SECTION .1200 – MEDICAL WASTE MANAGEMENT

15A NCAC 13B .1201
DEFINITIONS

(1) "Blood and body fluids" means liquid blood, serum, plasma, other blood products, emulsified human tissue, spinal fluids, and pleural and peritoneal fluids. Blood and body fluids does not include dialysates, feces, or urine.
(2) “Division” means the North Carolina Department of Environmental Quality (NCDEQ), Division of Waste Management.
(3) "Generator/Generating facility" means any business or integrated medical facility where medical waste is produced, including but not limited to a medical and dental practice, mortuary, laboratory, veterinary hospital, and blood bank. Generator/generating facility does not include medical waste produced by, or associated with, an individual at a residence or other residential sources.
(4) "Medical waste" is solid waste generated by medical and dental facilities and mortuaries or in the research, testing, diagnosis, treatment, or immunization of human beings or animals and includes non-hazardous pharmaceutical waste. Medical waste does not include hazardous waste or wastes exhibiting the characteristics of a hazardous waste, radioactive waste, residential waste or those substances excluded from the definition of "solid waste" in this section.
(5) "Microbiological waste" means cultures and stocks of infectious agents, including but not limited to specimens from medical, pathological, pharmaceutical, research, commercial, and industrial laboratories.
(6) “Non-hazardous pharmaceutical waste” is a medical drug that is expired, unused, contaminated, damaged, or no longer needed or used for its intended purpose and which is not designated as a hazardous waste or does not exhibit the characteristics of a hazardous waste.
(7) “Nuisance” means odorous beyond the property boundary, uncontrolled vermin and/or disease vectors, or interfering unreasonably with the enjoyment of life or property. Treatment facilities in operation when these rules come into effect shall not be held to the standard of “interfering unreasonably with the enjoyment of life or property” if the treatment facility takes steps that are reasonably practicable to mitigate the allegation. Treatment facilities in operation after these rules come into effect shall identify potential nuisance conditions in the facility operations plan submitted to the Division.
(8) “Package” is the sum of a box, drum, or vessel containing medical waste.
(9) "Pathological waste" means human tissues, organs, and body parts; and the carcasses and body parts of animals that were known to have been exposed to pathogens that are potentially dangerous to humans during research, were used in the production of biologicals or in vivo testing of pharmaceuticals, or that died with a known or suspected disease transmissible to humans. Pathological waste does not include tissues that have been fixed with formaldehyde or other approved preserving agent so long as the process renders the tissues noninfectious.
(10) “Putrescent/Putrescible" means solid waste capable of being decomposed by microorganisms with sufficient rapidity as to cause nuisance odors and gases.
(11) “Record” means any data required to be maintained and/or submitted to the Division. A record may be in any commonly accepted format that is easily observable and written in English.
(12) “Regulated medical waste” is medical waste and consists, in whole or in part, of microbiological waste, pathological waste, and blood and body fluids in individual containers in volumes greater than 20 ml. In the event of emerging infection, the Division can expand its guidance of, and authority over, regulated medical waste.
(13) “Responsible party” means the entity responsible for regulated medical waste identified by the chain of custody or similar documentation.

(14) "Sharps" means needles, syringes, capillary tubes, scalpel blades, lancets, auto injectors, connection needles/sets, exposed ends of dental wires, and objects that can penetrate the skin.
(15) "Trace chemotherapy waste" means no more than 3% by weight of a medical drug used for chemotherapy. Trace chemotherapy waste includes gowns, gloves, wipes, and other routine handling, preparation, administration, cleaning, and decontamination items associated with chemotherapy.
(16) "Transfer and/or storage operations" is the act of, and process by which, regulated medical waste is removed from a transport vehicle and placed in another transport vehicle or in storage awaiting transport.
(17) "Transport vehicle" means a vehicle or other conveyance type used to transport medical waste for treatment to transfer and/or storage operations and/or a treatment facility.
(18) "Treatment" is the method by which regulated medical waste is rendered noninfectious.
(19) "Treatment facility" means permitted regulated medical waste treatment facility.
(20) "Solid waste" as defined in NCGS 130A-290(35).

History Note: Authority G.S. 130A-309.26;
Eff. October 1, 1990; Amended Eff. April 1, 1993; Amended Eff. XX/XX/XX.

15A NCAC 13B .1202
GENERAL REQUIREMENTS FOR MEDICAL WASTE

(1) Medical waste is subject to 15A NCAC 13B, "Solid Waste Management" regulations.
(2) The responsible party shall maintain control of regulated medical waste at all times.
(3) Only authorized personnel shall have access to regulated medical waste.
(4) Medical waste shall not become putrescent. If deemed putrescent, its disposal or treatment shall be expedited within three calendar days.
(5) Medical waste shall not become a nuisance.
(6) Regulated medical waste shall not be compacted prior to treatment.
(7) Medical waste accepted at transfer and/or storage operations and/or a treatment facility shall be considered regulated medical waste. It shall not be subject to the requirements of 15A NCAC 13B .1203(1) and (2)(b).
(8) Sharps must be placed in a rigid, leak-proof, and puncture-resistant container.
(9) Medical waste treatment and disposal methods:
    a. blood and body fluids in individual containers in volumes greater than 20 ml – Incineration, steam sterilization, or sanitary sewer provided the sewage treatment authority has been notified;
    b. microbiological waste - incineration, steam sterilization, ozonation, or chemical treatment;
    c. non-hazardous pharmaceutical waste – incineration, return to vendor, reuse, or municipal solid waste landfill;
    d. pathological waste – incineration or ozonation;
    e. trace chemotherapy waste – incineration or ozonation, except that ozonation may be used so long as supporting documentation submitted to and accepted by the Division demonstrates that the combination of parameters used is an effective form of treatment;
    f. other treatment and disposal methods as accepted by the Division.
(10) Medical waste treated at the generating facility is not subject to the requirements of 15A NCAC 13B .1202(15), (16), and (17) and .1204(1)(b)(i)(iii) and (c).
(11) Crematoriums are not subject to the requirements of 15A NCAC 13B .1200.
(12) A record pertaining to the proper management of regulated medical waste, to include a contingency plan, compliant with 15A NCAC 13B .1200 shall be prepared, current, and readily accessible at the generating facility, transfer and/or storage operations, and treatment facility.

(13) Transport vehicles, transfer and/or storage operations, and treatment facilities shall:
   a. be kept clean;
   b. not contain porous floor coverings;
   c. be adequately ventilated;
   d. not create a nuisance;
   e. have a method of leak control and/or spill cleanup, to include decontamination.
   f. a responsible party shall be present when regulated medical waste is in transfer between transport vehicles and shall ensure the integrity of each package.

(14) regulated medical waste shall be transported and stored in a manner that ensures it is not exposed to the environment and is resistant to inclement weather.

(15) Unrefrigerated regulated medical waste shall be treated within 21 calendar days of shipment from the generator.

(16) Refrigeration at an ambient temperature of a maximum of 45 degrees Fahrenheit (7.22 degrees Celsius) shall be maintained for regulated medical waste not treated within 21 calendar days of shipment from the generator.

(17) All regulated medical waste shall be treated within 60 calendar days of shipment from the generator.

History Note: Authority G.S. 130A-309.26;
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15A NCAC 13B .1203
REQUIREMENTS FOR REGULATED MEDICAL WASTE GENERATORS, TRANSPORTERS, AND TRANSFER AND STORAGE OPERATIONS

(1) Regulated medical waste packaging requirements:
   a. all Sections of the Code of Federal Regulations (CFR) cited in this paragraph are hereby incorporated by reference, including subsequent amendments or additions.
   b. regulated medical waste may be packaged in accordance with 49 CFR 173.134, "Definitions and Exceptions," 49 CFR 173.196, "Category A Infectious Substances," 49 CFR 173.197, "Regulated Medical Waste," or 49 CFR 173.199, "Category B Infectious Substances."
   c. a plastic film bag shall be used as inner packaging compliant with (1)(b) of this paragraph, unless not required as per the regulated medical waste type when used with a specific package design.
   d. the plastic film bag used as inner packaging shall be sealed to prevent leaks.
   e. a rigid box, drum, or vessel constructed to prevent leakage shall be used as outer packaging.
   f. outer package labeling shall be written in English.
   g. outer packaging shall be labeled with the universal biohazard symbol.
   h. each package shall be handled in a manner that prevents leakage and maintains the integrity of the packaging, labeling, and markings.
   i. each package shall have the following outer package labeling:
      i. "infectious substance" or "biohazard;"
      ii. generator name, address, and phone number;
      iii. transporter name, address, and phone number;
      iv. treatment facility name, address, and phone number;
      v. date of shipment from the generating facility;

The requirement of (1)(i)(v) in this paragraph does not apply to customer loaded trailers, except that all packages accessible from the cargo area door(s) shall be marked with the date of shipment from the generator prior to transport from the generating facility and that the remaining packages shall be marked with the date of shipment from the generator if removed from the customer loaded

trailer other than for treatment to occur, where the packages have been removed from the customer loaded trailer, within a 12-hour period, excluding unforeseen circumstances for which a record shall be maintained and made available upon request.

(2) Generator requirements:
   a. the generating facility is responsible to package medical waste by treatment method type in accordance with 15A NCAC 13B .1202(9).
   b. the generating facility shall maintain a record of each shipment of regulated medical waste for a period of three years to include the following:
      i. number of packages;
      ii. transporter name, address, and phone number;
      iii. treatment facility name, address, and phone number;
      iv. date of shipment from the generating facility.

The requirements of (2)(b) in this paragraph do not apply to generating facilities that generate less than 50-lbs of regulated medical waste per month.

(3) Transporter requirements:
   a. the transporter shall not knowingly accept regulated medical waste that is improperly packaged.
   b. the universal biohazard symbol shall be displayed on all transport vehicles. It shall be easily visible and displayed on all sides of the vehicle's cargo area.
   c. transport vehicles are prohibited from transporting any material other than medical waste for treatment, solid waste, and supplies related to the handling of medical waste. If a medical waste package leaks the contents of the transport vehicle is considered contaminated and shall be treated at a treatment facility or brought to a hazardous waste facility, if applicable.
   d. transport vehicles shall be thoroughly cleaned and disinfected with a mycobacteriocidal disinfectant before being used for any other purpose and in the event of leakage from a package.
   e. a written contingency plan shall be maintained in each transport vehicle. The vehicle operator shall be knowledgeable of the contingency plan.
   f. compliance with 15A NCAC 13B .1202(15), (16), and (17).

(4) Transfer and storage operations requirements:
   a. transfer and/or storage operations occurring at a treatment facility shall ensure that a description of the transfer and/or storage operation is included in the treatment facility permit application submitted to the Division. The description shall address applicable sections of 15A NCAC 13B .1200.
   b. transfer and/or storage operations occurring at a location other than a treatment facility shall provide a record, in written or electronic form, to the Division within fourteen calendar days of commencing transfer and/or storage operations, and biennially thereafter, that it manages a transfer and/or storage operation. The record shall include the following:
      i. name, mailing address, work and mobile phone numbers, and email address for the physical location, responsible party(s), and operator(s);
      ii. county GIS property data for the location where transfer and/or storage operations occur;
      iii. a description as to the proper management of medical waste as required by 15A NCAC 13B .1202(12);
      iv. a flowchart of the transfer and/or storage operations process;
      v. frequency that transfer and/or storage operations occur;
      vi. estimated amount of medical waste located at the transfer and/or storage operations at any given time;
      vii. additional information as deemed by the Division;

viii. if any of the requirements to be submitted by this paragraph change, the Division shall be informed within fourteen calendar days via update record.

c. if the transfer and/or storage operations cease, a record, in written or electronic form, shall be submitted to the Division within fourteen calendar days. The record shall include the following:
   i. a signed statement by the responsible party(s) listed in the record as required by 15A NCAC 13B .1203(4)(b) that transfer and/or storage operations have ceased and that no regulated medical waste remains;
   ii. digital pictures of the area that had been utilized for transfer and/or storage operations;
   iii. additional information as deemed by the Division.

d. within 90-days of these rules coming into effect, existing transfer and/or storage operations shall comply with (4)(b) of this section.

e. compliance with 15A NCAC 13B .1202(15), (16), and (17).

History Note: Authority G.S. 130A-309.26;
Eff. October 1, 1990; Amended Eff. October 1, 1992; December 1, 1991; March 1, 1991; Amended Eff. XX/XX/XX.

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

(1) General requirements:

a. treated regulated medical waste:
   i. stored treated regulated medical waste shall be covered in a manner that ensures it is not exposed to the environment and is resistant to inclement weather.
   ii. treated regulated medical waste may be placed uncovered in/under a weather resistant structure while de-watering or while actively being made ready to be covered.
   iii. treated regulated medical waste shall be stored no longer than 14 calendar days after treatment unless the treated regulated medical waste storage unit, being manufactured to be fully enclosed, tightly sealed and watertight, is integral to the operation of the treatment process.
   iv. treated regulated medical waste storage and transport containers, compactors, trailers, and cargo bays shall be maintained such that they function as intended when manufactured.
   v. treated regulated medical waste shall not be transported off site uncovered.
   vi. the exterior of treated regulated medical waste storage and transport containers, compactors, trailers, and cargo bays shall be kept visually clean and free of treated regulated medical waste.
   vii. treated regulated medical waste shall not become putrescent. If deemed putrescent its disposal shall be expedited within three calendar days.
   viii. treated regulated medical waste shall not become a nuisance.

b. treatment facility:
   i. the treatment facility shall be compliant with 15A NCAC 13B .1202(15), (16), and (17).
   ii. the treatment facility should notify the generating facility if it becomes aware of a package of medical waste received that is not in compliance with 15A NCAC 13B .1202(9) for the treatment method utilized. The treatment facility should act to reinforce the importance of packaging medical waste per treatment method type.

iii. 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:
(1) number of packages;
(2) generator name, address, and phone number;
(3) transporter name, address and phone number;
(4) date each package received;
(5) weight of each package in pounds (lbs);
(6) date each package treated.

iv. the treatment facility shall maintain a record of the disposal facility's contact information, to include: facility name, permit number, physical location and mailing address, and contact name and phone number.

v. the treatment facility shall maintain a record of the dates and tonnages of treated regulated medical waste shipments to the disposal facility.

vi. the treatment facility shall maintain treatment unit operating records and monitoring, testing, treatment unit verification, and maintenance records for a period of three years.

vii. the treatment facility shall adhere to the treatment procedures which has demonstrated that medical waste is noninfectious prior to disposal. Tests for full loading for effectiveness of treatment shall confirm the waste load is uniformly noninfectious.

viii. the treatment facility contingency plan shall include a section referring to regulated medical waste re-routing due to scheduled maintenance and unforeseen events.

c. treatment facilities that treat medical waste generated off-site shall submit to the Division an annual report by August 1st of each year on a form and in a submittal method 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 demonstrates the effective treatment of regulated medical waste and as shown in the treatment facility's documentation submitted to and accepted by the Division.

b. the steam sterilization unit shall be provided with a recording device which accurately records the 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 for full loading for effectiveness of treatment shall be performed no less than once per week, or as specified by the Division, using biological indicators of Geobacillus stearothermophilus spores having a population of at least 1.0×10^4 placed within the waste load or other combinations of parameters that demonstrates the effective treatment of regulated medical waste and as shown in the treatment facility's documentation submitted to and accepted by the Division.

e. a written plan to ensure consistent procedures are used to treat regulated medical waste shall be prepared, current, and readily accessible at the treatment facility.

f. a record of each test for full loading for effectiveness of treatment performed shall be maintained and shall include: type of indicator used, date, start and end times, and result.

(3) Incineration requirements:

a. the treatment facility shall obtain a permit from the NCDEQ, Division of Air Quality (DAQ) prior to the construction and operation of the incinerator.

b. the treatment facility shall maintain the DAQ permit for the operation of the incinerator.

c. the treatment facility shall achieve compliance with the DAQ permit for the operation of the incinerator.

d. regulated medical waste shall be subjected to a burn temperature in the primary chamber of not less than 1200 degrees Fahrenheit or to the burn temperature as defined by the incinerator manufacturer or incinerator updates that demonstrates the effective treatment of regulated medical waste and as shown in the treatment facility's documentation submitted to and accepted by the Division.
e. a record of the continuous monitoring of the primary chamber temperature shall be maintained.
f. 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.
g. the incinerator primary chamber temperature shall be compliant with the requirement of (3)(d) in this paragraph.
h. the primary chamber charge/loading rate shall be compliant with the DAQ permit for the operation of the incinerator.
i. procedures for obtaining representative weekly and monthly composite ash samples shall be submitted to the Division for approval prior to new incineration system start up and operation. If design or operation of an incineration system is substantially changed or modified, or if the regulated medical waste composition, charge/loading rate or loading method are substantially changed, the ash sampling plan will be subject to modification to accommodate such changes. Ash sampling procedures, compliant with 3(j) of this section, shall be initiated at the time the incineration system is first started for normal operation.
j. at a minimum, a representative ash sample of about one kilogram (2.20 lbs) 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 ash samples shall be collected from either the discharge of the ash conveyor or from the ash collection containers prior to disposal. The ash samples shall be composited in a closed container weekly and shall be thoroughly mixed and reduced to a representative ash sample. The representative ash sample shall be composited into monthly ash samples. For the first three months of operation, each monthly ash sample shall be analyzed.
k. for the remainder of the first year of incinerator operation, representative monthly ash samples shall be composited into a quarterly ash samples and analyzed at the end of each quarter.
l. after the first year of incinerator operation, representative incinerator ash samples shall be analyzed biannually, approximately every six months.
m. ash samples shall be tested in accordance with the provisions of 15A NCAC 13B .0103(d) and submitted to the Division. After the first year of incinerator operation, ash samples shall be submitted to the Division upon request.
n. the Toxicity Characteristic Leaching Procedure (TCLP) shall be used to analyze ash samples. It shall be conducted for the RCRA eight metals (arsenic, barium, cadmium, chromium, lead, mercury, selenium, and silver) and shall demonstrate that the incinerator ash is nonhazardous. Additional monitoring and testing, as deemed by the Division, may also be required.
o. the treatment facility shall maintain a record of each ash sample to include the following:
    i. composite ash sample date;
    ii. composite ash sample time;
    iii. ash sample date;
    iv. ash sample time;
    v. ash sample identification number;
    vi. ash sample analysis results;

vii. testing laboratory contact information and identification/certification number.

p. a written plan to ensure consistent procedures are used to treat regulated medical waste shall be prepared, current, and readily accessible at the treatment facility.

(4) Chemical treatment requirements:

a. microbiological waste shall be treated with 10 percent chlorine solution ensuring exposure between the disinfectant and pathogen with a minimum of 1 hour contact time.

b. a request for other chemical treatment methods must be submitted for acceptance to the Division. The request must be substantiated by results of demonstrated effectiveness of the chemical to treat the specific microbiological agent(s) of concern for the regulated medical waste type. Consideration must be given to such factors as temperature, contact time, pH, concentration, and the presence and state of dispersion, penetrability, and reactivity of organic material at the site of application.

c. monitoring to ensure factors that affect disinfection and sterilization are controlled shall be conducted no less than once per week or as specified by the Division. Monitoring under conditions for full loading for effectiveness (temperature, contact time, pH, concentration, and the presence and state of dispersion, penetrability and reactivity of organic material at the site of application) of treatment shall be performed using a biological indicator of Bacillus atrophaeus spores having a population of at least 1.0×10^6 or other combinations of parameters that demonstrates the effective treatment of regulated medical waste and as shown in the treatment facility's documentation submitted to and accepted by the Division.

d. a written plan to ensure consistent procedures are used to treat regulated medical waste shall be prepared, current, and readily accessible at the medical waste treatment facility.

e. a record of each test for full loading for effectiveness of treatment performed shall be maintained and shall include: type of indicator used, date, start and end times, and result.

(5) Microwave treatment requirements:

a. microwave energy of appropriate output frequency shall be provided such that a minimum temperature of 203 degrees Fahrenheit (95 degrees Celsius) is maintained for a minimum of 30 minutes each cycle; or other combinations of parameters that demonstrates the effective treatment of regulated medical waste and as shown in the treatment facility's documentation submitted to and accepted by the Division.

b. the microwave treatment system shall be provided with a means to continually monitor and record time and temperature of each cycle.

c. monitoring under conditions for full loading for effectiveness of treatment shall be performed using a biological indicator of Bacillus atrophaeus spores having a population of at least 1.0×10^6 and according to the equipment manufacturer's instructions or other combinations of parameters that demonstrates the effective treatment of regulated medical waste and as shown in the treatment facility's documentation submitted to and accepted by the Division.

d. 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 (5)(a) of this section.

e. a written plan to ensure consistent procedures are used to treat regulated medical waste shall be prepared, current, and readily accessible at the regulated medical waste treatment facility.

f. a record of each test for full loading for effectiveness of treatment performed shall be maintained and shall include: type of indicator used, date, start and end times, and result.

(6) Ozonation:

a. monitoring under conditions for full loading for effectiveness of treatment shall be performed using a biological indicator of Bacillus atrophaeus spores having a population of at least 1.0 x 10^6 and according to the equipment manufacturer's instructions or other combinations of parameters that demonstrates the effective treatment of regulated medical waste and as shown in the treatment facility's documentation submitted to and accepted by the Division.
b. testing shall be performed no less than once per week or as specified by the Division.
c. independent laboratory verification shall be conducted biannually for full loading for effectiveness of treatment, approximately every six months.
d. a written plan to ensure consistent procedures are used to treat regulate d medical waste shall be prepared, current, and readily accessible at the medical waste treatment facility.
e. a record of each test for full loading for effectiveness of treatment performed shall be maintained and shall include: type of indicator used, date, ozonation time, incubation time, and result.

History Note: Authority G.S. 130A-309.26; Eff. October 1, 1990; Amended Eff. April 1, 1993; January 4, 1993; Amended Eff. XX/XX/XX.