

SECTION .1200 - MEDICAL WASTE MANAGEMENT

15A NCAC 13B .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 in G.S. 130A-290(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: Authority G.S. 130A-309.26;
Eff. October 1, 1990;
Amended Eff. April 1, 1993.

15A NCAC 13B .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-resistant. 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 individual 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 in a 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.

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Amended Eff. January 4, 1993; March 1, 1991.*

15A NCAC 13B .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: Authority G.S. 130A-309.26;
Eff. October 1, 1990;
Amended Eff. April 1, 1993.*

15A NCAC 13B .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, 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.

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

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.

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.

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

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

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

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

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

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