REGULATORY AND FISCAL IMPACT ANALYSIS FOR READOPTION AND AMENDMENTS TO 15A NCAC 13B SECTION .1200 MEDICAL WASTE MANAGEMENT

February 21, 2019

General Information

Agency/Commission:	Environmental Management Commission
Department:	Department of Environmental Quality, Division of Waste Management, Solid Waste Section
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Title of Rule Set:	Medical Waste Management
Citation:	15A NCAC 13B .1201 - .1207
Authority:	G.S. 130A-309.26; G.S. 150B-21.3A
Impact Summary:	State government: Yes Local government: No Private Sector: Yes Substantial Impact: No Federal Requirement or Impact: No

Proposed Rule-Making Schedule:

Date	*Action*
3/13/2019	GWWMC Meeting: Approval of proposed text to go to EMC.
5/9/2019	EMC Meeting: Approval of rule text and impact analysis for public comment.
6/17/2019	Rules published in NC Register and Agency website Comment Period Begins.
7/2/2019	Earliest date for public hearing.
8/16/2019	Comment Period Ends.
9/12/2019	EMC Meeting: Approval of Hearing Officer's Report and Adoption of Rules.
10/17/2019	RRC meeting: Approval of rule text
11/1/2019	Earliest effective date for rules.

Necessity and Purpose of Rule Change

It is the responsibility of the Division of Waste Management (Division) Solid Waste Section (Section) to regulate how solid waste is managed within the state under the statutory authority of the Solid Waste Management Act, Article 9 of Chapter 130A of the General Statutes. State rules governing solid waste management are found in Title 15A, Subchapter 13B of the North Carolina Administrative Code. Rules adopted under the authority of 130A-309.26 which collectively establish standards for the transportation, storage, treatment, and disposal of medical waste are found in Subchapter 13B, Rules .1201 - .1207 *Medical Waste Management*. These rules are proposed for readoption in accordance with G.S. 150B-21.3A, and are required to be readopted by the deadline established by the Rules Review Commission of April 30, 2021.

Proposed amendments to the rules include consolidation of the requirements of the rules into Rules .1201 - .1204 and repeal of Rules .1205 - .1207, technical corrections, updates to information such as Department names, addresses, websites, and references, clarification of vague or unclear language, and removal of redundant or unnecessary language. Additional amendments are proposed in response to stakeholder meetings and comments received and are discussed in more detail below.

Fiscal Summary

The proposed amendments to the Medical Waste Management Rules are expected to result in a net economic benefit to the private sector regulated community and to state government; but are not expected to have a substantial impact. No impacts to local governments or private households are expected as a result of the amendments.

Fiscal Analysis

Private Sector Impact

Types of Businesses or Facilities Potentially Affected by Rule Changes:

- Medical Waste Treatment and Processing Facilities Permitted by the Division (5 Processing Facilities, one of these is an Incineration Facility)
- Medical Waste Generators, Transfer or Storage Operations, and Transporters (the number of these types of operations in NC is unknown as they are not required to obtain a permit from the Division)

Benefits

The amendments in the proposed rule provide a benefit to the medical waste management industry by extending time limits for storage of unrefrigerated medical waste in proposed Rule .1202(o), (p), and (q). These changes were made in response to a comment letter from private industry submitted in 2016 requesting that the Division revise the rules during readoption to allow for extended storage times without refrigeration to reduce costs, since no clear added value is realized from keeping

shorter time limits. However, the amendments still require that the waste not become putrescent or a nuisance, which are the main intentions of refrigeration and having storage time limits on unrefrigerated waste; and therefore, the rules remain protective of human health and the environment. A copy of the comment letter is included. The benefits for this amendment are difficult to quantify since an estimation of cost would depend on how the industry will choose to or be able to modify their current procedures as a result of the extended limits while still ensuring that the waste will not be putrescent or a nuisance, but this amendment is expected to reduce the burden on the regulated community.

An amendment in proposed Rule .1203(a) provides a benefit by simplifying packaging requirements by referring to and incorporating the federal requirements for packaging based on waste type; which in practice should not change the behavior of the medical waste industry, but provides clarification in rule that following the Federal CFR is sufficient for State requirements. An additional proposed amendment to Rule .1203(a) states that treatment facilities receiving shipments of customer loaded-trailers are not required to label all packages with the shipping date. This amendment is proposed because it is not practical or feasible for a receiving facility to completely unload a customer-loaded trailer to label all boxes with a date, when they would not otherwise need to be unloaded because the shipment is meant for further transportation. A treatment facility estimated that a trailer may contain 600 packages, and approximately 21 trailers might arrive per week. Assuming 2 employees would be needed at 40 hours per week to unload these 21 trailers at an hourly rate of $20.00, the benefit for clarifying this exception in the proposed amendments can be estimated at $83,200 per year.

Additional benefits to the medical waste management industry in proposed Rule .1202(i) include clarification on treatment and disposal options for additional waste types that are not specifically addressed in existing rule such as trace chemotherapy waste and pharmaceutical waste; adding ozonation as an option for a treatment method; and clearly stating that noninfectious waste types may be disposed of via municipal solid waste landfill or sanitary sewer and do not require treatment. These amendments clarify in rule what is currently done in practice. Proposed Rule .1204 (g) also describes the requirements for ozonation as a treatment method. While existing rules for treatment methods allowed facilities to request alternate methods or procedures for treatment, proposed Rule .1204(h) also clarifies the procedures to be used when making that request, and what factors the Division will consider for approval.

While existing rules for permitting requirements in Subchapter 13B require that a facility operations plan be included in a permit application for medical waste facilities permitted by the Division, the amendments in proposed Rule .1204(b)(4) clarify the type of information required to be submitted in the facility operations plan, and puts into rule what is generally being done in practice as a permitting requirement.

Costs

Estimated costs to the medical waste management industry as a result of the proposed amendments include costs resulting from the requirement in proposed Rule .1203(c)(3) that any waste transported in the same storage area of the vehicle as a leaking or spilled package be treated as medical waste, or be treated as hazardous waste if the leaking or spilled package contains hazardous waste. While this requirement may have been implied in existing rule, since any package that had been contaminated with medical or hazardous waste would become medical or hazardous waste, this is now clearly stated in the proposed amendments. However, since the rules for packaging also require that the packages shall not leak, this circumstance is not expected to occur or would occur only rarely.

A potential cost to transfer or storage operations for medical waste may result from the requirement in proposed Rule .1203(d)(2) to submit notification documentation for transfer or storage operations not located at a permitted medical waste treatment facility when beginning the operation and every two years thereafter while in operation, when there is a change to the operation, and when ending the operation. Based on past information that was requested to be submitted voluntarily for these operations, the Division estimates there may be between 5 and 10 operations of this type in NC. These operations will be required to submit the initial notification documentation within 90 days of the readopted effective date of the proposed rule, and submit a renewal notification every two years thereafter. The document with the required information is expected to be a one or two page letter and may take one or two hours of staff time to generate. Assuming a transfer or storage operations staff hourly rate of $20.00 - $30.00, the cost in 2020 and every two years thereafter to these operations can be estimated between $100.00 and $600.00. The cost in subsequent years would also depend on whether the operations are changed or ended, but these submittals would not be substantially different from the initial notification documents.

Medical waste treatment facilities may incur a minimal cost to produce a document due to the requirement in proposed Rule .1204(b)(2) that they notify the generating facility in writing when medical waste packages are received that are not in compliance with packaging requirements in these rules. Existing treatment facilities have indicated that they currently notify the generating facility in practice, but may not send the notification in writing and are not required to keep records of this notification. The notification document is expected to be a one or two page letter and may take one or two hours of staff time to generate. Assuming a transfer or storage operations staff hourly rate of $20.00 - $30.00, and assuming that notifications may need to be sent out three to five times per year depending on how often there are packaging issues with the generating facility, the additional cost per year to these operations following the readopted effective date of the proposed rules can be estimated between $60.00 and $300.00.

State Government Impact

The proposed amendments to the rules will not require the distribution of state funds, and will have a net benefit to state government. Assuming a staff salary of $30.00 per hour, and assuming that staff may save two hours per month as a result of reduced staff time spent on correspondence with permit applicants to produce a complete facility operations plan, and providing technical assistance for disposal of noninfectious medical waste and other specific wastes not mentioned in existing rule, packaging requirements, or procedures for requesting alternate treatment methods, the benefit to state government may be $720 per year. Staff may spend additional time reviewing the submittal of records for transfer or storage operations, but the cost is not expected to exceed $600.00 per year, assuming 10 operations in NC, and a staff hourly rate of $30.00.

APPENDIX 1

Comment Letter

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June 27, 2016

Via Electronic and First Class Mail

Michael E. Scott
NCDEQ, Director of Division of Waste Management
1601 Mail Service Center
Raleigh, NC 27699-1601

Re: Stericycle, Inc. –Information Related to Proposed Petition for Rulemaking

Dear Michael:

Thank you for meeting with me on March 7, 2016 regarding Stericycle, Inc.'s ("Stericycle") interest in amending certain elements of the North Carolina transport and storage requirements for medical waste. As you are aware, Stericycle operates regulated medical waste treatment and transfer facilities in Haw River and Concord, North Carolina pursuant to Solid Waste Permit No. 01-02-I and Solid Waste Permit No. 1305TP-TP, respectively. As we discussed on March 7, the purpose of this letter to provide you with additional information regarding Stericycle's proposed rule changes. To support these proposed changes, I have provided below: (i) the proposed amendments; (ii) information supporting the proposed amendments; and (iii) a description of the potential effects of the proposed amendments.

Proposed Amendments

Pursuant to N.C. Gen. Stat. § 130A-309.26, the Environmental Management Commission has the authority to promulgate the proposed revised rules.

The proposed amendments to 15A NCAC 13B §§ .1205(7), (8) are as follow:

CHAPTER 13. SOLID WASTE MANAGEMENT
SUBCHAPTER 13B. SOLID WASTE MANAGEMENT
SECTION .1200. MEDICAL WASTE MANAGEMENT

.1205 REQUIREMENTS FOR TRANSPORTERS OF REGULATED MEDICAL WASTE

. . .

A person who transports Regulated medical waste that has not been treated as the generating facility shall meet the following requirements:

. . .

(7) Except as allowed by subsection (8) of this rule, Regulated medical waste shall be delivered in a non-putrescent state to a permitted storage or treatment facility within ~~seven~~ fourteen calendar days of the date of shipment from the generator.

(8) Refrigeration at an ambient temperature between 35 and 45 degrees Fahrenheit shall be maintained for Regulated medical waste that will not be delivered for treatment within ~~seven~~ fourteen calendar days.

. . .

The proposed amendment to 15A NCAC 13B § .1206(4) is as follows:

CHAPTER 13. SOLID WASTE MANAGEMENT
SUBCHAPTER 13B. SOLID WASTE MANAGEMENT
SECTION .1200. MEDICAL WASTE MANAGEMENT

.1206 REQUIREMENTS FOR STORAGE OF REGULATED MEDICAL WASTE

. . .

A person who stores Regulated medical waste that has not been treated at the generating facility shall meet the following requirements:

. . .

(4) Regulated medical waste shall be stored in a non-putrescent state ~~not be stored~~ and no longer than ~~seven~~ fourteen calendar days from the date of shipment from the generator unless the Regulated ~~M~~medical ~~W~~waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit. Provided that Regulated medical waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit in a non-putrescent state, such waste shall be stored no longer than sixty calendar days from the date of shipment from the generator.

. . .

The proposed amendment to 15A NCAC 13B § .1207(1) is as follows:

CHAPTER 13. SOLID WASTE MANAGEMENT
SUBCHAPTER 13B. SOLID WASTE MANAGEMENT
SECTION .1200. MEDICAL WASTE MANAGEMENT

.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.~~

(a) ~~(b)~~ Regulated medical waste shall be ~~stored prior to treatment for~~ treated or placed into refrigerated storage consistent with 15A NCAC § 13B .1206(4) no more than seven calendar days after receipt.

. . .

Basis for Proposed Amendments

Currently, the North Carolina regulations addressing the storage of Regulated medical waste provide that such waste: (i) shall be delivered to a permitted storage or treatment facility

within seven calendar days of the date of shipment from the generator unless the Regulated medical waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit; (ii) shall not be stored longer than seven calendar days from the date of shipment from the generator unless the Regulated medical waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit; and (iii) shall be stored prior to treatment for no more than seven calendar days after receipt unless the Regulated medical waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit.

Limiting storage of Regulated medical waste to seven days without refrigeration provides no health or environmental benefit and extending the storage time from seven to fourteen days will not harm public health or the environment. In our meeting on March 7, the Division of Waste Management specifically asked what happens to unrefrigerated Regulated medical waste between seven and fourteen days. Based on Stericycle's experience in other states, the most correct answer is "nothing." In almost every case, there is no difference in the characteristics of Regulated medical waste that is not refrigerated during the period of seven to fourteen days when compared to refrigerated. Importantly, unlike in other states, the North Carolina regulations prohibit the transport or storage of Regulated medical waste in a putrescent state. These protections ensure that Stericycle does not at any time transport or store Regulated medical waste that is in a putrescent state.

Stericycle or its competitors operate regulated medical waste incinerators in the following states: North Carolina, Florida, Maryland, Ohio, Illinois, Minnesota, Kansas, and Utah. The storage requirements for each of these states and South Carolina are summarized below.

State	Storage Requirements	Cite
Florida	30-day limit for storage of biomedical waste at the generating facility and in a place other than the generating facility.	FLA. ADMIN. CODE § 64E-16.004(a)
Maryland	Except under the supervision of the Department during an emergency, a special medical waste hauler may not store special medical waste except in an approved facility. Storage in a special medical waste vehicle does not include periods of stoppage. Stoppage is a period of time not to exceed 72 hours during which a special medical waste vehicle is at rest. The cumulative period of stoppage may not exceed 5 days for a particular shipment of special medical waste within the State. Any stoppage in excess of 12 hours shall be at an authorized facility or other suitable site. Pursuant to a permit condition, there is a 10-day	CODE OF MD. REGS. § 26.13.13.01(E); Permit conditions

	storage limit for non-refrigerated special medical waste from the date of receipt at the treatment facility.	
South Carolina	Infectious waste must be maintained in a non-putrescent state, and storage of infectious waste shall not exceed twenty-eight (28) days without refrigeration or sixty (60) days if maintained at or below 42 degrees Fahrenheit.	S.C. Code Ann. § 61-105(K)(5)
Ohio	14-day time limit to process regulated medical waste as long as it is not putrescent. If waste becomes putrescent, then the waste must be immediately refrigerated or frozen and shall be treated and disposed of as soon as possible regardless of any storage time frame.	OHIO ADMIN. CODE § 3745-27-35
Illinois	Unless otherwise permitted, 3-day time limit for storage at storage or transfer operation with no refrigeration. 30-day time limit regardless of temperature.	35 IL. ADMIN. CODE § 1422.111
Minnesota	No time restrictions. Infectious waste must not be allowed to become putrescent during transportation. A person who stores, incinerates, or decontaminates infectious or pathological waste, other than at the facility where the waste was generated, or a person who incinerates infectious or pathological waste on site, must submit a copy of a management plan to the commissioner of the Pollution Control Agency.	MINN. ADMIN. CODE §§ 7035.9120.2, 7035.9120.4 MINN. GEN. STAT. § 116.79(4)
Kansas	No time restrictions. All medical services waste shall be stored in a manner and in a container that will prevent the transmission of disease or the causing of injury. Medical services wastes shall be collected at least daily from the point of origin for transport to a storage or disposal area or a processing facility. All medical services wastes transported off-site shall be transported in a manner that will prevent the spread of disease or the causing of injury to persons.	KAN. ADMIN. CODE 28-29-27
Utah	7-day time limit without refrigeration and no longer than 60 days.	UTAH ADMIN. CODE § 315-316-3(9), (10)

Other states in the Southeast generally provide for periods longer than seven (7) days for storage of Regulated medical waste. *See, e.g.*, Fla. Admin. Code § 64E-16.004(a) (providing 30-day limit for storage of biomedical waste at the generating facility and in a place other than the generating facility); Ga. Comp. R. & Regs. § 391-3-4-.15(4) (containment of biomedical waste shall be in manner that minimizes exposure to the public); *but see* 9 Va.

Admin. Code §§ 10-120-360, 20-120-430 (providing that Regulated medical waste stored for more than seven days must be refrigerated, and no Regulated medical waste shall be stored for more than fifteen days at the site of generation). Thus, other states in which medical waste incinerators are located generally provide for periods longer than seven days for storage of regulated medical waste.

With respect to the transporter requirements set forth in 15A NCAC § 13B .1205, transporters often use consolidation facilities. However, the current regulation requires shipment or refrigeration within seven days of shipment from the generator and does not provide for additional time if consolidation facilities are used. Delivery or refrigeration of Regulated medical waste within seven days of shipment from the generator without consolidation is impracticable and unworkable. For example, Stericycle has determined that in a typical year this requires an additional sixty-nine (69) refrigerated trailers resulting in significant, unnecessary costs to Stericycle.

Limiting storage of Regulated medical waste to seven days without refrigeration has significant economic impacts on the regulated community with no corresponding benefits to public health or the environment. Stericycle estimates that such a restriction results in economic losses of at least $675,000 per year to Stericycle. This amount is based upon the costs associated with leasing additional refrigerated trailers and/or diverting waste to other facilities to avoid the burdensome restrictions in North Carolina. Further, limiting the use of diesel engines to provide power to refrigerated trailers will result in a decrease in criteria pollutant emissions and benefit public health and the environment.

There have been no spills of regulated medical waste at Stericycle's Haw River facility in the last five years. In addition, Stericycle has received no odor complaints related to the Haw River facility in the last five years.

Effect of the Proposed Rule

The effect of these proposed amendments on existing rules would be to extend the time for delivery of unrefrigerated Regulated medical waste by transporters to a permitted storage or treatment facility from seven to fourteen calendar days provided that such waste is in a non-putrescent state. The proposed amendments would allow Regulated medical waste to remain unrefrigerated in a non-putrescent state for a maximum of 21 days after shipment from the generator (14 days during shipment plus 7 days after receipt at the treatment facility). In addition, the proposed amendments clarify that there is a 60-day time limit on the refrigerated storage of Regulated medical waste at an ambient temperature between 35 and 45 degrees Fahrenheit provided that it remains in a non-putrescent state.

Effect of the Proposed Rule on Existing Practices

The proposed rule changes would have a significant beneficial effect on Regulated medical waste transporters, storage facilities, and treatment facilities. First, the proposed rule changes would allow Regulated medical waste transporters to continue the practice of using consolidation facilities without incurring substantial and unnecessary costs of purchasing additional refrigerated trailers. Second, the proposed rule changes would allow Regulated medical waste transporters, storage facilities, and treatment facilities operational flexibility to store such waste for an additional seven days without refrigeration. The proposed rule changes would also harmonize North Carolina regulations with the majority of Southeastern states. These proposed rule changes would provide operational flexibility while at the same time protecting the public health and environment.

We look forward to hearing back from you regarding Stericycle's proposed petition for rulemaking, and thank you for your assistance with this matter. If you need additional information or would like to discuss, please do not hesitate to contact me.

Sincerely,

Alan H. McConnell
Counsel for Stericycle, Inc.

cc: Don Nuss
Ellen Lorscheider

APPENDIX 2

Proposed Rules

15A NCAC 13B .1201 is proposed for readoption with substantive changes as follows:

SECTION .1200 - MEDICAL WASTE MANAGEMENT

15A NCAC 13B .1201 DEFINITIONS

For the purpose of ~~the~~ 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. ~~Dialysates are not blood or body fluids under this definition.~~

(2) "Generator" and "Generating facility" ~~means~~ mean any business, integrated medical facility, and volunteer or non-profit healthcare services where medical waste is produced, ~~first becomes a waste,~~ including ~~but not limited to~~ any medical or dental facility, mortuary, ~~funeral home,~~ laboratory, veterinary ~~hospital~~ hospital, and blood ~~bank.~~ 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" ~~as~~ means the term defined in G.S. 130A-290(17a). ~~130A-290(18).~~

(5) "Microbiological waste" means the term defined in Rule .0101(26) of this Subchapter. ~~cultures and stocks of infectious agents, including but not limited to specimens from medical, pathological, pharmaceutical, research, commercial, and industrial laboratories.~~

~~(6) "Microwave treatment" means treatment by microwave energy for sufficient time to render waste non-infectious.~~

~~(7) "Off-site" means any site which is not "on-site".~~

~~(8) "On-site" means the same or geographically contiguous property which may be divided by public or private right-of-way.~~

(6) "Non-hazardous pharmaceutical waste" is a medical waste. It is 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(8).

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

(8) "Package" is 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. ~~human tissues, organs and body parts; and the carcasses and body parts of all 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.~~

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

(11)~~(10)~~ "Regulated Medical Waste" means the term defined in Rule .0101(34) of this Subchapter. ~~blood and body fluids in individual containers in volumes greater than 20 ml, microbiological waste, and pathological waste that have not been treated pursuant to Rule .1207 of this Section.~~

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

(13)~~(11)~~ "Sharps" means the term defined is G.S. 130A-309.26(a)(1). ~~and includes needles, syringes with attached needles, capillary tubes, slides and cover slips, and scalpel blades.~~

(14) "Trace chemotherapy waste" means no more than three percent by weight of a medical drug used for chemotherapy. Trace chemotherapy waste includes gowns, gloves, wipes, and other handling, preparation, administration, cleaning, and decontamination items associated with chemotherapy.

(15) "Transfer 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.

(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)~~(12)~~ "Treatment" ~~as~~ means the term 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 Subchapter.

(19) "Solid waste" means the term defined in 130A-290(a)(35).

History Note: *Authority G.S. 130A-309.26;*
Eff. October 1, 1990;
Amended Eff. April 1, ~~1993.~~1993;
Readopted Eff. November 1, 2019.

15A NCAC 13B .1202 is proposed for readoption with substantive changes as follows:

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

(a) Medical waste is subject to the ~~requirements in all applicable~~ rules in 15A NCAC ~~13B.~~ 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 ~~At the generating facility, sharps~~ shall be placed in a rigid, leak-proof when in an upright position, and puncture-resistant container, and ~~container which is rigid, leak-proof when in an upright position and puncture-resistant. Contained sharps~~ shall not be compacted prior to off-site ~~transportation.~~ transportation unless placed in a sealed compactor unit that is hauled off for disposal by the transporter. ~~After leaving the generating facility, the container and its contents shall be handled in a manner that avoids human contact with the sharps.~~

(c) Blood and body fluids in individual containers in volumes of 20 milliliters ~~ml~~ or less ~~which are not stored in a secured area restricted to authorized personnel prior to off-site transportation shall be packaged in accordance with the regulated medical waste packaging requirements as described in Rule .1204(a)(1) of this Section or in a container suitable for sharps. Containers of blood and body fluids which are packaged in accordance with Rule .1204(a)(1) of this Section or in a container suitable for sharps as required by this Rule~~ shall be stored in a secured area and shall not be compacted prior to off-site transportation.

(d) Regulated medical waste shall not be ~~compacted.~~ 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. Putrescent medical waste shall be disposed of or treated within three calendar days.

(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 Rules .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, returned to the vendor, reused, or disposed of at a municipal solid waste landfill.

(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 ml or less may be recycled, disposed of in a municipal solid waste landfill or sanitary sewer, or treated by the treatment methods as described in this Paragraph.

(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.

History Note: *Authority G.S. 130A-309.26;*
Eff. October 1, 1990;
Amended Eff. January 4, 1993; March 1, ~~1991.~~ 1991;
Readopted Eff. November 1, 2019.

15A NCAC 13B .1203 is proposed for readoption with substantive changes as follows:

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

~~(a) Regulated medical waste shall be treated prior to disposal. Acceptable methods of treatment are as follows:~~

~~(1) blood and body fluids in individual containers in volumes greater than 20 ml - Incineration or sanitary sewage systems, provided the sewage treatment authority is notified;~~

~~(2) microbiological waste - Incineration, steam sterilization, microwave treatment, or chemical treatment;~~

~~(3) pathological wastes - Incineration.~~

~~(b) Other methods of treatment shall require approval by the Division.~~

~~(c) Regulated medical waste treated in accordance with Paragraph (a) of this Rule may be managed in accordance with 15A NCAC 13B .0100 - .0700.~~

~~(d) Crematoriums are not subject to the requirements of Rule .1207(3) of this Section.~~

~~(e) A person who treats Regulated medical waste at the generating facility or within an integrated medical facility is not subject to the storage and record keeping requirements of Rule .1207(1) of this Section.~~

~~(f) Generating facilities and integrated medical facilities in operation on October 1, 1990 that incinerate Regulated medical waste are not subject to the requirements of Rule .1207(3)(a-l) of this Section until January 1, 1995.~~

(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 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; and

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

The requirement in Part (E) of this Subparagraph 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. The remaining medical waste packages shall be marked with the date of shipment from the generator when they are removed from the customer loaded trailer unless the medical waste packages are treated at that site within 24 hours.

(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 contents, 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 mycobacteriocidal disinfectant before being reused if any packages spilled or leaked while in the vehicle.

(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, or 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.

History Note: *Authority G.S. 130A-309.26;*
Eff. October 1, 1990;
Amended Eff. April 1, ~~1993.~~ 1993;
Readopted Eff. November 1, 2019.

15A NCAC 13B .1204 is proposed for readoption with substantive changes as follows:

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

~~(a) A person who ships regulated medical waste from the generating facility for off site treatment shall meet the following requirements:~~

~~(1) Regulated medical waste shall be packaged in a minimum of one plastic bag placed in a rigid fiberboard box, rigid drum, or other rigid container constructed in a manner that prevents leakage of the contents. The plastic bag shall be impervious to moisture and have a strength sufficient to preclude ripping, tearing or bursting the waste filled bag under normal conditions of usage and handling. Each bag shall be constructed of material of sufficient single thickness strength to pass the 165 gram dropped dart impact resistance test as prescribed by Standard D 1709 91 of the American Society for Testing and Materials, which is incorporated by reference including subsequent amendments and editions, and certified by the bag manufacturer. A copy is available for inspection at the Department of Environment, Health, and Natural Resources, Division of Solid Waste Management, 401 Oberlin Road, Raleigh, North Carolina. Copies may be requested by mail at American Society for Testing and Materials, 1916 Race Street, Philadelphia, P.A. 19103 or by calling (215) 299 5400 for a cost of twelve dollars ($12.00) plus one dollar and fifty cents ($1.50) for shipping and handling unless prepaid, then the fee is twelve dollars ($12.00).~~

~~(2) Regulated medical waste shall be stored in a manner that maintains the integrity of the packaging at all times.~~

~~(3) Each package of regulated medical waste shall be labeled with a water resistant universal biohazard symbol.~~

~~(4) Each package of regulated medical waste shall be marked on the outer surface with the following information:~~

~~(A) the generator's name, address, and telephone number;~~

~~(B) the transporter's name, address, and telephone number;~~

~~(C) storage facility name, address, and telephone number, when applicable;~~

~~(D) treatment facility name, address and telephone number;~~

~~(E) date of shipment; and~~

~~(F) "INFECTIOUS WASTE" or "MEDICAL WASTE".~~

~~(b) 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 generating facility for no less than three years.~~

~~(1) amount of waste by number of packages (piece count);~~

~~(2) date shipped off site;~~

~~(3) name of transporter;~~

~~(4) name of storage or treatment facility.~~

~~The requirements of this Paragraph shall not apply to persons who generate less than 50 pounds of regulated medical waste per month.~~

~~(c) A plan to ensure proper management of regulated medical waste shall be prepared and maintained at the generating facility.~~

(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;

(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 will respond to incidents or emergencies, 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 Paragraph (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 thereafter shall be maintained at the facility and available for inspection by the Division, and shall be submitted upon request from the Division, and shall include:

(A) the composite ash sample date and time;

(A) the ash sample date and time;

(B) the ash sample identification number;

(C) the ash sample analysis results; and

(D) 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 Paragraph (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 1.0×10^6.

(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 results.

(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 Paragraph (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 1.0×10^6 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 Paragraph (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 1.0×10^6 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 Paragraph (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 ozonation time, the incubation time, 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 may 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;*
Eff. October 1, 1990;
Amended Eff. October 1, 1992; December 1, 1991; March 1, ~~1991.~~ 1991;
Readopted Eff. November 1, 2019.

15A NCAC 13B .1205 is proposed for readoption as a repeal as follows:

15A NCAC 13B .1205 REQUIREMENTS FOR TRANSPORTERS OF REGULATED MEDICAL WASTE

~~A person who transports Regulated medical waste that has not been treated at the generating facility shall meet the following requirements:~~

~~(1) Transporters shall not accept waste which is improperly packaged.~~

~~(2) Regulated medical waste shall be transported in a manner that prevents leakage of the contents of the package.~~

~~(3) The integrity of the package shall be maintained at all times.~~

~~(4) The labeling and marking of the package shall be maintained at all times.~~

~~(5) All loads containing Regulated medical waste shall be covered during transportation.~~

~~(6) The universal biohazard symbol shall be displayed on all transportation vehicles, in accordance with Department of Transportation Standards and 49 CFR 172 Subpart F.~~

~~(7) Regulated medical waste shall be delivered to a permitted storage or treatment facility within seven calendar days of the date of shipment from the generator.~~

~~(8) Refrigeration at an ambient temperature between 35 and 45 degrees Fahrenheit shall be maintained for Regulated medical waste that will not be delivered for treatment within seven calendar days.~~

~~(9) A contingency plan shall be prepared and maintained in each vehicle used in the transporting of Regulated medical waste. The operator of each vehicle shall be knowledgeable of the plan.~~

~~(10) Vehicles used for the transportation of Regulated medical waste shall be thoroughly cleaned and disinfected with a mycobacteriocidal disinfectant before being used for any other purpose and in the event of leakage from packages.~~

~~(11) While transporting Regulated medical waste, vehicles are prohibited from transporting any material other than solid waste and supplies related to the handling of medical waste.~~

History Note: *Authority G.S. 130A-309.26;*
Eff. October 1, ~~1990.~~1990;
Repealed Eff. November 1, 2019.

15A NCAC 13B .1206 is proposed for readoption as a repeal as follows:

15A NCAC 13B .1206 REQUIREMENTS FOR STORAGE OF REGULATED MEDICAL WASTE

~~A person who stores Regulated medical waste that has not been treated at the generating facility shall meet the following requirements:~~

~~(1) Regulated medical waste shall be stored in a manner that prevents leakage of the contents of the package.~~

~~(2) Regulated medical waste shall be stored in a manner that maintains the integrity of the packaging at all times.~~

~~(3) The labeling and marking of the package required in Rule .1204 of this Section shall be maintained at all times.~~

~~(4) Regulated medical waste shall not be stored longer than seven calendar days from the date of shipment from the generator unless the Regulated Medical Waste is refrigerated at an ambient temperature between 35 and 45 degrees Fahrenheit.~~

~~(5) Only authorized personnel shall have access to areas used to store Regulated medical waste.~~

~~(6) All areas used to store Regulated medical waste shall be kept clean. Vermin and insects shall be controlled.~~

~~(7) 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.~~

~~(8) A plan shall be prepared, maintained and updated as necessary to ensure continued proper management of Regulated medical waste at the facility.~~

History Note: *Authority G.S. 130A-309.26;*
Eff. October 1, ~~1990.~~1990;
Repealed Eff. November 1, 2019.

15A NCAC 13B .1207 is proposed for readoption as a repeal as follows:

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. gonorrhea, 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;*
Eff. October 1, 1990;
Amended Eff. April 1, 1993; January 4, ~~1993.~~ 1993;
Repealed Eff. November 1, 2019.

From: Hollis, Carrie
To: Montie, Jessica; Patrone, John; Everett, Jennifer
Cc: Masich, Molly; McGhee, Dana; Grozav, Anca
Subject: Approval - Medical Waste Management, 15A NCAC 13B .1201 - .1207
Date: Thursday, February 21, 2019 3:20:34 PM
Attachments: DEQ_2019-02-21.pdf

OSBM has reviewed the Division of Waste Management's proposed amendments to rules 15A NCAC 13B .1201 - .1207 in accordance with G.S. 150B-21.4 and with E.O. 70 from 10/21/2010 as amended by E.O. 48 from 4/9/2014. The fiscal note is approved for publication. Please ensure that the state government impact is included in the Notice of Text.

The .pdf file of the rule impact analysis (attached) will be posted on our website at the following URL (please allow for some time):
https://files.nc.gov/ncosbm/documents/files/DEQ_2019-02-21.pdf
Please post this link on your agency's website to ensure compliance with G.S. 150B-19.1(c)(5).

Please let me know if you have any questions.
-Carrie

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