

APA-1

TRANSMITTAL SHEET FOR NOTICE
OF INTENDED ACTION

Control: 335

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

Rule No.: Chapter 335-17-6

Rule Title: Treatment of Medical Waste

Intended Action Amend

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

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

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

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

To what degree?: N/A

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

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

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

Does the proposed rule have an economic impact? No

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

Certification of Authorized Official

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

Signature of certifying officer

Jeffery W. Kitchens
Jeffery W. Kitchens

Date

Tuesday, March 18, 2025

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

ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
LAND DIVISION – MEDICAL WASTE PROGRAM

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Environmental Management

RULE NO. & TITLE: Chapter 335-17-6 Treatment of Medical Waste

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:

Changes are being proposed to 335-17-6 to add new treatment measures, add permitting requirements, update requirements for Medical Waste Management Plans, and add language for transportation after treatment.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:

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

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Tuesday, May 6, 2025

CONTACT PERSON AT AGENCY:

Lynn T. Roper, 334-271-7728

Jeffery W. Kitchens

Jeffery W. Kitchens

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

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

CHAPTER 335-17-6
TREATMENT OF MEDICAL WASTE

TABLE OF CONTENTS

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 somean 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.

~~(1)~~ (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;

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

(d) All ~~combustible medical waste shall be rendered~~medical waste 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).

~~(2)-(10) 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.~~ Medical waste may be treated by steam sterilizers (autoclaves) as outlined in the following requirements:

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

(b) ~~Certain medical waste, including sharps and~~ 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.

~~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 that enable transport and disposal without leakage or spillage.~~

(d) Steam sterilizers ~~should~~ 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 ~~of an equivalent test~~ 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 ~~15 pounds of pressure for 30~~ 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 ~~40 hours of combined operation. Biological indicators such as spores of "Bacillus~~ forty (40) hours of combined operation. Biological indicators such as spores of "Geobacillus 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 medical waste treatment shall not be utilized for sterilization of equipment, food, or other related items.

~~(3)~~ (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 pyrolysis medical waste 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 ~~intent of this Division. A person must~~ 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 ~~(1) and (2)~~ (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 ; effective .