

**SUMMARY OF REASONS/CHANGES
PROPOSED FOR RULE 335-13-7-.01(2), NOTIFICATION OF MEDICAL
WASTE GENERATION, ADEM ADMINISTRATIVE CODE**

RULE	COMMENTS/REASONS FOR CHANGE
335-13-7-.01(2)	Narrative in the current subsection is deleted and the name of this subsection is retitled “Notification of Medical Waste Generation.”
335-13-7-.01(2)(a) Registration	“Name and address of generator” is deleted. Subsection is retitled “Registration.” Medical waste generators currently submit ADEM Form 410, Medical Waste Notification Form, to request an identification number. The current regulations do not specifically require use of Form 410. This amendment requires the form to be used to register as a medical waste generator.
335-13-7-.01(2)(b) Reporting	“Name and telephone of responsible person” is deleted, and the subsection is retitled “Reporting.” Medical waste generators currently do not have to make routine reports of their activities to manage and treat their medical waste. This Rule requires each medical waste generator to submit an annual notification to ADEM using ADEM Form 410 and provide information on the quantity of waste generated during 12 months, the name of permitted medical waste transporters used to transport the medical waste off-site for treatment, the name of the permitted medical waste treatment facility used by the generator, and whether the generator treated the waste on-site. There is also a requirement that each generator making their annual notification submit an Annual Notification Fee as specified in 335-1-6, Fee Schedule G. The data submitted on Form 410 will provide information necessary to properly implement and enforce its medical waste program. New subsections in 335-13-7-1-.02(2)(b) specify use of Form 410 and when it is to be submitted.
335-13-7-.01(2)(c) Exemptions	“Street address, including nearest city, of generator’s facility” and narrative following is deleted, and the subsection is retitled “Exemptions.” Certain small quantity generators of medical waste do not require the same regulatory oversight as larger quantity generators, and ADEM is proposing that they be exempted if they meet certain requirements. The subsections in 335-13-7-.01(2)(c) define a small quantity medical waste generator and provides that these small quantity generators may apply for an exemption if they generate less than 25

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pounds or 7 cubic feet of medical waste per month. These new subsections also include recordkeeping requirements, voiding of exemptions, and other requirements for exemptions.

335-13-7-.01(2)(d)

This is a new subsection which provides for a registered medical waste generator to request removal from the list of medical waste generators in Alabama. Subsections under 335-13-7-.01(d) specify how the generator can request to be removed from the list of medical waste generators.

335-13-7-.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 storage 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) Notification of Medical Waste Generation.~~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) Registration. ~~Name and mailing address of generator;~~A person who will begin generation of medical waste after the effective date of this Division must submit ADEM Form 410 to register with ADEM and obtain a medical waste generator identification number. The registration must be submitted at least ninety (90) days prior to generation of medical waste. The generator shall prepare a Medical Waste Management Plan prior to any waste generation, treatment, transportation, or disposal activity.

1. A medical waste generator who did not register with ADEM and obtain a medical waste generator identification number prior to the effective date of this Division shall submit ADEM Form 410 to be assigned a medical waste generator identification number.

2. Each medical waste generator shall maintain monthly records on the amount of medical waste generated, the amount of medical waste transported off-site for treatment, and the amount of medical waste treated on-site.

(b) ~~Name and telephone number of responsible person;~~Reporting. Each medical waste generator shall submit ADEM Form 410, Notification of Medical Waste Generation, to report that medical waste has been generated and to report how the medical waste has been managed. Reporting shall be according to the schedule in 335-13-7-.01(2)(b)4., unless exempt in 335-13-7-.01(2)(c).

1. Each notification form shall be accompanied by the Annual Notification fee for medical waste generators in 335-1-6, Fee Schedule G, unless exempt in 335-13-7-.01(2)(c).

2. If no medical waste was generated at any time in the twelve (12) months prior to the reporting month specified in 335-13-7-.01(2)(b)4., the generator may:

(i) Maintain registration as a medical waste generator by submitting ADEM Form 410 and report that no medical waste was generated. The Annual Notification fee for medical waste generators in 335-1-6, Fee Schedule G, shall be paid with submittal of the form.

(ii) Apply for an exemption as a small quantity medical waste generator, as provided in 335-13-7-.01(2)(c).

(iii) Request to be removed from the list of registered medical waste generators, as provided in 335-13-7-.01(2)(d).

3. Generators shall report the following on ADEM Form 410:

(i) Total quantity of medical waste generated during the twelve-month reporting period;

(ii) Total quantity of medical waste shipped off-site during the twelve-month reporting period;

(iii) Total quantity of medical waste treated on-site during the twelve-month reporting period;

(iv) Medical Waste Transporters used during the twelve-month reporting period;

(v) Medical Waste Treatment Facilities used during the twelve-month reporting period.

4. Generators shall submit the annual Notification of Medical Waste Generation form by the date specified below for the county in which the generating facility is physically located. The reporting period shall be for twelve (12) consecutive months as specified.

(i) In Autauga, Covington, Dale, Elmore, Escambia, Franklin, Jackson, Macon, Russell and Talladega Counties, for the reporting period January through December, notifying not later than January 20.

(ii) In Dallas, Houston, Marshall, St. Clair, Tallapoosa and Walker Counties, for the reporting period February through January, notifying not later than February 20.

(iii) In Jefferson County and for all out-of-state medical waste generators whose waste is imported into the State of Alabama for storage or treatment, for the reporting period March through February, notifying not later than March 20.

(iv) In Cullman, Lee and Montgomery Counties, for the reporting period May through April, notifying not later than May 20.

(v) In Barbour, Butler, Chambers, Cherokee, Chilton, Choctaw, Clay, Geneva, Lamar, Lawrence, Marengo, Monroe, Pike, Randolph, Sumter and Winston Counties, for reporting the period June through May, notifying not later than June 20.

(vi) In Etowah, Lauderdale and Morgan Counties, for the reporting period July through June, notifying not later than July 20.

(vii) In Bibb, Bullock, Cleburne, Conecuh, Coosa, Crenshaw, Fayette, Greene, Hale, Henry, Lowndes, Perry, Pickens, Washington and Wilcox Counties, for the reporting period August through July, notifying not later than August 20.

(viii) In Colbert, Shelby and Tuscaloosa Counties, for the reporting period September through August, notifying not later than September 20.

(ix) In Blount and Madison Counties, for the reporting period October through September, notifying not later than October 20.

(x) In Baldwin, Calhoun, Coffee, DeKalb, Limestone and Marion Counties, for the reporting period November through October, notifying not later than November 20.

(xi) In Clarke and Mobile Counties, for the reporting period December through November, notifying not later than December 20.

(c) Exemptions. ~~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.~~

1. A small quantity medical waste generator is exempt from annual notification requirements and payment of the Annual Notification fee for medical waste generators in 335-1-6, Fee Schedule G. A small quantity medical waste generator is defined as a person who generates less than twenty-five (25) pounds or seven (7) cubic feet of medical waste per calendar month.

(i) A generator may request an exemption as a small quantity medical waste generator by submitting ADEM Form 410 and a written request which includes the quantity of medical waste generated during each calendar month for a twelve-month period. The twelve-month period of record to qualify as a small quantity medical waste generator shall have begun not later than fifteen (15) months prior to the submittal date of the request for an exemption as a small quantity medical waste generator.

(ii) If the medical waste generator generates more than twenty-five (25) pounds or seven (7) cubic feet of medical waste in any one calendar month during which time it is classified as a small quantity medical waste generator, the exemption as a small quantity medical waste generator is voided and the generator must notify ADEM within thirty (30) calendar days by submitting ADEM Form 10 and pay the Annual Notification fee.

2. Medical waste generators must have a medical waste generator identification number and must collect and maintain records as required in 335-7-1-.02(2)(a)2. to be exempt from any requirement of 335-7-1-.02

(d) A generator may request to be removed from the list of registered medical waste generators if the generator has not generated any medical waste in the twelve (12) months prior to submitting the request.

1. The generator must submit ADEM Form 410 indicating that no waste was generated in the prior twelve (12) months and a written request to be removed from the registered generator list.

2. The generator will be notified by ADEM within thirty (30) days of actions to remove the generator from the registered generator list. ADEM will revoke the medical waste generator identification number of the generator requesting to be removed.

3. If a person wishes to resume generation of medical waste, it shall comply with 335-13-7-.01(2)(a) and apply as a new medical waste generator.

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Statutory Authority: Code of Alabama 1975, §§22-27-1 to 7.

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Amended: xxxxxxxxxx.