

**15A NCAC 13B .1204 REQUIREMENTS FOR THE TREATMENT OF REGULATED MEDICAL WASTE**

(a) General requirements for treated regulated medical waste:

- (1) Treated regulated medical waste shall be covered to prevent exposure to the environment and inclement weather.
- (2) Treated regulated medical waste may be placed uncovered in or under a weather resistant structure while dewatering or while in the process of being covered.
- (3) Treated regulated medical waste shall be stored no longer than 14 calendar days after treatment unless the facility's operations plan states that the storage unit is a necessary part of the operation of the treatment process and is enclosed, sealed, and watertight.
- (4) Treated regulated medical waste storage and transport containers, compactors, trailers, and cargo bays shall be maintained in accordance with the manufacturer's specifications.
- (5) Treated regulated medical waste shall not be transported off site uncovered.
- (6) The exterior of treated regulated medical waste storage and transport containers, compactors, trailers, and cargo bays shall be free of solid waste and solid waste residue.
- (7) Treated regulated medical waste shall not become putrescent. Putrescent treated regulated medical waste shall be disposed of within three calendar days.
- (8) Treated regulated medical waste shall not become a nuisance.
- (9) Treated regulated medical waste shall be noninfectious.

(b) General requirements for treatment facilities:

- (1) The treatment facility shall be compliant with Rule .1202(o), (p), and (q) of this Section.
- (2) The treatment facility shall issue a written record notifying the generating facility if it becomes aware of a package of medical waste received that is not in compliance with Rule .1202(i) of this Section for the treatment method utilized. A copy of the record shall be maintained at the treatment facility.
- (3) The treatment facility shall maintain a record of each shipment of regulated medical waste received for treatment for a period of three years to include the following information:
  - (A) the number of packages;
  - (B) the generator name, physical address, and phone number;
  - (C) the transporter name, physical address, and phone number;
  - (D) the date each package was picked up from the generator;
  - (E) the date each package was received at the treatment facility;
  - (F) the weight of each package in pounds; and
  - (G) the date each package was treated.
- (4) The treatment facility shall submit a facility operations plan to the Division with the permit application required in accordance with the rules of this Subchapter that shall include the following information:
  - (A) the name, mailing address, physical address, office and mobile phone numbers, and email address for the responsible party(s), owner(s), and operator(s);
  - (B) the physical address and the county GIS property data for the facility location;
  - (C) types and estimated amounts of medical waste to be accepted at and shipped out from the facility;
  - (D) a description of the treatment process or processes, and treatment unit specifications;
  - (E) procedures for how the medical waste will be received, handled, stored, transferred, or treated at the facility;
  - (F) procedures for sampling or testing required by the rules of this Section;
  - (G) procedures that the facility shall use to prevent medical waste from becoming a nuisance or putrescent, and procedures for abatement if medical waste becomes a nuisance or putrescent;
  - (H) contingency plan identifying risks and describing how the facility or transporter will respond to incidents or emergencies, including a phone number for a facility or transporter representative that is available to respond 24 hours a day and seven days a week, and how regulated medical waste will be handled or redirected when facilities or transport vehicles are unavailable due to maintenance, adverse weather, or other emergencies; and

- (I) additional information that the Division may request pertaining to the facility operations if it is necessary to determine compliance with the rules of this Section.

A copy of the operations plan shall be kept at the facility and shall be available for review by the Division during facility inspections or upon request by the Division. If the information required by this Paragraph changes, the facility shall submit a revised facility operations plan to the Division and update the copies of the plan kept by the facility.

- (5) The treatment facility shall maintain a record of the disposal facility's contact information including the facility name, permit number, physical location and mailing address, and contact name and phone number.
- (6) The treatment facility shall maintain a record of the dates and tonnages of treated regulated medical waste sent for disposal.
- (7) The treatment facility shall maintain operating records and monitoring, testing, and maintenance records required in accordance with the rules of this Section for a period of three years.
- (8) The facility shall submit an annual report to the Division in accordance with G.S. 130A-309.09D(b).

(c) Steam sterilization treatment requirements:

- (1) Steam under pressure shall be provided to maintain a temperature of not less than 250 degrees Fahrenheit for 45 minutes at 15 pounds per square inch of gauge pressure during each cycle.
- (2) The steam sterilization unit shall have a device that records the start and end time of each cycle.
- (3) The steam sterilization unit shall have a device that records the pressure and a device that records the temperature throughout each cycle.
- (4) Testing of treatment under conditions of full loading to confirm compliance with Subparagraph (a)(9) of this Rule shall be performed no less than once per week using a biological indicator of *Geobacillus stearothermophilus* spores having a population of not less than  $1.0 \times 10^4$  placed within the waste load.
- (5) A record of each test performed shall be maintained and shall include the type of indicator used, the test date, the start and end times, and the test result.

(d) Incineration treatment requirements:

- (1) The Division shall not issue a solid waste management permit in accordance with the rules of this Subchapter to the treatment facility unless the Division of Air Quality (DAQ) has issued a permit for operation of the incinerator.
- (2) The treatment facility shall maintain the DAQ permit for the operation of the incinerator.
- (3) Regulated medical waste shall be subjected to a burn temperature in the primary chamber of not less than 1200 degrees Fahrenheit.
- (4) The incinerator shall have a monitoring device that records the primary chamber temperature. A record of the continuous monitoring of the primary chamber temperature while in use shall be maintained.
- (5) Interlocks or other process control devices shall be provided to prevent the introduction of regulated medical waste into the primary chamber until the secondary chamber achieves operating temperature as defined in the permit for incinerator operation issued by DAQ.
- (6) Procedures for obtaining uniform representative composite ash samples shall be submitted to the Division for approval in the facility operations plan in accordance with Rule .1204(b)(4) of this Section. Ash sampling procedures shall be approved if the procedures are compliant with the requirements of this Subchapter, are protective of human health and the environment, and if the samples collected using the procedures are representative of the incinerator ash shipped from the facility for disposal.
- (7) The ash samples shall be collected from the dewatered ash collection container or containers.
- (8) For the first three months of incinerator operation, the ash sampling procedures required by Subparagraph (6) of this Paragraph shall include the collection of a representative ash sample of one kilogram (2.2 pounds):
  - (A) once for every eight hours of operation for an incinerator that is operated on a continuous schedule;
  - (B) once for every 24 hours of operation for an incinerator that is operated on an intermittent schedule; or
  - (C) once for every batch for an incinerator that is batch-loaded.

The ash samples shall be composited in a closed container weekly and shall be mixed and reduced to a uniform ash sample. The weekly ash samples shall be composited into a monthly ash sample, and the monthly ash sample shall be analyzed.

- (9) For the remainder of the first year of incinerator operation, a representative ash sample shall be collected once per month using the procedures described in the facility operations plan. The monthly ash samples shall be composited and reduced to a uniform quarterly ash sample, and the quarterly ash samples shall be analyzed.
  - (10) After the first year of incinerator operation, representative composite ash samples shall be collected using the procedures described in the facility operations plan twice per calendar year, with no less than four months between sample collection, and the samples shall be analyzed.
  - (11) Ash samples required to be analyzed in accordance with Subparagraphs (8) through (10) of this Paragraph shall be analyzed in accordance with 40 CFR 261.24 for the eight metals listed in Table 1 (arsenic, barium, cadmium, chromium, lead, mercury, selenium, and silver). 40 CFR 261 is incorporated by reference including subsequent amendments and editions; and can be accessed at no cost at <https://www.gpo.gov/>.
  - (12) A record of the testing and analysis results shall be submitted to the Division for the first year of incinerator operation, and upon request from the Division thereafter. The record shall be maintained at the facility and available for inspection by the Division. The record shall include:
    - (A) the composite ash sample date and time;
    - (B) the ash sample date and time;
    - (C) the ash sample identification number;
    - (D) the ash sample analysis results; and
    - (E) the testing laboratory name and contact information and certification number.
  - (13) The Division may require the treatment facility to collect additional composite ash samples or analyze the samples for the full contaminant list in accordance with 40 CFR 261.24 Table 1 if the results of the analysis required in Subparagraphs (8) through (11) of this Paragraph indicate an exceedance of the regulatory level provided in 40 CFR 261.24 Table 1; or during a permitting action, a facility inspection, or when a complaint is received if it is necessary to determine compliance with the rules of this Subchapter. The requirements of this Paragraph shall not prevent a municipal solid waste landfill that is accepting incinerator ash from a treatment facility from requiring that additional ash samples be taken and analyzed to determine compliance with the rules of this Subchapter before the ash is accepted for disposal.
- (e) Chemical treatment requirements:
- (1) Microbiological waste shall be treated with 10 percent chlorine solution for no less than one hour.
  - (2) Testing of treatment under conditions of full loading to confirm compliance with Subparagraph (a)(9) of this Rule shall be performed no less than once per week using a biological indicator of *Bacillus atrophaeus* spores having a population of not less than  $1.0 \times 10^6$ .
  - (3) A record of each test performed shall be maintained and shall include the type of indicator used, the test date, the start and end times, and the test result.
- (f) Microwave treatment requirements:
- (1) Microwave energy of appropriate output frequency shall be provided at a temperature of not less than 203 degrees Fahrenheit (95 degrees Celsius) for no less than 30 minutes each cycle.
  - (2) The microwave treatment system shall be provided with a monitoring device that records time and temperature of each cycle. A record of the monitoring of the time and temperature of each cycle shall be maintained.
  - (3) Testing of treatment under conditions of full loading to confirm compliance with Subparagraph (a)(9) of this Rule shall be performed no less than once per week using a biological indicator of *Bacillus atrophaeus* spores having a population of not less than  $1.0 \times 10^6$  and in accordance with the equipment manufacturer's instructions.
  - (4) A record of each test performed shall be maintained and shall include the type of indicator used, the test date, the start and end times, and the test result.
- (g) Ozonation treatment requirements:
- (1) Testing of treatment under conditions of full loading to confirm compliance with Subparagraph (a)(9) of this Rule shall be performed no less than once per week using a biological indicator of *Bacillus atrophaeus* spores having a population of not less than  $1.0 \times 10^6$  and in accordance with the equipment manufacturer's instructions.

- (2) Once every six months samples collected under conditions of full loading shall be submitted to an independent laboratory to confirm compliance with Subparagraph (a)(9) of this Rule.
  - (3) A record of each test performed shall be maintained and shall include the type of indicator used, the test date, the start and end times, and the test result.
- (h) Alternative treatment methods.
- (1) A treatment facility owner or operator may request to use a method of, or procedures for, regulated medical waste treatment not listed or described in this Rule by submitting a request to the Division for approval. The request shall include documentation that describes the alternative treatment method, explains the procedures and provides analysis results to demonstrate that the treatment method will render the regulated medical waste noninfectious, and describes how the treatment method meets the requirements of the rules of this Section.
  - (2) A request for an alternate method of chemical treatment shall also describe the chemical used to treat the specific microbiological agent(s) of concern for the regulated medical waste type, and shall consider factors such as temperature, contact time, pH, concentration, and the presence and state of dispersion, penetrability, and reactivity of organic material at the site of application.
  - (3) The Division shall approve the alternative treatment method by issuing the permit or an approval letter if the alternative treatment method renders the regulated medical waste noninfectious, and the alternative treatment method is compliant with the rules of this Section and protective of human health and the environment.

*History Note: Authority G.S. 130A-309.26;  
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