

Appendix A

Look Here First

This Document Contains a Discussion of Medical Waste Issues, [Medical Waste Management Rules](#), and a List of Medical Waste Treatment Facilities

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Introduction

This document is provided to help you understand the North Carolina medical waste management rules.

If you would like further information, please contact the Solid Waste Section in the Department of Environment and Natural Resources (DENR). The number in Raleigh is 919-733-0692.

You may also contact a local Waste Management Specialist in one of the seven DENR regional offices.

In the West: Brent Rockett (336) 771-4600

In the East: Mark Fry (910) 486-1191

General Information

The Solid Waste Section regulates the packaging, labeling, storage, transportation, treatment and disposal of medical waste in North Carolina. Treatment, storage and disposal facilities that accept waste from outside of the facility cannot operate without a permit from the Solid Waste Section.

Please read this entire document. Due to the complex nature of medical waste regulations, failure to read this entire document may result in failure to comply with the rules.

This guide is not intended as legal advice, but as an aid to understanding the current North Carolina medical waste management rules.

Effective Date

The medical waste management rules became effective October 1, 1990. The most recent amendments were made in April 1993.

Enforcement of the Rules

The medical waste management rules are enforced by the Solid Waste Section and, in some cases, the local law enforcement authority.

Pre-Emption of Local Solid Waste Laws on Medical Waste

These rules pre-empt local solid waste laws on medical waste where local laws are more lenient.

Joint and Several Liability

Under state regulations a solid waste generator is responsible for the storage, collection and disposal of his or her solid waste. The generator is responsible for ensuring that solid waste is disposed at a site or facility that has all applicable permits required to receive waste. (15A NCAC 13B .0106)

Medical Waste Definition

Medical waste means any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, but does not include any hazardous waste identified or listed pursuant to this Article, radioactive waste, household waste as defined in 40 Code of Federal Regulations § 261.4(b)(1) in effect on 1 July 1989, or those substances excluded from the definition of solid waste in this section. (NCGS 130A-290(a)(18))

Regulated Medical Waste Definition

Regulated medical waste means 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 .1207. (.1207 is the definition of treatment - see rules on page 22.) Regulated medical waste must be treated prior to disposal. After treatment these wastes may be handled as general solid waste. (.1201(9))

Percentage of the Medical Waste Stream That Is Regulated Medical Waste

Most medical waste may be handled as general solid waste and does not require treatment. Regulated medical waste makes up only a very small portion of the total medical waste stream. The percentage of a facility's waste stream comprised of regulated medical waste is dependant on the activities at that facility. Roughly 9 percent to 15 percent of the waste stream at hospitals is regulated medical waste. Some facilities, such as long-term care facilities, generate medical waste but little or no regulated medical waste.

Microbiological Waste

Microbiological waste means cultures and stocks of infectious agents, including but not limited to specimens from medical, pathological, pharmaceutical, research, commercial and industrial laboratories. (.1201(5))

Pathological Waste

Pathological waste means 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 of a known or suspected disease transmissible to humans. (.1201(8))

Blood and Body Fluids

Blood and body fluids means liquid blood, serum, plasma, other blood products, emulsified human tissue, spinal fluids and pleural and peritoneal fluids. Dialysates are not blood or body fluids under this definition. Please note that the definition of regulated medical waste specifies blood and body fluids that are in a liquid state and in a container, such as a suction canister. This does not refer to blood absorbed by materials such as bandages and dressings. (Some waste items contaminated with blood may be subject to OSHA labeling requirements). (.1201(1))

Medical Waste Such as Dressings, Bandages, Sponges, Used Gloves, and Tubing

These items are not included in the definition of regulated medical waste and may be disposed of without treatment. (.1201(9))

Requirements for **Blood and Body Fluids in Individual Containers** in Volumes Equal to or Less Than 20 ml

These "containers" are commonly vacuum tubes used for blood samples. If not stored in a secured area, accessible only to authorized personnel, these containers must be packaged either in a container suitable for sharps or in a plastic bag in a rigid fiberboard box or drum. Treatment is not required prior to disposal. (.1202(c))

Urine and Feces

Urine and feces should be disposed of through sanitary sewage or septage disposal practices. Soiled diapers are not regulated medical waste and may be disposed as general solid waste.

Registration of Medical Waste Generators

North Carolina does not require generators of medical waste to register.

Artificial Body Parts and Implants Removed or Replaced During Surgical Procedures
Items such as artificial limbs and pacemakers are considered medical waste. However, they are not generally considered regulated medical waste because they do not fall within a class of regulated medical waste.

Medical Waste Reduction Techniques

Information about medical waste reduction techniques is available from the Solid Waste Section and the Division of Pollution Prevention and Environmental Assistance.

Sharps

Sharps

.1201(10) "Sharps" means and includes needles, syringes with attached needles, capillary tubes, slides and cover slips, and scalpel blades.

Disposal of Sharps

The rules do not require treatment of sharps before disposal. They must be packaged in a container that is rigid, leak-proof when in an upright position and puncture resistant. The package then may be disposed of with general solid waste. (Generators should comply with any relevant OSHA requirements for labeling and packaging). (.1202(b))

Compaction of Sharps

Sharps cannot be processed in small compaction units inside the generating facility. The rule does not prohibit hauling sharps to the landfill on trucks that compact waste. Also, it does not prohibit processing sharps containers in large commercial compactors where the waste will be transported to a disposal facility without being transferred to another container. (.1202(b))

Sharps Generated in Private Households

Household waste is not included in the definition of medical waste and is not subject to the medical waste management rules. However, home users of sharps are urged to place sharps in hard wall containers before disposal in order to protect garbage collectors from needlesticks. A few counties have imposed local restrictions on sharps disposed from private homes. Home healthcare agencies may find it prudent to assist in proper disposal of sharps used to administer care to patients in their homes. This is not specifically required by the rules. Used needles from farms are subject to the rules and are not considered household waste. Such waste is more similar to veterinary waste than household waste.

Packaging and Storage

Packaging Regulated Medical Waste for Off-Site Treatment

Regulated Medical Waste must be packaged in a plastic bag in a rigid fiberboard box or drum in a manner that prevents leakage of the contents. The outer surface must be labeled with a biohazard symbol; the words "INFECTIOUS WASTE" or "MEDICAL WASTE"; the date of shipment; and the name, address and phone number of the generator, transporter, storage facility and treatment facility. The medical waste management rules do not require a biohazard label on the plastic bag or use of red bags. However, generators should be aware that OSHA rules may require labeling of bags containing some types of medical waste. (.1204(a)(1))

Storage of Regulated Medical Waste Prior to Shipment Off Site for Treatment

- All medical waste, including regulated medical waste, must be stored in a manner so as not to create a nuisance either by noxious odors or by encouraging the presence of vermin. Regulated medical waste must be maintained in a non-putrescent state. - Regulated medical waste must be stored in a manner that maintains the integrity, including labels and markings - Areas used to store regulated medical waste must be accessible only to authorized personnel. - Vermin and insects must be controlled. - All floor drains in the storage area must discharge directly to an approved sanitary sewer (sewer or septic system). - Ventilation must be provided. - A plan must be maintained at the facility to ensure proper management of regulated medical waste. (.1206)

Storage of Regulated Medical Waste That Will Be Shipped Off Site for Treatment

A waste generator who stores regulated medical waste that will be shipped off site for treatment must store the waste in a package suitable for transportation. (.1204(a))

Packaging Requirements for Regulated Medical Waste Which Will Be Treated On Site

The packaging requirements in section .1204 only apply to regulated medical waste that is being shipped off site for treatment. There is no packaging requirement for regulated medical waste treated on site.

Storage Requirements for Medical Waste Which Is Not Classified as Regulated Medical Waste

If none of the medical waste being stored is regulated medical waste, the waste is subject to the storage requirements of general solid waste. As with regulated medical waste, non-regulated medical waste must be stored in a non-putrescent state, and vermin and insects must be controlled.

Transportation

Manifesting Requirements

North Carolina does not have a manifesting requirement and does not require "cradle to grave" tracking of medical waste.

Generator Responsibilities for Proper Disposal by Commercial Facilities

Generators are responsible for ensuring that waste is disposed of properly. If there is any question about a commercial treatment facility's permit, please contact the Solid Waste Section. (15A NCAC 13B .0106)

Self-Transporting Regulated Medical Waste

The requirements in Section .1205 apply to any person transporting waste off site for treatment. There are no manifest or registration requirements. Haulers must comply with any relevant Department of Transportation regulations.

Shipping Non-Regulated Medical Waste Off-Site for Treatment

Only regulated medical waste is subject to the packaging, labeling and transportation requirements. Other waste may be handled as general solid waste so long as it meets applicable packaging requirements for sharps and containers of blood with 20 cc or less.

Packaging and Labeling Requirements for Regulated Medical Waste That Will Be Treated On Site

Regulated medical waste that will be treated on site is not subject to the packaging and labeling requirements. Generators still must comply with any relevant OSHA requirements for packaging and labeling for workplace safety.

Treatment and Disposal

Treatment Facilities for Regulated Medical Waste

Regulated Medical Waste may be treated on site or at a facility that is an integrated part of the generating facility (See .1201(3) for definition of integrated). Otherwise, it must be sent to a medical waste treatment facility permitted by the Solid Waste Section (See list on page 29). Many generators choose to ship and incinerate non-regulated medical waste such as gloves, bloody bandages, dressings, and tubing. Generators who incur this expense should be reminded that this is not required by OSHA or any other state agency. Such waste may be landfilled untreated even though it may be designated as regulated waste by OSHA. (.1203(a))

Permitting of Medical Waste Treatment Facilities

Solid waste permits are not required for facilities that treat only waste generated within the facility. Permits are required for facilities that treat medical waste generated off site and not within an integrated medical facility.

Disposal of Large Volumes of Blood and Body Fluids

Incineration or sanitary sewage are acceptable treatments for blood and body fluids in individual containers in volumes greater than 20 ml. If neither of these options is available on site, a vendor must be obtained to treat the material. A list of permitted disposal services is located at the back of this document. (.1203(a)(1))

Urine and Feces

Disposal of Items Such as Bloody Gauze, Used Gloves, Tubing, and Dressings. These materials are not regulated medical waste and, therefore, do not have any specific treatment requirement. They may be disposed of as general solid waste. Note that some of these items may be subject to packaging and labeling requirements by OSHA. The Solid Waste Section does not recommend removing these labels at the point of disposal.

Arranging for Incineration of Regulated Medical Waste by a Neighboring Hospital

Any facility treating waste that is generated off site and outside of an integrated medical facility must obtain a permit from the Solid Waste Section. All packaging, labeling, transportation, storage, and treatment requirements apply.

The "50 Pound per Month" Record-Keeping Exemption

This exemption, in Section .1204(b), exempts generators from the record-keeping requirement if they ship less than 50 pounds per month of regulated medical waste.

Rejection of Properly Packaged Sharps or Treated Regulated Medical Waste at the Local Municipal Landfill

Landfill operators have the right to reject any waste for disposal in the landfill, even if state regulations allow landfill disposal of such wastes.

Managing Medical Waste After It Has Been Treated

Treated medical waste is subject to the same requirements as general solid waste. (.1203(c))

Funeral Home Practices

Disposal of Regulated Medical Waste with Casketed Remains

Caskets containing human remains were intended for interment or cremation, so they will not be regulated under the rules. Remains intended for disposal may not be placed in a casket as a means of disposal; such wastes are considered pathological wastes and are subject to all applicable requirements.

Special Cases Where Religious Practices Require That a Body Be Interred with Removed Organs as Well as Tubing and Sharps

These practices are acceptable. The rules are not intended to interfere with the religious preferences of any individual.

Sharps Used During the Course of Preparing a Body for Interment, Including Scalpels, Needles and Other Instruments

These sharps are medical waste and therefore subject to all applicable requirements in the medical waste rules. (.1202(b))

Using Crematoriums for Incineration of Regulated Medical Waste

Crematoriums do not meet the incineration requirements of the medical waste management rules. All medical waste incinerators must meet the requirements. Cremation is an acceptable form of disposal for fetal remains. (.1207(3))

Contracts with Commercial Medical Waste Treatment Companies to Treat Funeral Home Waste

With the exception of blood, which can be treated by sanitary sewer, most funeral homes do not generate regulated medical waste. Non-regulated medical waste may require special packaging (see .1202), but it does not require incineration.

Special Arrangements for Treating Waste Generated Off-Site - Examples

Facility "G" (the generator) sends its regulated medical waste to facility "T" for treatment.

What packaging, labeling, record-keeping, transportation and treatment requirements apply?

To answer this question, two determinations must be made:

1. whether sites G and T are an "integrated medical facility" (See definition below); and
2. whether G is "on-site" or "off-site" relative to facility T. That is, if you are at one facility, is the other on-site? (See definition below).

After determining whether a facility is an integrated medical facility and/or on or off- site, the table below may be used to find out what requirements apply. See examples.

	Integrated Facility	Non-Integrated Facility
On-site	Exempt from packaging, labeling, storage, and record-keeping requirements.	Exempt from packaging and labeling requirements. Subject to storage and record-keeping requirements. Treatment facility must hold a permit issued by the Solid Waste Section
Off-site	Exempt from recordkeeping and storage requirements. Subject to packaging, labeling and transportation requirements.	Subject to all packaging, labeling, storage, record-keeping and transportation requirements. Treatment facility must hold a permit issued by the Solid Waste Section.

Definitions:

Integrated medical facility means one or more health service facilities as defined in NCGS 131E-176(9b) (see definition on page 21) 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. (.1201(3))

"Health service facility" means a hospital; psychiatric facility; rehabilitation facility; long term health care facility; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for the mentally retarded; home health agency; chemical dependency treatment facility; and ambulatory surgical treatment facility. (131E-176(9b))

Funeral homes, veterinary hospitals, dental and research labs are not integrated facilities.

On-site means the same or geographically contiguous property which may be divided by public or private right-of-way. (.1201(7))

Off-site means any site which is not on-site. (.1201(6))

The following examples will help to determine what requirements apply under a variety of situations.

Example A

Facility G is a hospital sending its pathological and microbiological waste across town to facility T, also a hospital, for treatment. G and T are under common ownership and in the same county but not on a geographically contiguous piece of property. What requirements apply?

Step 1. Are G and T an integrated medical facility?

Yes. G and T meet the three criteria for being an integrated facility - they are under common ownership, serve a single service area and are located in a single county.

Step 2. Are T and G on-site? (Or, if you are at facility T, is G on-site?)

No. The facilities are not on-site because they are not on a geographically contiguous piece of property.

Answer: The table shows facilities that are integrated and off-site are exempt from the record-keeping and storage requirements, but must comply with packaging, labeling and transportation requirements.

Example B

Facility G, a veterinary hospital, is sending animal carcasses that are infected with rabies to facility T, a hospital, for treatment. The facilities are not under common ownership and are on separately owned pieces of property that are geographically contiguous. What requirements apply?

Step 1. Are the facilities an integrated medical facility?

No. The facilities are not under common ownership. Furthermore, veterinary facilities are not included in the definition of a health care facility.

Step 2. Are the facilities on-site?

Yes. The facilities are on geographically contiguous property. Answer: The facilities are non-integrated and on-site. The table shows they are exempt from the packaging and labeling requirements, but are not exempt from the storage and record-keeping requirement. Additionally, the treatment facility must hold a permit issued by the Solid Waste Section.

Example C

A university hospital, T, treats waste from a hospital affiliated lab, G, across campus. The campus is a geographically contiguous piece of property. What requirements apply?

Step 1. Are they an integrated medical facility?

Yes. The facilities are located in the same county, affiliated with a university medical school and serve the same area.

Step 2. Are the facilities on-site?

Yes. They are on a geographically contiguous piece of property.

Answer: The facilities are on-site and integrated. The table shows that they are exempt from packaging, labeling, storage and record-keeping requirements.

Example D

A pathology laboratory, G, sends regulated medical waste to a local hospital, T, across town. The pathology lab and the hospital are not under common ownership or on geographically contiguous property.

Step 1. Are the facilities integrated?

No. They are not under common ownership.

Step 2. Are the facilities on-site?

No. They are not on the same or geographically contiguous property.

Answer: The facilities are off-site and non-integrated. The table shows that they are each subject to the packaging, labeling, storage, record keeping and transportation requirements. The treatment facility would need a permit issued by the Solid Waste Section.

Interface with OSHA Regulations

Impact of the OSHA Bloodborne Pathogen Standards on Medical Waste Disposal Requirements

The new OSHA standards do not address disposal methods, and no changes have been made in state medical waste treatment and disposal rules. OSHA Instruction CPL 2-2.44D states "that while OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incineration, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations.

Comparison of the Definition of Regulated Medical Waste with the OSHA Definition of Regulated Waste

There are substantial differences in the two definitions. For example, the OSHA definition of regulated waste may include waste such as bloody gauze, blood-saturated dressings, used gloves, or tubing. These items are not included in the state definition of regulated medical waste and are exempt from treatment requirements. It is essential the generator understand both definitions. Generators who apply the OSHA definition of regulated waste to designate waste for treatment by incineration may unintentionally incur additional expense. The OSHA definition of regulated waste is not intended to designate waste that must be incinerated or otherwise treated before landfilling.

Disposal of Blood and Body Fluids into the Sanitary Sewer

The sanitary sewage treatment system is designed for disposal of body fluids. OSHA regulations do not address disposal and do not prohibit such disposal. Workers disposing blood are of course subject to OSHA requirements, such as wearing protective clothing.

Different Labeling Requirements

Generators must be familiar with both sets of requirements. OSHA may require a red bag or biohazard-labeled bag for some waste that can be safely disposed in the landfill without treatment. That could include properly containerized sharps, used gloves, bloody gauze and dressings, and properly containerized blood and body fluids in volumes of 20 mL or less. State waste disposal regulations require the words "INFECTIOUS WASTE" or "MEDICAL WASTE" on packages of regulated medical waste that are taken off site for treatment and disposal. State medical waste disposal regulations no longer require the use of red bags since the red dyes may contribute heavy metals, such as lead and cadmium, to incinerator ash disposed in landfills. State solid waste goals include reducing the toxicity of landfilled waste. Users of red bags should check with their vendors to ensure they are using bags that do not create toxic residues after incineration.

Disposal of Red Bags That Contain Only Medical Waste Not Classified as Regulated Medical Waste by the State Medical Waste Management Definition

Bags that contain only non-regulated medical waste in accordance with state rules and are labeled as biohazardous in the workplace, are "over-labeled" for disposal purposes. Such labels were previously reserved to designate waste that was banned from the landfill and must be treated. Red bags and biohazard-labeled bags that contain only non-regulated medical waste may be disposed with general solid waste, provided no local rules prohibit it.

The Solid Waste Section has alerted North Carolina landfills to expect increased disposal of non-regulated medical waste in red bags or biohazard-labeled bags as the OSHA rules are implemented. In some counties, landfill operators initially may not accept such bags, even though they had previously accepted the same waste in plain, unlabeled bags.

In most cases, this can be worked out through local discussions and better communications with the landfill. Landfill operation is regulated by the Solid Waste Section, and local waste

management specialists are available to provide assistance, guidance, and education for landfill operators.

As described in paragraphs (g)(1)(i)(B),(C),(D), and (E) of the OSHA standards, the OSHA labeling requirements can be satisfied by the use of either red bags or bags with a biohazard label. Facilities sending waste to the landfill may find plain bags with the appropriate biohazard label an easy solution.

Risks to Waste Industry Workers

Waste transport and disposal is mechanized, and waste handlers are trained to safely deal with all types of waste that contain human pathogens. To keep things in perspective, it is important to realize that household garbage has on average 100 times more pathogenic microorganisms than general medical waste.

Problems with Using the OSHA Definition of Regulated Waste to Designate Waste That Must Be Treated and Cannot Be Disposed at the Landfill

The OSHA definition designates waste that poses a threat in the workplace, and does not designate waste that should be incinerated or treated by other means. Applying this definition to disposal would constitute imposing treatment requirements to additional categories of medical waste. Requiring treatment of very broad categories of medical waste may increase waste management costs substantially, while providing no benefit for the environment or public health.

Adopting Uniform Definitions for the Department of Labor and Department of Environment and Natural Resources

The rules do not conflict, but they address two entirely different concerns. Federal OSHA rules address waste management in the workplace to ensure worker safety; state solid waste management rules ensure storage, shipping, and disposal practices that protect the environment and public health. Categories of waste that present special infectious hazards in the workplace do not necessarily present the same hazards to the environment or public health once in the disposal process.

Definitions

Medical waste means any solid waste which is generated in the diagnosis, treatment, or immunization of human beings or animals, in research pertaining thereto, or in the production or testing of biologicals, but does not include any hazardous waste identified or listed pursuant to this Article, radioactive waste, household waste as defined in 40 Code of Federal Regulations § 261.4(b)(1) in effect on 1 July 1989, or those substances excluded from the definition of solid waste in this section. (NCGS 130A-290(18))

Health service facility means a hospital; psychiatric facility; rehabilitation facility; long term care facility; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for the mentally retarded; home health agency; chemical dependency treatment facility; and ambulatory surgical facility. (NCGS 131E-176(9b))

Treatment means any method, technique or process, including neutralization, designed to change the physical, chemical or biological character or composition of any hazardous waste so as to neutralize such waste or so as to render such waste nonhazardous, safer for transport, amenable for recovery, amenable for storage or reduced in volume. Treatment includes any activity or processing designed to change the physical form or chemical composition of hazardous waste so as to render it nonhazardous.(NCGS 130A-290(a)(42))

Medical Waste Disposal Facilities

American Waste Industries
508 East Indian River Road
Norfolk, VA 23523
757-543-7661
800-872-2876

Micro-Med Industries, Inc.
4403 Republic Court
Concord, NC 28027
(704) 795-1112

SafeWaste Corporation
9209 Forsyth Park Drive
Suite A
Charlotte, NC 28273
704-588-2100

Stericycle, Inc.
28161 N. Keith Drive
Lake Forest, IL 60045
[HTTP://www.stericycle.com](http://www.stericycle.com)

If you have questions or comments, please email [Ernie Lawrence](#).

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SECTION .1200 – MEDICAL WASTE MANAGEMENT

.1201 DEFINITIONS

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

- (2) “Generating facility” means any facility where medical waste first becomes a waste, including but not limited to any medical or dental facility, funeral home, laboratory, veterinary hospital and blood bank.
- (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 defined G>S> 130A-209(18).
- (5) “Microbiological waste” means cultures and stocks of infectious agents, including but not limited to specimens from medical, pathological, pharmaceutical, research, commercial, and industrial laboratories.
- (6) “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.
- (9) “Pathological waste” means 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) “Regulated Medical Waste” means 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.
- (11) “Sharps” means and includes needles, syringes with attached needles, capillary tubes, slides and cover slips, and scalpel blades.
- (12) “Treatment” as defined in G.S. 130A-309.26(a)(2).

History Note: Statutory Authority G>S> 130A-309.26;Eff. Oct. 1, 1990; Amended EFF. April 1, 1993.

.1202 GENERAL REQUIREMENTS FOR MEDICAL WASTE

- (a) Medical waste is subject to all applicable rules in 15A NCAC 13B.
- (b) At the generating facility, sharps shall be placed in a container which is rigid, leak-proof when in an upright position and puncture-resistance. Contained sharps shall not be compacted prior to off-site transportation. 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 individuals containers of 20 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 ina container suitable for sharps as required by this Rule shall not be compacted prior to off-site transportation.
- (d) Regulated medical waste shall not be compacted.

History Note: Statutory Authority G.S. 130A-309.26; Eff. October 1, 1990; Amended Eff. January 4, 1993; March 1, 1991.

.1203 GENERAL REQUIREMENTS FOR REGULATED MEDICAL WASTE

(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-1) of this Section until January 1, 1995.

History Note: Statutory Authority G.S. 130A-309.26; Eff. October 1, 1990; Am. Eff. April 1, 1993.

.1204 REQUIREMENTS FOR GENERATORS 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, PA 19103 or by calling 215.299.5400 for a cost of \$12.00 plus \$1.50 for shipping and handling unless prepaid, then the fee is \$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" OF "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.

History Note: Statutory Authority G.S. 130A-309.26; Eff. October 1, 1990; Amended Eff. October 1, 1992.

.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) White 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: Statutory Authority G.S. 130A-309.26; Eff. October 1, 1990.

.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: Statutory Authority G. S. 130A-309.26; Eff. October 1, 1990.

.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 Control 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 operations. 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 composite

in a closed container weekly and shall be thoroughly mixed and reduced to a representative sample. These shall be composite 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 composite 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 15 A 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.

(1) Records of stack testing as prescribed in the Air Quality Permit shall be maintained at the facility.

(m) Existing generating facilities shall conduct one weekly representative ash sampling and testing in accordance with Sub-Items (3) (f), (g) and (j) of this Rule annually during the second quarter of each calendar year.

(4) Chemical treatment requirements:

(a) Cultures of throat, urine, sputum, skin and genitourinal tract which contain only the following organisms: *N. gonorrhoea*, *E. coli*, *staphylococcus*, *proteus*, *Candida albicans*, and *B. cereus* or normal flora in individual plates or tubes containing 5-20 ml media shall be covered, for a minimum of one hour, with a 1:5 dilution of household bleach (5.25 percent sodium hypochlorite) in water. The solution shall remain on the treated plates which are to be stacked in a plastic bag prior to disposal. The bag is to be sealed to prevent leakage.

(b) Approval for other types of chemical treatment must be obtained from the Division. Request for approval must be substantiated by results of demonstrated effectiveness of the chemical to treat the specific microbiological agent(s) of concern for the waste disposed. Consideration must be given to such factors as temperature, time of contact, pH, concentration and the presence and state of dispersion, penetrability and reactivity of organic material at the site of application.

(c) A written plan must be maintained at the facility and units of the facility as necessary to ensure consistent procedures are used to treat the waste.

(5) Microwave treatment requirements:

(a) Microwave energy of appropriate output frequency shall be provided such that a minimum temperature of 95 degrees Centigrade (203 degrees Fahrenheit) is maintained for a minimum of 30 minutes each cycle; or other combinations of parameters that are shown to effectively treat the waste.

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

(c) Monitoring under conditions of full loading for effectiveness of treatment shall be performed through the use of a biological indicator or other methods approved by the Division. Testing shall be performed no less than once per week or as specified by the Division. Additional testing shall be performed if temperature/time monitoring indicates a variation from requirements in Sub-Item (5)(a) of this Rule.

(d) A log of each test of effectiveness of treatment performed shall be maintained and shall include the type of indicator used, date, time, and result of test.

(e) Regulated medical waste may be disposed of until or unless monitoring as required in Sub-Item (5)(c) of this Rule does not confirm effectiveness.

History Note: Statutory Authority G. S. 130-A309.26; Eff. October 1, 1990; Amended Eff. April 1, 1993; January 4, 1993.

<http://wastenot.ehnr.state.nc.us/SWHOME/medrules.htm>