

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

(a) Regulated medical waste packaging requirements:

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

(b) Generator requirements:

- (1) The generating facility shall package medical waste by treatment method type in accordance with Rule .1202(i) of this Section.
- (2) The generating facility shall maintain a record of each shipment of regulated medical waste transported off-site for a period of three years that includes the following information:
 - (A) the number of packages;
 - (B) the transporter name, physical address, and phone number;
 - (C) the treatment facility name, physical address, and phone number; and
 - (D) the date of shipment from the generating facility.The requirements of this Subparagraph do not apply to generating facilities that generate less than 50 pounds of regulated medical waste per month.

(c) Transporter requirements:

- (1) The transporter shall not accept regulated medical waste that does not meet the requirements of Paragraph (a) of this Rule.
- (2) The universal biohazard symbol shall be displayed on the outside of a transport vehicle on both sides and rear of the vehicle's cargo area, shall be legible, and shall not be obstructed from view.
- (3) Transport vehicles shall only transport medical waste for treatment, other solid wastes, and supplies related to the handling of solid wastes. If a medical waste package leaks or spills, all of the solid waste, except for hazardous waste, within the same storage area of the transport vehicle as the leaking or spilled package shall be treated at a medical waste treatment facility. If the solid waste that leaked or spilled is a hazardous waste, all of the solid waste within the same storage area of the transport vehicle as the leaking or spilled package shall be brought to a hazardous waste treatment facility.
- (4) Transport vehicles shall be free of medical waste and disinfected with a mycobactericidal disinfectant before being reused if any packages spilled or leaked while in the vehicle, and prior to discontinuing use of the transport vehicles to haul medical waste.

- (5) The vehicle operator shall keep a contingency plan as described in Rule .1204(b)(4)(H) of this Section in the transport vehicle and shall be trained to implement the contingency plan prior to transporting medical waste.
 - (6) The transporter shall be in compliance with Rule .1202(o), (p), and (q) of this Section.
- (d) Transfer or storage operations requirements:
- (1) The responsible party for transfer or storage operations occurring at a treatment facility shall include a description of the transfer or storage operations in the facility operations plan submitted to the Division in accordance with Rule .1204(b)(4) of this Section.
 - (2) The responsible party for transfer or storage operations occurring at a location other than a treatment facility shall submit a record to the Division within 14 calendar days of commencing transfer or storage operations, and once every two years thereafter, while the responsible party is managing the transfer or storage operations. The record shall include the following information:
 - (A) the name, mailing address, physical address, office and mobile phone numbers, and email address for the responsible party(s) and operator(s);
 - (B) county GIS property data for the location where transfer or storage operations occur;
 - (C) procedures for how the medical waste will be received, handled, stored, and transferred;
 - (D) the frequency that transfer or storage operations occur;
 - (E) the amount of medical waste that is expected to be on site at the transfer or storage operations; and
 - (F) additional information that the Division may request pertaining to the transfer or storage operations if it is necessary to determine compliance with the rules of this Subchapter.The responsible party shall submit an updated record to the Division within 14 calendar days if any of the information required to be submitted by this Subparagraph changes.
 - (3) If the transfer or storage operations cease, the responsible party shall submit to the Division a record within 14 calendar days. The record shall include the following information:
 - (A) a signed statement by the responsible party(s) that transfer or storage operations have ceased and all medical waste has been removed;
 - (B) digital pictures of the area that was utilized for transfer or storage operations taken after operations have ceased and all medical waste has been removed; and
 - (C) additional information that the Division may request pertaining to the transfer or storage operations if it is necessary to determine compliance with the rules of this Subchapter.
 - (4) Within 90 days of the readopted effective date of this Rule, existing transfer or storage operations shall comply with Subparagraph (2) of this Paragraph.
 - (5) The transfer or storage operations shall comply with Rule .1202(o), (p), and (q) of this Section.

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