

**15A NCAC 13B .1207 OPERATIONAL REQ/REGULATED MEDICAL WASTE TREATMENT FACILITIES**

A person who treats Regulated medical waste shall meet the following requirements for each type of treatment in addition to the requirements in Rule .1203 of this Section.

- (1) General requirements:
  - (a) Refrigeration at an ambient temperature between 35 and 45 degrees Fahrenheit shall be maintained for Regulated medical waste not treated within seven calendar days after shipment.
  - (b) Regulated medical waste shall be stored prior to treatment for no more than seven calendar days after receipt.
  - (c) Regulated medical waste shall be stored no longer than seven calendar days after treatment.
  - (d) Only authorized personnel shall have access to areas used to store Regulated medical waste.
  - (e) All areas used to store Regulated medical waste shall be kept clean. Neither carpets nor floor coverings with seams shall be used in storage areas. Vermin and insects shall be controlled.
  - (f) Prior to treatment, all Regulated medical waste shall be confined to the storage area.
  - (g) All floor drains shall discharge directly to an approved sanitary sewage system. Ventilation shall be provided and shall discharge so as not to create nuisance odors.
  - (h) A plan shall be prepared, maintained and updated as necessary to ensure continued proper management of Regulated medical waste at the facility.
  - (i) Records of Regulated medical waste shall be maintained for each shipment and shall include the information listed in this Paragraph. This information shall be maintained at the treatment facility for no less than three years.
    - (i) name and address of generator;
    - (ii) date received;
    - (iii) amount of waste received by number of packages (piece count) from each generator;
    - (iv) date treated;
    - (v) name and address of ultimate disposal facility.
  - (j) Regulated medical waste treatment facilities that treat waste generated off-site shall submit to the Division an annual report, by August 1 of each year on a form prescribed and approved by the Division.
- (2) Steam sterilization requirements:
  - (a) Steam under pressure shall be provided to maintain a minimum temperature of 250 degrees Fahrenheit for 45 minutes at 15 pounds per square inch of gauge pressure during each cycle; or other combinations of parameters that are shown to effectively treat the waste.
  - (b) The steam sterilization unit shall be provided with a chart recorder which accurately records time and temperature of each cycle.
  - (c) The steam sterilization unit shall be provided with a gauge which indicates the pressure of each cycle.
  - (d) Monitoring under conditions of full loading for effectiveness of treatment shall be performed no less than once per week through the use of biological indicators or other methods approved by the Division.
  - (e) Regulated medical waste may be disposed of until or unless monitoring as required in Sub-Item (2)(d) of this Rule does not confirm effectiveness.
  - (f) A log of each test of effectiveness of treatment performed shall be maintained and shall include the type of indicator used, date, time, and result of test.
- (3) Incineration requirements:
  - (a) Regulated medical waste shall be subjected to a burn temperature in the primary chamber of not less than 1200 degrees Fahrenheit.
  - (b) Automatic auxiliary burners which are capable, excluding the heat content of the wastes, of independently maintaining the secondary chamber temperature at the minimum of 1800 degrees Fahrenheit shall be provided. Interlocks or other process control devices shall be provided to prevent the introduction of waste material to the primary chamber until the secondary chamber achieves operating temperature.
  - (c) Gases generated by the combustion shall be subjected to a minimum temperature of 1800 degrees Fahrenheit for a period of not less than one second.
  - (d) Continuous monitoring and recording of primary and secondary chamber temperatures shall be performed. Monitoring data shall be maintained for a period of three years.

- (e) An Air Quality Permit shall be obtained from the Division of Environmental Management prior to construction and operation.
  - (f) A plan of procedures for obtaining representative weekly and monthly composite ash samples shall be submitted for Division approval prior to system start-up and operation. If design or operation of the system is substantially changed or modified, or if the waste composition, loading rate or loading method are substantially changed, the ash sampling plan will be subject to modification to accommodate such changes. Ash sampling procedures shall be initiated at the time the incineration system is first started for normal operation.
  - (g) As a minimum, a representative sample of about one kilogram (2.2 lb) shall be collected once for every eight hours of operation of a continuously fed incinerator; once for every 24 hours of operation of an intermittently operated incinerator; or once for every batch of a batch loaded incinerator. The samples shall be collected from either the discharge of the ash conveyor or from the ash collection containers prior to disposal. Samples shall be composited in a closed container weekly and shall be thoroughly mixed and reduced to a representative sample. These shall be composited into monthly samples. For the first three months of operation, each monthly sample shall be analyzed.
  - (h) For the remainder of the first year of operation, representative monthly samples shall be composited into a quarterly sample and analyzed at the end of each quarter.
  - (i) After the first year, representative samples shall be analyzed at least twice a year.
  - (j) Ash samples shall be tested in accordance with provisions of 15A NCAC 13B .0103(e) and submitted to the N.C. Solid Waste Section.
  - (k) A log shall be kept documenting ash sampling, which shall include the date and time of each sample collected; the date, time, and identification number of each composite sample; and the results of the analyses, including laboratory identification.
  - (l) Records of stack testing as prescribed in the Air Quality Permit shall be maintained at the facility.
  - (m) Existing generating facilities shall conduct one weekly representative ash sampling and testing in accordance with Sub-Items (3)(f), (g) and (j) of this Rule annually during the second quarter of each calendar year.
- (4) Chemical treatment requirements:
- (a) Cultures of throat, urine, sputum, skin and genitourinal tract which contain only the following organisms; *N. gonorrhoea*, *E. coli*, *staphylococcus*, *proteus*, *Candida albicans*, and *B. cereus* or normal flora in individual plates or tubes containing 5-20 ml media shall be covered, for a minimum of one hour, with a 1:5 dilution of household bleach (5.25 percent sodium hypochlorite) in water. The solution shall remain on the treated plates which are to be stacked in a plastic bag prior to disposal. The bag is to be sealed to prevent leakage.
  - (b) Approval for other types of chemical treatment must be obtained from the Division. Request for approval must be substantiated by results of demonstrated effectiveness of the chemical to treat the specific microbiological agent(s) of concern for the waste disposed. Consideration must be given to such factors as temperature, time of contact, pH, concentration and the presence and state of dispersion, penetrability and reactivity of organic material at the site of application.
  - (c) A written plan must be maintained at the facility and units of the facility as necessary to ensure consistent procedures are used to treat the waste.
- (5) Microwave treatment requirements:
- (a) Microwave energy of appropriate output frequency shall be provided such that a minimum temperature of 95 degrees Centigrade (203 degrees Fahrenheit) is maintained for a minimum of 30 minutes each cycle; or other combinations of parameters that are shown to effectively treat the waste.
  - (b) The microwave system shall be provided with a means to continually monitor and record time and temperature of each cycle.
  - (c) Monitoring under conditions of full loading for effectiveness of treatment shall be performed through the use of a biological indicator or other methods approved by the Division. Testing shall be performed no less than once per week or as specified by the Division. Additional testing shall be performed if temperature/time monitoring indicates a variation from requirements in Sub-Item (5)(a) of this Rule.

- (d) A log of each test of effectiveness of treatment performed shall be maintained and shall include the type of indicator used, date, time, and result of test.
- (e) Regulated medical waste may be disposed of until or unless monitoring as required in Sub-Item (5)(c) of this Rule does not confirm effectiveness.

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