.
- (2) As determined by the Director, substantial non-compliance with Department regulations or permits at any facility owned or operated by the applicant, including any facility for which the pending permit application is requested, will be grounds for denial of the application, or alternatively, for suspension of further consideration of the application until such non-compliance is corrected.
- (3) Duration of Permits.
- (a) Transporter permits shall be valid for three (3) years.
- (b) Treatment facility permits and storage facility permits shall be valid for five (5) years.
- (4) Continuation of Expiring Permits. The terms and conditions of an expiring medical waste permit are automatically extended pending issuance of a new permit if the permittee has submitted a complete application for reissuance of a permit in accordance with 335-17-8-.03 at least ninety (90) days prior to permit expiration, and the delay in permit issuance has not been caused by the actions of the permittee. A complete application is one that contains all items required in the permit application and its accompanying instruction, and the items contain enough information to allow the Department to conduct a detailed review of the application. Failure to submit a complete renewal application and reapply at least ninety (90) days prior to permit expiration may result in expiration before reissuance.

Author: James L. Bryant. Ashley S. Powell. Clethes Stallworth. **Statutory Authority:** Code of Ala. 1975, §\$22-27-9, 22-27-12, 22-27-48.

History: New Rule: Filed December 12, 2011; effective January 16, 2012. Amended: Published December 31, 2024; effective February 14, 2025. Amended: Published June 30, 2025; effective August 14, 2025.

335-17-8-.05 Changes to Registrations and Permits.

- (1) Application for the modification or transfer of a Medical Waste Registration shall be submitted utilizing Form 410 to the Department at least thirty (30) days prior to the change.
- (2) <u>Transfer of a Treatment, Storage, or Transporter Permit.</u>
 Permits are not transferable except as follows:
- (a) A notification must be submitted to and approved by the Department prior to any proposed permit transfer from one person or company to another or the name change of any permitted facility subject to the fee in 335-1-6-.04(2).
- (b) The notification must be submitted to the Department at least thirty (30) days prior to the proposed transfer or name change.
- (c) Information regarding the transfer or name change must be submitted on form(s) designated by the Department.
- (d) Treatment and Storage permits are attached to the property to which it pertains and may not be transferred from one location to another.
- (3) Permit Modification. The Department may modify a permit after receiving a satisfactory request that is found in compliance with the Department rules and regulations. Permit modifications shall be requested in writing utilizing application forms designated by the Department when the permittee proposes to modify its operations in any of the ways listed in 335-17-8-.05.
- (a) Major Modifications
- 1. The following are causes for major modification of a storage facility permit:
- (i). Material and substantial alterations or additions to the permitted facility that occur after permit issuance.
- 2. The following are causes for major modification of a treatment permit:
- (i) Material and substantial alterations or additions to the permitted facility that occur after permit issuance.
- (ii) The change of treatment methods or the addition of treatment methods.

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- (iii) Change in the types of medical waste to be treated.
- (b) Minor Modifications
- 1. The following are causes for minor modifications for permitted facilities:
- (i) Correction of typographical errors and informational changes as requested by the permittee.
- (ii) Changes to remove permit conditions to conform with Department guidance or regulations (i.e. permit conditions that are no longer applicable because the standards upon which they were based are no longer applicable to the facility).
- (iii) Changes, by the permittee, to approved applicable plans as included in the permit application, that increase the frequency, duration, or stringency of the action covered by the applicable plan.
- (iv) The office or place of business has moved.
- (4) Procedures. The Permittee shall request a permit modification in accordance with the following procedures:
- (a) Submit a request for modification to the Department at least thirty (30) days prior to the proposed change.
- (b) Identify each part of the permit or plans to be modified.
- (c) Submit revised plans and narratives as required by the Department.

Note: Major modifications as listed in 335-17-8-.05(3) a are subject to the provisions of 335-17-8-.08 for public notice and may require a public hearing under 335-17-8-.09.

Author: James L. Bryant. Ashley S. Powell Statutory Authority: Code of Ala. 1975, §\$22-27-9, 22-27-12, 22-27-48.

History: New Rule: Filed December 12, 2011; effective January 16, 2012. Amended: Published December 31, 2024; effective February 14, 2025. Amended: Published June 30, 2025; effective August 14, 2025.

335-17-8-.06 Permit Denial, Suspension, or Revocation.

(1) <u>Conditions</u>. The Department may deny, suspend or revoke any permit if:

- (a) The permittee is found to be in violation of any of the permit conditions.
- (b) The permittee fails to perform the permitted activity in accordance with 335-17.
- (c) The permittee fails in the application or during the permit issuance process to disclose fully all relevant facts, or the permittee's misrepresentation of relevant facts.
- (d) A change in a condition that requires either a temporary or a permanent cessation of activities controlled by the permit.
- (e) The permittee fails to submit a complete application to include additional information, or items requested by the Department.
- (f) A determination that continued operation of the facility or activity endangers human health or the environment.
- (g) The permittee fails to submit a complete renewal application at least ninety (90) days prior to permit expiration.

Author: Clethes Stallworth.

History: New Rule: Published June 30, 2025; effective August 14, 2025.

335-17-8-.07 Permit Fees.

- (1) No permit application as described in 335-17-8-.03 is complete without payment of the permit application fees specified in 335-1-6.
- (2) An initial permit shall be submitted with the applicable fee specific for that permit, along with a Greenfield fee.

Author: Clethes Stallworth.

Statutory Authority: Code of Ala. 1975, \$\$22-27-9, 22-27-12, 22-27-48.

History: New Rule: Published June 30, 2025; effective August 14, 2025.

335-17-8-.08 Public Notice.

(1) Notice Requirements.

- (a) The Department shall provide notice and an opportunity to comment and request a public hearing on any medical waste treatment or storage facility permit initial issuance, renewal, a modification listed in 335-17-8-.05(3)(a) to the facility permit, or if otherwise determined necessary to meet the requirements of this Division.
- (b) The following procedures shall be observed:
- 1. The Department shall send a copy of the notice to persons on a mailing list developed by:
- (i) Including those who request in writing to be on the list;
- (ii) Notifying the public of the opportunity to be put on the mailing list through the Department's website, periodic publication in the public press and in such publications as regional and state funded newsletters, environmental bulletins, or state law journals (the Director may update the mailing list from time to time by requesting written indication of continued interest from those listed and may delete from the list the name of any person who fails to respond to such a request).
- 2. The Department shall notify interested and potentially interested persons of the proposed permit action for a medical waste treatment or storage facility by posting a notice to the Department's website. The draft permit action shall be posted on the website for the duration of the public comment period.
- 3. The notice shall be given not less than thirty-five (35) days prior to the proposed issuance of a permit action.
- 4. The notice shall contain the specific type and nature of the medical waste treatment or storage facility, the owner or operator requesting the permit action, and the description of the facility, address and telephone number of the Department, and how the public may submit comments and request a public hearing on the proposed permit action.
- (2) <u>Departmental Action</u>. After the comment period closes, the Department shall review, consider and respond to all public comments received by the close of the comment period and take one of the following actions:
- (a) Issue the permitting action if the application complies with this Division; or
- (b) Deny the permitting action, stating in writing the reasons for denial and informing the person requesting the permitting action of appeal procedures described in 335-2-1;

(c) Require additional information or additional elements of design for the facility. If required, the applicant must specify procedures for inclusion into the permit of any additional information prior to issuance of the permit action.

Author: Clethes Stallworth.

Statutory Authority: Code of Ala. 1975, §\$22-22A-5, 22-27-7. History: New Rule: Published June 30, 2025; effective August 14, 2025.

335-17-8-.09 Public Hearing.

- (1) <u>Authorization</u>. The Department shall authorize a public hearing at its discretion, or upon receipt of significant number of technical requests as provided in 335-17-8-.09(2).
- (2) Procedures.
- (a) Requests for public hearings shall be submitted in writing to the Department.
- 1. Frivolous or nontechnical requests shall be denied by the Department.
- 2. Requests for public hearings must be submitted within thirty-five (35) days after the publication of the public notice and must contain the following:
- (i) The name, address and telephone number of the person requesting the hearing.
- (ii) A brief statement of the person's interest and the information the person wishes to submit.
- (iii) The person's signature, if an individual, or the signature of a responsible officer of an organization or legal entity.
- (b) When a hearing has been authorized, the Department shall appoint a hearing officer to conduct the hearing and shall establish a time, date, and location for the hearing. The location for the hearing shall comply with the requirements of the Americans with Disabilities Act.
- (c) The Department shall give notice of the public hearing in the manner set forth in 335-17-8-.08(1), and to the persons requesting the hearing in 335-17-8-.09(2). The notice shall be given not less than thirty-five (35) days prior to the time of the public hearing and shall include:

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- 1. A summary of the proposed permitting action.
- 2. The place, time, and date of the hearing.
- 3. The name, address, and telephone number of an office at which interested persons may receive further information.
- (3) <u>Departmental Action.</u> After the public hearing and close of the comment period, the Department shall review, consider, and respond to comments received by the close of the comment period and take one of the following actions:
- (a) Issue the permitting action if the application complies with this Division; or
- (b) Deny the permitting action, stating in writing the reasons for denial and inform the person requesting the permitting action of appeal procedures described in 335-2-1;
- (c) Require additional information or additional elements of design for the facility. If required, the applicant must specify procedures for inclusion into the permit of any additional information prior to issuance of the permit action.

Author: Clethes Stallworth.

Statutory Authority: Code of Ala. 1975, §\$22-22A-5, 22-27-7. History: New Rule: Published June 30, 2025; effective August 14, 2025.

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

CHAPTER 335-17-9 PROCEDURES FOR VARIANCES

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335-17-9-.01 Variances.

(1) The Department may grant individual variances from the specific provisions of 335-17 based upon the procedures of 335-17-9-.02 through 335-17-9-.05 whenever it is found by the Department, upon presentation of adequate proof, that noncompliance with 335-17 will not threaten the public health or unreasonably create environmental pollution. Specifically, variances may only be granted for those provisions of 335-17 that are in addition to or more stringent than analogous federal regulations. Variance requests will not be granted for provisions of 335-17 that are identical to a federal rule (i.e. those provisions that are not a state specific rule. Variances per se are not favored by the Department.

Author: James L. Bryant. Ashley S. Powell

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

History: New Rule: Published December 31, 2024; effective

February 14, 2025. Amended: Published June 30, 2025; effective

August 14, 2025.

335-17-9-.02 Petition for Variance.

(1) Applicability. Any person may request a variance from specific provisions of 335-17 by filing a Petition for Variance with the Department at least 120 days prior to the anticipated change and shall receive approval from the Department prior to the implementation of the proposed change.

- (2) <u>Petition Requirements</u>. To enable the Department to rule on the <u>Petition</u> for Variance, the following information, where determined applicable by the Department, shall be included in the petition:
- (a) A clear and complete statement of the precise extent of the relief sought including specific identification of the particular provisions of the regulations from which the variance is sought;
- (b) An assessment, with supporting factual information, of the impact that the variance will impose on the public health and the environment in the affected area.
- (c) Any additional information requested by the Department as necessary to evaluate the variance request.
- (d) A concise factual statement of the reasons the petitioner believes that non-compliance with the particular provisions of 335-17 will not threaten the public health or unreasonably create environmental pollution.
- (e) Applicable fees in accordance with 335-1. **Author:** James L. Bryant. Ashley S. Powell **Statutory Authority:** Code of Ala. 1975, \$\$22-27-9, 22-27-12. **History:** New Rule: Published December 31, 2024; effective

 February 14, 2025. **Amended:** Published June 30, 2025; effective August 14, 2025.

335-17-9-.03 Extension of Prior or Existing Variance.

- (1) A petition to extend a prior or existing variance granted by the Department shall be commenced by filing a Petition for Variance with the Department in accordance with the requirements of 335-17-9-.02.
- (2) For petitions to extend an existing variance, the information required by 335-17-9-.02 that was included in the prior Petition for Variance for which extension is sought, shall be submitted, along with any additional information as necessary to update the existing Petition for Variance.

Author: James L. Bryant. Ashley S. Powell

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

History: New Rule: Published December 31, 2024; effective
February 14, 2025. Amended: Published June 30, 2025; effective
August 14, 2025.

335-17-9-.04 Reserved.

Author: James L. Bryant. Ashley S. Powell

Statutory Authority: <u>Code of Ala. 1975</u>, §§22-27-9, 22-27-12. History: New Rule: Published December 31, 2024; effective February 14, 2025. **Amended:** Published June 30, 2025; effective

August 14, 2025.

335-17-9-.05 Termination of Variance.

(1) Any variance granted by the Department may be terminated by the Department whenever the Department finds, after notice to the petitioner, that the petitioner is in violation of any requirement, condition, schedule, limitation or any other provision of the variance or that operation under the variance does not meet the minimum requirements established by state and federal laws and regulations or is unreasonably threatening the public health.

Author: James L. Bryant. Ashley S. Powell

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

History: New Rule: Published December 31, 2024; effective
February 14, 2025. Amended: Published June 30, 2025; effective

August 14, 2025.

335-17-9-.06 Public Notice.

This rule applies only to variances requested by medical waste treatment and storage facilities.

- (1) Notice Requirements.
- (a) The Department shall provide notice and an opportunity for a public hearing on Petition for Variance from a specific provision of this Division.
- (b) The following procedures shall be observed:
- 1. The Department shall send a copy of the notice to persons on a mailing list developed by:
- (i) Including those who request in writing to be on the list;
- (ii) Notifying the public of the opportunity to be put on the mailing list through the Department's website, periodic

publication in the public press and in such publications as regional and state funded newsletters, environmental bulletins, or state law journals (the Director may update the mailing list from time to time by requesting written indication of continued interest from those listed and may delete from the list the name of any person who fails to respond to such a request).

- 2. The Department shall notify interested and potentially interested persons of the Petition for Variance by posting a notice to the Department's website. The Petition for Variance shall be posted on the website for the duration of the public comment period.
- 3. The notice shall be given not less than thirty-five (35) days prior to the proposed approval of the petition.
- 4. The notice shall contain the specific type and nature of the petition, the owner or operator requesting the petition, and the descriptive location of the subject facility or unit, address and telephone number of the Department, and how the public may submit comments and request a public hearing on the proposed petition.
- (2) <u>Departmental Action</u>. After the comment period closes, the Department shall review, consider and respond to all public comments received by the close of the comment period and take one of the following actions:
- (a) The petition may be dismissed if the Department determines that it is not adequate under 335-17-9-.02;
- (b) The Department may grant the variance as petitioned or by imposing such conditions as the Division may require, including the establishment of schedules of compliance and monitoring requirements; or
- (c) The Department may deny the petition. If such a denial is made, the Department shall notify the petitioner in writing the reasons for denial and outline procedures for appeal as described in 335-2-1.

Author: Clethes Stallworth.

Statutory Authority: Code of Ala. 1975, <a href="\$\\$\\$22-27-9, 22-27-12.

History: New Rule: Published June 30, 2025; effective August 14, 2025.

335-17-9-.07 Public Hearing.

- (1) <u>Authorization</u>. The Department shall authorize a public hearing at its discretion, or upon receipt of significant number of technical requests as provided in 335-17-9-.07(2).
- (2) Procedures.
- (a) Requests for public hearings shall be submitted in writing to the Department.
- 1. Frivolous or nontechnical requests shall be denied by the Department.
- 2. Requests for public hearings must be submitted within thirty-five (35) days after the publication of the public notice and must contain the following:
- (i) The name, address and telephone number of the person requesting the hearing.
- (ii) A brief statement of the person's interest and the information the person wishes to submit.
- (iii) The person's signature, if an individual, or the signature of a responsible officer of an organization or legal entity.
- (b) When a hearing has been authorized, the Department shall appoint a hearing officer to conduct the hearing and shall establish a time, date, and location for the hearing. The location for the hearing shall comply with the requirements of the Americans with Disabilities Act.
- (c) The Department shall give notice of the public hearing in the manner set forth in 335-17-9-.07(1), and also to the persons requesting the hearing in 335-17-9-.07(2). The notice shall be given not less than thirty-five (35) days prior to the time of the public hearing and shall include:
- 1. A summary of the Petition for Variance.
- 2. The place, time, and date of the hearing.
- 3. The name, address, and telephone number of an office at which interested persons may receive further information.

- (3) <u>Departmental Action</u>. After the public hearing and close of the comment period, the Department shall review, consider and respond to comments received by the close of the comment period and take one of the following actions:
- (a) The petition may be dismissed if the Department determines that it is not adequate under 335-17-9-.02;
- (b) The Department may grant the variance as petitioned or by imposing such conditions as the Division may require, including the establishment of schedules of compliance and monitoring requirements; or
- (c) The Department may deny the petition. If such a denial is made, the Department shall notify the petitioner in writing the reasons for denial and outline procedures for appeal as described in 335-2-1.

Author: Clethes Stallworth.

Statutory Authority: Code of Ala. 1975, §\$22-27-9, 22-27-12. History: New Rule: Published June 30, 2025; effective August 14, 2025.