

TRANSMITTAL SHEET FOR  
NOTICE OF INTENDED ACTION

Control 335 Department or Agency Environmental Management

Rule No. 335-17

Rule Title: Medical Waste

New  Amend  Repeal  Adopt by Reference

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

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

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

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? NO

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NO

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? YES

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Does the proposed rule have an economic impact? NO

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


\*\*\*\*\*

Certification of Authorized Official

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

Signature of certifying officer Nancy Elliott

Date September 20, 2011

Date Filed 

APA-2  
11/96

**ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
LAND DIVISION**

**NOTICE OF INTENDED ACTION**

**AGENCY NAME:** Alabama Department of Environmental Management

**RULE NO. & TITLE:** 335-17                      **Medical Waste (New)**

**INTENDED ACTION:** The Alabama Department of Environmental Management proposes to add new rule 335-17.

**SUBSTANCE OF PROPOSED ACTION:**


The Alabama Department of Environmental Management proposes to add new rule 335-17. In a separate action, ADEM is proposing to amend 335-13-1-.03 by deleting medical waste definitions and to repeal Chapter 335-13-7. The repealed chapter will be replaced by proposed rule 335-17, wherein medical waste definitions deleted from 335-13-1-.03 will be included.

**TIME, PLACE, MANNER OF PRESENTING VIEWS:**

Comments may be submitted in writing or orally at a public hearing to be held at 11:00 a.m., November 9, 2011, in the ADEM Main Hearing Room, 1400 Coliseum Boulevard, Montgomery, Alabama 36110.

**FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:** November 10, 2011

**CONTACT PERSON AT AGENCY:** James L Bryant, (334) 271-7771

  
Lance R. LeFleur  
Director

ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

LAND DIVISION - MEDICAL WASTE PROGRAM

DIVISION 17

[New]

1400 Coliseum Boulevard  
Montgomery, Alabama 36110  
(334) 271-7700

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CITE AS

ADEM Admin. Code R. 335-17-x-.xx

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EFFECTIVE:

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

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**ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
LAND DIVISION – MEDICAL WASTE PROGRAM**

**CHAPTER 335-17-1  
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**335-17-1-.01**      **Purpose.** The purpose of ADEM Administrative Code 335-17 is to establish minimum criteria for the storage, transportation, treatment and disposal of medical wastes under authority of the Alabama Solid Wastes and Recyclable Materials Management Act, Code of Alabama 1975, Section 22-27-1, et seq. 335-17 is to comprise all regulations of ADEM dealing with medical waste management.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXX~~.

**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.the Alabama Solid Wastes and Recyclable Materials Management Act, Code of Ala. 1975, Section 22-27-1, et seq.

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

grossly contaminated with bulk blood, blood components, or body fluids shall be treated as specified for surgical waste.

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

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

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

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

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

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

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

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

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

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

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

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

(15) Health Department - an approved county or district health department, including the Alabama State Department of Public Health and the affected state and county health department.

(16) Health Officer - the State or affected county health officer or his or her designee.

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

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

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

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

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

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



generated from a single-family residential dwelling by someone other than a health care professional.

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

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

(25) Medical Waste Transportation - the movement of medical waste after leaving the generator's building to any intermediate transfer points, and finally to the landfill unit. The mode of transport may be by air, highway, rail, or water.

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

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

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

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

(30) 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 (Strain 19 Brucellosis Vaccine, Feline Pneumonitis Vaccine, contagious Eczema Vaccine for Sheep, Newcastle Disease Vaccine, Anthrax Spore Vaccine, and Venezuelan Equine Encephalitis Vaccine) shall be considered microbiological waste.

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

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

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

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

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

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

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

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

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

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

(41) Sharps - any used or unused discarded article that may cause punctures or cuts and which has been or is intended for use in animal or human medical care, medical research, or in laboratories utilizing microorganisms. Such waste includes, but is not limited to, hypodermic

needles, IV tubing with needles attached, scalpel blades, and syringes (with or without a needle attached). Items listed above that have been removed from their original sterile containers are included in this definition. Glassware, blood vials, pipettes, and similar items are to be handled as sharps if they are contaminated with blood or body fluids.

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

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

(44) State - the State of Alabama.

(45) State Health Department - the Alabama Department of Public Health as defined by §22-2-1, Code of Ala. 1975.

(46) State Health Officer - the Health Officer for the State of Alabama as set out in §22-2-8, Code of Ala. 1975, or his designee provided by law.

(47) 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 contained in (b) above. Extracted teeth are not included in this definition.

**Author:** James L. Bryant

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

**History:** XXXXXXXX.

**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:** XXXXXXXX.

**335-17-1-.04**      **Penalty for Violations.** No person shall violate any of the provisions of these rules and regulations. Violation of these rules and regulations shall be deemed to be a violation of the Act, Code of Ala. 1975, §§22-27-7 and 22-27-11, and shall be punishable as provided therein or by other applicable penalties which may be more stringent.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXXX.~~

**335-17-1-.05**      **Appeals.** Any person aggrieved by any ruling of the Department with respect to these regulations, has the right of appeal in accordance with procedures established in Division 2 of the ADEM Administrative Code.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXXX.~~

**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:** ~~XXXXXXXX.~~

**335-17-1-.07**      **Repealer.** All rules and regulations promulgated and adopted by the Department which are in conflict with this Division or any provision thereof is hereby expressly repealed. This Division is intended to be comprehensive and include all the regulations of the Department dealing with medical waste management as enforced by the Land Division.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXXX.~~

**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:** ~~XXXXXXXX.~~

**ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
LAND DIVISION – MEDICAL WASTE PROGRAM**

**CHAPTER 335-17-2  
MEDICAL WASTE GENERATORS**

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**335-17-2-.01 Generators.**

**335-17-2-.01 Generators.**

(1) Within 90 days from the effective date of this Division, each generator 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 if applicable to the generators:

- (a) The type of medical waste generated;
- (b) Proper segregation, packaging and labeling procedures of untreated medical waste intended for off-site transportation;
- (c) Treatment method to be utilized on-site;
- (d) Transporter of any untreated medical waste transported off-site;
  - 1. Name, address and telephone number of a responsible person;
  - 2. ADEM permit number;
- (e) Storage facilities utilized both on-site and off-site;
  - 1. Name, address and telephone number of a responsible person for all off-site storage facilities.
  - 2. ADEM permit number for all off-site facilities.
- (f) All treatment/processing facilities utilized;
  - 1. Name, address and telephone number of all facilities.
  - 2. ADEM permit number for all off-site facilities.
- (g) All disposal facilities utilized;
  - 1. Name of disposal facility as it appears on their permit;
  - 2. Permittee of disposal facility;

3. ADEM permit number.

(h) Frequency medical waste is removed off-site from medical waste generator's facility.

(i) Training of employees

1. Steps that will be taken to minimize the exposure of their employees to infectious agents.

2. Name of the individual who is responsible for training.

(2) Each generator shall notify the Department in writing, within 90 days from the effective date of this Division. This notification shall address the following:

(a) Name and mailing address of generator;

(b) Name and telephone number of responsible person;

(c) Street address, including nearest city, of generator's facility.

A person who will begin the generation of medical waste after the effective date of this Division must submit the above notification and prepare a written Medical Waste Management Plan prior to initiating any waste generation, treatment, transportation or disposal activity.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXX~~.

**ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
LAND DIVISION – MEDICAL WASTE PROGRAM**

**CHAPTER 335-17-3  
COLLECTION OF MEDICAL WASTE**

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**335-17-3-.01      Collections of Untreated Waste.** Collection of untreated medical waste intended for transport off-site, except where interment will be utilized, 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 shall utilize letters two inches or larger in size, and the International Biological Hazard Symbol, must be six inches or larger in diameter. The wording and symbol, if utilized, must be in a contrasting color to the background color.

(b) The ink utilized must be indelible and considered permanent when exposed to the environment under normal weather conditions.

(2) Containers shall be impermeable to moisture and shall have a strength which prevents ripping, tearing, or bursting under normal conditions of use.

(3) Sharps shall be placed directly into leak 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 (1) above unless placed in rigid shipping containers that meet this requirement.

(4) Small containers used to collect untreated medical waste 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 paragraph 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 utilized in paragraph 335-17-3-.01(1) shall be utilized. The wording shall be either printed on the container or securely attached by label on two or more sides. The wording shall utilize letters one inch or larger in size, and the International Biological Hazard Symbol must be three inches or larger in diameter.

(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. Indelible ink shall be used to print the information on the label or container.

(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 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, 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 178.210 of the Code of Federal Regulations for a classified strength of at least 200 pound test and be marked DOT-12A65. All containers must be sealed prior to shipment. The maximum gross weight of fiberboard containers shall be 65 pounds.

(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.

(10) 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.

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

**History:** ~~XXXXXXX~~.

**335-17-3-.02**      **Collection of Treated Waste.** The collection of treated medical waste intended for transport off-site shall comply with the following requirements:

(1) All containers shall not be red in color, and display the International Biological Hazard Symbol or display one of the following phrases:

(a) "Medical Waste";

(b) "Infectious" or "Infectious Waste";

(c) "Bio Hazardous";

(d) Any other identification normally used to indicate medical waste as being untreated.

(e) Containers which cannot meet the above requirements shall be further processed by incineration, grinding, shredding, or some other means to achieve this requirement.

(3) Containers which are treated but did not lose their identity as untreated medical waste shall not be placed into a container used for shipment of treated medical waste.

(4) 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.

(5) Treated medical waste shall be delivered to an approved sanitary landfill for disposal.

(6) Written certification, to the effect that all treatment requirements contained in this Chapter 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, provided by the person who treated the waste, to the permittee or his designee of the disposal facility utilized at the time of disposal. Appropriate documentation to confirm this certification may be required from the treatment facility.

(7) Pursuant to the provisions of Code of Alabama 1975, §22-22A-4(i), additional regulations addressing the storage of solid waste remain within the function of the State Health Department pursuant to Code of Ala. 1975, §22-22A-5 and §22-22A-8.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXXX.~~

**ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT  
LAND DIVISION – MEDICAL WASTE PROGRAM**

**CHAPTER 335-17-4  
STORAGE OF MEDICAL WASTE**

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| <b>335-17-4-.02</b> | <b>Storage of Treated Waste</b>   |

**335-17-4-.01      Storage of Untreated Waste.** Persons engaged in the storage of untreated medical waste shall comply with the following. Storage as used in this rule would begin after a shipping container is prepared for shipment to a storage or treatment facility.

(1) No person shall operate or maintain a facility for storage of untreated medical waste without a valid permit granted by the Department. Storage facilities 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 or leaking 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) Storage of untreated medical waste shall meet the following criteria:

(a) Storage of medical waste by the generator shall not exceed seven calendar days from the date initial storage begins unless waste is refrigerated at a temperature less than 45 degrees Fahrenheit. This requirement shall not apply to generators who generate less than 220 pounds per month of medical waste.

(b) Transportation of medical waste and subsequent storage prior to treatment shall be at temperatures less than 45 degrees Fahrenheit unless said transportation can be accomplished within in less than four hours.

(12) The permittee or his designee shall allow inspection of the storage facility by Department Personnel during normal working hours.

(13) The permittee shall maintain records as required by the Department for a period of three years. Records shall contain the following as minimum requirements:

(a) The name and location of any generator or transporter who utilize the storage facility.

1. Generators shall provide name and street address of business, name and telephone number of a contact person.

2. Transporters shall provide name and street address of business, name and telephone number of a contact person and list of any permits obtained for the transportation of untreated medical waste from a regulatory agency or.

(b) The quantity of medical waste stored 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 a contact person for the transporter removing the waste to another facility and any permits which have been issued to that transporter.

(e) The quantity of medical waste removed from the storage facility. The quantity may be recorded in tons, pounds, cubic yards, cubic feet, or gallons.

(14) The Permittee of a medical waste storage facility shall prepare a Management Plan for the medical waste handled and stored at their facility. Multiple locations covered by a single permit may be included in one overall plan if each facility is adequately addressed.

(a) The Management Plan must address to the extent the information is applicable to the storage facility:

1. The types of medical waste handled;
2. Storage procedures that will be followed;
3. Treatment facilities that will be utilized;
4. Steps that will be taken to minimize the exposure of employees to untreated medical waste;
5. Name of the individual responsible for the storage facility.

(b) The Management Plan must be kept at the permittee's principal place of business;

(c) The Management Plan must be made available to the Department upon request;

(d) The Management Plan must be updated as needed.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXXX~~.

**335-17-4-.02      Storage of Treated Waste.**

(1) Containerized treated medical waste 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, provided by the person who treated the waste, to be delivered to the permittee or his designee of the disposal facility utilized.

(3) Pursuant to the provisions of Code of Ala. 1975, §22-22A-4(i), additional regulations addressing the storage of solid waste remain within the function of the State Health Department pursuant to Code of Ala. 1975, §22-22A-5 and §22-22A-8.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXXX~~.

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

**CHAPTER 335-17-5  
TRANSPORTATION OF MEDICAL WASTE**

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**335-17-5-.01      Transportation of Untreated Waste.** Untreated medical waste transported off-site from the medical facility generating the waste, shall comply with the following requirements.

(1) No medical waste transporter shall accept untreated medical waste which contains hazardous waste or radioactive waste, for transportation to a medical waste treatment facility.

(2) 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.

(3) No medical waste transporter shall accept any container of untreated medical waste for transport which shows visible signs of leakage, or which is not properly sealed and labeled.

(4) No medical waste transporter shall compact untreated medical waste in a transport vehicle.

(5) No medical waste transporter shall allow untreated medical waste to escape from a transport vehicle into the environment. All vehicles utilized must be enclosed.

(6) No medical waste transporter shall deliver untreated medical waste to an unapproved storage, treatment, or disposal facility in Alabama. All out-of-state shipments should be coordinated with the appropriate regulatory authority of the receiving State.

(7) 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.

(8) Surfaces of medical waste transport vehicles which may come into contact with medical waste must be constructed of durable, easily cleanable materials.

(9) Surfaces of medical waste transport vehicles which have been in contact with untreated medical waste shall be decontaminated.

(10) All owners of medical waste transport vehicles shall apply within 90 days from the effective date of this Division for a permit to transport untreated medical waste in Alabama.

(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) All medical waste transporters shall notify the Solid Waste Program of the Department immediately by telephone if a spill 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 calendar days from the date the spill occurred.

(15) All medical waste transporters shall maintain records for a period of at least three 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 MWSF 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.

(16) All medical waste transport vehicles shall be equipped with refrigeration if necessary to comply with 335-17-4-.01(11).

(17) Each medical waste transporter shall prepare a Management Plan for the medical waste they handle.

(a) The 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. Steps that will be taken to minimize the exposure of employers to untreated medical waste throughout the process of transporting and handling the waste;
5. The name of the individual responsible for the transportation and management of medical waste.

(b) The Management Plan must be kept at the permittee's principal place of business.

(c) The Management Plan must be made available to the Department upon request.

(d) The Management plan must be updated as needed.

(18) All medical waste transporters shall notify the Solid Waste Branch of the Department immediately by telephone when untreated medical waste has been or is anticipated to be out of compliance with the refrigeration requirement as contained in paragraph 335-17-3-.01(11) while in their possession. A written report addressing why the waste was kept longer than seven days, without refrigeration being provided, 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 calendar days from the date noncompliance was noted.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXX~~.

**335-17-5-.02      Transportation of Treated Waste.** Medical Waste which has been treated shall meet the following requirements when transported off-site for disposal.



(1) Containers or vehicles cannot be red in color, or contain markings that would indicate the material is untreated medical waste. Containers may be repacked or relabeled to indicate that treatment has occurred.

(2) Transporters shall deliver the waste to an approved sanitary landfill for disposal.

(3) Treated medical waste may be mixed with other solid waste for transportation to a disposal facility in vehicles where compaction of the waste will take place.

(4) 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.

(5) Pursuant to the provisions of 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 Code of Alabama 1975, §22-22A-5 and §22-22A-8.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXXX.~~

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

**CHAPTER 335-17-6  
TREATMENT OF MEDICAL WASTE**

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**335-17-6-.01 Treatment Measures**

**335-17-6-.01 Treatment Measures.** Medical waste intended for transport to a solid waste disposal facility shall be treated on-site or at some 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 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.

(1) Incinerators. Persons owning or operating an incinerator (combustion unit) shall comply with the ADEM requirements in 335-3 regarding air pollution control.

(a) Storage requirements for untreated medical waste located at the incinerator facility shall comply with 335-17-4-.01.

(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 solid waste which is not classified as untreated medical waste shall comply with 335-17-5-.02.

(d) All combustible medical waste shall be rendered 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-.22.

(2) Steam Sterilizers. Persons owning or operating a commercial medical waste facility used to treat medical waste by steam sterilization shall apply for a permit within 90 days of the effective date of this Division. After the effective date of this Division, a person shall not start operating a new facility of this type without obtaining a valid permit from the Department. Medical waste may be treated by steam sterilizers (autoclaves) provided the following requirements are met:

(a) Medical waste containing hazardous chemicals, or radioactive waste shall not be approved for this method of treatment.

(b) Certain medical waste, including sharps and recognizable human tissue, organs, body parts, and infected animals, shall be further processed after the steam sterilization process.

1. The additional processing methods for sharps includes, but is not limited to, grinding, incineration, or packaging in puncture proof containers.

2. The additional processing methods for recognizable human tissue, organs, and body parts includes, but is not limited to, incineration, grinding and/or interment. The method selected must render the waste unrecognizable prior to containment for shipment to a disposal facility, or place of interment.

(d) Steam sterilizers should 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 of an equivalent test.

1. Each bag or container shall be exposed to a minimum temperature of 250 degrees Fahrenheit and at least 15 pounds of pressure for 30 minutes. Processing requirements may be altered if proper decontamination is assured by appropriate testing, and approval is received from the Department.

2. Each sterilizer shall be evaluated for effectiveness under full loading by an approved method at least once for each 40 hours of combined operation. Biological indicators such as spores of "Bacillus stearothermophilus" 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 waste treatment shall not be utilized for sterilization of equipment, food, or other related items.

(3) Other treatment methods may be approved by the Department which are consistent with the intent of this Division. A person must 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.

(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(1) and (2).

(g) A demonstration of the effectiveness of the proposed treatment method.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXX~~.

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

**CHAPTER 335-17-7  
DISPOSAL OF MEDICAL WASTE**

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**335-17-7-.01**      **Disposal of Untreated Waste.** Medical waste shall be treated on-site at the point of generation or off-site at an approved treatment facility prior to delivery to a solid waste disposal facility. If the Department determines that the generator or treater of medical waste cannot comply with this requirement, a variance may be granted. Rules relating to collection, storage and transportation must be addressed in the variance request. In addition, the request must address why treatment facilities within a reasonable distance cannot handle their waste if temporary storage was utilized.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXX.~~

**335-17-7-.02**      **Disposal of Treated Waste.** All treated medical waste intended for disposal in a sanitary landfill shall be disposed of in an approved facility.

(1) Requirements for disposal in an approved solid waste disposal facility is as follows:

(a) Medical waste containing liquids must be further processed to eliminate free liquids and further reduce the liquid consistency to the point where the waste would be considered bladeable by disposal facility personnel.

(b) Written certification to the effect that medical waste has been properly treated shall be provided to the permittee or his designee.

1. The minimum frequency for providing this certification shall be annually. The treater shall be responsible for providing this certification.

2. The permittee or the Department may require more frequent certification.

(i) Certifications provided on a per-load basis shall be made available to the permittee or his designee prior to unloading.

(ii) Certifications required more frequently than yearly, but less frequently than a per-load basis, shall be provided as required by the permittee or the Department.

(c) 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.

(d) All records shall be maintained by the permittee for at least three years and shall be available upon request for review by the Department.

(e) No untreated medical waste shall be accepted for disposal without Departmental approval

1. Packaging, as required in 335-17-3-.01, shall not be accepted for disposal without a variance being granted by the Department.

2. Containers showing signs of leakage shall not be accepted.

(f) Medical waste properly treated shall be placed directly in the active face for putrescibles and managed accordingly.

**Author:** James L. Bryant.

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

**History:** ~~XXXXXXX~~.

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

**CHAPTER 335-17-8  
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**335-17-8-.01**     **Variances.**     The Department may grant individual variances from the specific provisions of Division 17 based upon the procedures of 335-17-8-.02 through 335-17-8-.05 whenever it is found by the Department, upon presentation of adequate proof, that non-compliance with Division 17 will not threaten the public health or unreasonably create environmental pollution. Variances per se are not favored by the Department.

**Author:** James L. Bryant.

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

**History:** **XXXXXXX.**

**335-17-8-.02**     **Petition for Variance.**

(1)     **Applicability.**     Any person may request a variance from specific provisions of Division 17 by filing a Petition for Variance with the Department.

(2)     **Petition Requirements.**     To enable the Department to rule on the Petition 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 Division 17 will not threaten the public health or unreasonably create environmental pollution.

- (e) Applicable fees in accordance with Division 1.

**Author:** James L. Bryant.

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

**History:** **XXXXXXXX.**

**335-17-8-.03      Extension of Prior or Existing Variance.** 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 335-17-8-.02.

(1) To the extent that the information required by 335-17-8-.02 has been included in the prior Petition for Variance for which extension is sought, a submission of that information shall not be required provided that the petition shall request the incorporation of the record, opinion and order in the prior proceeding into the new petition.

(2) A petition to extend a prior or existing variance shall be a new petition for Variance before the Department and shall be subject to all of the requirements of this Division except as provided in 335-17-8-.03(1).

**Author:** James L. Bryant.

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

**History:** **XXXXXXXX.**

**335-17-8-.04      Department Action on Petitions for Variance.** On receipt of a Variance Petition the Department will authorize one of the following actions, as they shall determine:

(1) The petition may be dismissed if the Department determines that it is not adequate under 335-17-8-.02.

(2) The Department may grant the variance as petitioned or by imposing such conditions as this Division may require, including the establishment of schedules of compliance and monitoring requirements.

(3) 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.

**Author:** James L. Bryant.

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

**History:** **XXXXXXXX.**

**335-17-8-.05      Termination of Variance.** Any variance granted by the Department may be terminated by the Department whenever the Department finds, after notice and opportunity for hearing, 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.

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

**History:** ~~XXXXXXXX.~~