SECTION .1200 - MEDICAL WASTE MANAGEMENT

15A NCAC 13B .1201 DEFINITIONS

For the purpose of this Section, the following definitions apply:

(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 if not removed during surgeries and autopsies.

(2) "Generator" and "Generating facility" mean any business, integrated medical facility, and volunteer or non-profit healthcare services where medical waste is produced, including any medical or dental facility, mortuary, laboratory, veterinary hospital, and blood bank; but does not include households.

(3) "Integrated medical facility" means one or more health service facilities as defined in G.S. 131E-176(9b) that are:
   (a) located in a single county or two contiguous counties;
   (b) affiliated with a university medical school or that are under common ownership and control; and
   (c) serve a single service area.

(4) "Medical waste" means the term defined in G.S. 130A-290(17a).

(5) "Microbiological waste" means the term defined in Rule .0101(26) of this Subchapter.

(6) "Non-hazardous pharmaceutical waste" is a medical waste and means a medical drug that is expired, unused, contaminated, damaged, or no longer needed or used for its prescribed purpose and that is not a hazardous waste as defined in G.S. 130A-290(a)(8).

(7) "Nuisance" means odorous outside of the property boundary or transport vehicle; or attracting vermin or disease vectors.

(8) "Package" means the total contents of a box, drum, or vessel containing medical waste, including labeling and markings.

(9) "Pathological waste" means the term defined in Rule .0101(31) of this Subchapter.

(10) "Record" means any data required to be kept on file by the operator or responsible party, or submitted to the Division in accordance with the rules of this Section. A record may be a paper copy or electronic format that is legible and in English.

(11) "Regulated Medical Waste" means the term defined in Rule .0101(34) of this Subchapter.

(12) "Responsible party" means the entity that is in possession of and has accepted the regulated medical waste.

(13) "Sharps" means the term defined in G.S. 130A-309.26(a)(1).

(14) "Trace chemotherapy waste" means medical waste containing no more than three percent by weight of a medical drug used for chemotherapy, but is not a radioactive waste. Trace chemotherapy waste includes gowns, gloves, wipes, and other handling, preparation, administration, cleaning, and decontamination items used in association with chemotherapy.

(15) "Transfer or storage operations" means 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.

(16) "Transport vehicle" means a vehicle or other conveyance type used to transport regulated medical waste to and from transfer or storage operations or to and from a treatment facility.

(17) "Treatment" means the term as defined in G.S. 130A-309.26(a)(2).

(18) "Treatment facility" means a regulated medical waste treatment facility permitted by the Division in accordance with the rules of this Section.
(19) "Solid waste" means the term defined in G.S. 130A-290(a)(35).

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

(a) Medical waste is subject to the rules in 15A NCAC 13B, "Solid Waste Management."
(b) Sharps and other sharp objects such as syringes with attached needles, capillary tubes, slides and cover slips, lancets, auto injectors, connection needles and sets, exposed ends of dental wires, and objects that can penetrate the skin shall be placed in a rigid, leak-proof when in an upright position, and puncture-resistant container, and shall not be compacted prior to off-site transportation unless placed in a sealed compactor unit that is hauled off for disposal by the transporter.
(c) Blood and body fluids in individual containers in volumes of 20 milliliters or less shall be stored in an area accessible only to the responsible party or their designated representative, and shall not be compacted prior to off-site transportation.
(d) Regulated medical waste shall not be compacted prior to treatment.
(e) Only the responsible party or their designated representative shall have access to regulated medical waste.
(f) Medical waste shall not become putrescent. Medical waste shall be disposed of or treated within three calendar days of becoming putrescent.
(g) Medical waste shall not become a nuisance.
(h) Medical waste accepted at transfer or storage operations or a treatment facility shall not be subject to the requirements of Rule .1203(a) and (b)(2) of this Section.
(i) Medical waste treatment and disposal methods:
(1) Blood and body fluids in individual containers in volumes greater than 20 milliliters shall be disposed of by sanitary sewer if the local sewage treatment authority has been notified; or treated by incineration or steam sterilization.
(2) Microbiological waste shall be treated by incineration, steam sterilization, ozonation, microwave, or chemical treatment.
(3) Non-hazardous pharmaceutical waste shall be treated by incineration or disposed of at a municipal solid waste landfill. The requirements of this Subparagraph shall not prevent non-hazardous pharmaceuticals from being returned to the vendor.
(4) Pathological waste shall be treated by incineration or ozonation.
(5) Trace chemotherapy waste shall be treated by incineration or ozonation.
(6) Noninfectious medical waste and blood and body fluids in individual containers in volumes of 20 milliliters or less may be disposed of in a municipal solid waste landfill, or treated by the treatment methods as described in this Paragraph. Blood and body fluids in individual containers in volumes of 20 milliliters or less may also be disposed of in a sanitary sewer. The requirements of this Subparagraph shall not prevent noninfectious medical waste such as textiles, plastic, glass, or metal from being recycled.
(j) Medical waste treated at the generating facility is not subject to the requirements of Paragraphs (o), (p), and (q) of this Rule, and Rule .1204(b)(1), (b)(3), and (b)(8) of this Section.
(k) Crematoriums are not subject to the requirements of this Section.
(l) Transport vehicles, transfer or storage operations, and treatment facilities shall:

(1) be kept free of leaked, spilled, and unpackaged medical waste;
(2) not contain porous floor coverings;
(3) be ventilated;
(4) not create a nuisance; and
(5) have a method of leak control or spill cleanup, including decontamination.

(m) A responsible party shall be present when regulated medical waste is being transferred by means of transfer or storage operations.

(n) Regulated medical waste shall be transported and stored in a manner that prevents exposure to the environment and inclement weather.

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

(p) 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.

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

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15A NCAC 13B .1203 REQUIREMENTS FOR REGULATED MEDICAL WASTE GENERATORS, TRANSPORTERS, AND TRANSFER AND STORAGE OPERATIONS

(a) Regulated medical waste packaging requirements:

(1) All Sections of the Code of Federal Regulations (CFR) cited in this Paragraph are hereby incorporated by reference, including subsequent amendments and editions and can be accessed at no cost at https://www.gpo.gov/.
(2) Regulated medical waste may be packaged in accordance with 49 CFR 173.134, 49 CFR 173.196, 49 CFR 173.197, or 49 CFR 173.199.
(3) A plastic film bag shall be used as inner packaging, unless it is not required per the regulated medical waste type when used in conjunction with one of the package designs pursuant to Subparagraph (2) of this Paragraph.
(4) The plastic film bag used as inner packaging shall be sealed to prevent leaks.
(5) A rigid box, drum, or vessel constructed to prevent leakage shall be used as outer packaging.
(6) Outer package labeling shall be legible and written in English.
(7) Outer packaging shall contain the universal biohazard symbol as described in 29 CFR 1910.1030(g).
(8) Each package shall be handled to prevent leaks, damage, and changes to the package, labeling, and markings.
(9) Labels and markings on the outside of each package shall contain the following information:
(A) state that the content is an "infectious substance" or a "biohazard;"
(B) the generator name, physical address, and phone number;
(C) the transporter name, physical address, and phone number;
(D) the treatment facility name, physical address, and phone number, unless the label contains a tracking number that corresponds to a record that includes the

treatment facility name, physical address, and phone number, and the record is provided to the Division at the time of inspection and upon request; and

(E) the date of shipment from the generating facility, unless the label contains a tracking number that corresponds to a record that includes the date of shipment, and the record is provided to the Division at the time of inspection and upon request.

(b) Generator requirements:

(1) The generating facility shall package medical waste by treatment method type in accordance with Rule .1202(i) of this Section.

(2) The generating facility shall maintain a record of each shipment of regulated medical waste transported off-site for a period of three years that includes the following information:

(A) the number of packages;

(B) the transporter name, physical address, and phone number;

(C) the treatment facility name, physical address, and phone number; and

(D) the date of shipment from the generating facility.

The requirements of this Subparagraph do not apply to generating facilities that generate less than 50 pounds of regulated medical waste per month.

(c) Transporter requirements:

(1) The transporter shall not accept regulated medical waste that does not meet the requirements of Paragraph (a) of this Rule.

(2) The universal biohazard symbol shall be displayed on the outside of a transport vehicle on both sides and rear of the vehicle's cargo area, shall be legible, and shall not be obstructed from view.

(3) Transport vehicles shall only transport medical waste for treatment, other solid wastes, and supplies related to the handling of solid wastes. If a medical waste package leaks or spills, all of the solid waste, except for hazardous waste, within the same storage area of the transport vehicle as the leaking or spilled package shall be treated at a medical waste treatment facility. If the solid waste that leaked or spilled is a hazardous waste, all of the solid waste within the same storage area of the transport vehicle as the leaking or spilled package shall be brought to a hazardous waste treatment facility.

(4) Transport vehicles shall be free of medical waste and disinfected with a mycobactericidal disinfectant before being reused if any packages spilled or leaked while in the vehicle, and prior to discontinuing use of the transport vehicles to haul medical waste.

(5) The vehicle operator shall keep a contingency plan as described in Rule .1204(b)(4)(H) of this Section in the transport vehicle and shall be trained to implement the contingency plan prior to transporting medical waste.

(6) The transporter shall be in compliance with Rule .1202(o), (p), and (q) of this Section.

(d) Transfer or storage operations requirements:

(1) The responsible party for transfer or storage operations occurring at a treatment facility shall include a description of the transfer or storage operations in the facility operations plan submitted to the Division in accordance with Rule .1204(b)(4) of this Section.

(2) The responsible party for transfer or storage operations occurring at a location other than a treatment facility shall submit a record to the Division within 14 calendar days of commencing transfer or storage operations, and once every two years thereafter, while the responsible party is managing the transfer or storage operations. The record 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) and operator(s);
(B) county GIS property data for the location where transfer or storage operations occur;
(C) procedures for how the medical waste will be received, handled, stored, and transferred;
(D) the frequency that transfer or storage operations occur;
(E) the amount of medical waste that is expected to be on site at the transfer or storage operations; and
(F) additional information that the Division may request pertaining to the transfer or storage operations if it is necessary to determine compliance with the rules of this Subchapter.

The responsible party shall submit an updated record to the Division within 14 calendar days if any of the information required to be submitted by this Subparagraph changes.

(3) If the transfer or storage operations cease, the responsible party shall submit to the Division a record within 14 calendar days. The record shall include the following information:
(A) a signed statement by the responsible party(s) that transfer or storage operations have ceased and all medical waste has been removed;
(B) digital pictures of the area that was utilized for transfer or storage operations taken after operations have ceased and all medical waste has been removed; and
(C) additional information that the Division may request pertaining to the transfer or storage operations if it is necessary to determine compliance with the rules of this Subchapter.

(4) Within 90 days of the readopted effective date of this Rule, existing transfer or storage operations shall comply with Subparagraph (2) of this Paragraph.

(5) The transfer or storage operations shall comply with Rule .1202(o), (p), and (q) of this Section.

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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 1.0×10^4 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 x 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 x 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 x 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.

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15A NCAC 13B .1205 REQUIREMENTS FOR TRANSPORTERS OF REGULATED MEDICAL WASTE
15A NCAC 13B .1206 REQUIREMENTS FOR STORAGE OF REGULATED MEDICAL WASTE
15A NCAC 13B .1207 OPERATIONAL REQ/REGULATED MEDICAL WASTE TREATMENT FACILITIES

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