CHAPTER 33.1-20-12
REGULATED INFECTIOUS WASTE

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33.1-20-12-01. Definitions.

1. As used in this article, "regulated infectious waste" means an infectious waste which is listed in subdivisions a through g of this subsection. Ash from incineration and residues from disinfection processes are not infectious waste once the incineration or the disinfection has been completed.

   a. Cultures and stocks. Cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.

   b. Pathological waste. Human pathological waste, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.

   Human body fluids include: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

   c. Human blood and blood products. Liquid waste human blood; products of blood; items saturated or dripping with human blood; or items that were saturated or dripping with human blood that are now caked with dried human blood (including serum, plasma, and other blood components, and their containers) and are capable of releasing these materials during handling.

   d. Sharps. Any contaminated object that has been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, that can cut or penetrate the skin. This includes hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, culture dishes (regardless of presence of infectious agents), and exposed ends of dental wires. Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

   e. Animal waste. Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biological, or testing of pharmaceuticals.

   f. Isolation waste. Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

"Highly communicable diseases" means diseases, such as those caused by organisms classified by the federal centers for disease control and prevention as biosafety level IV organisms, that, in the opinion of the infection control staff, the department, local health
officer, attending physician and surgeon, or attending veterinarian, merit special precautions to protect staff, patients, and other persons from infection. "Highly communicable diseases" does not include diseases such as the common cold, influenza, or other diseases not representing a significant danger to nonimmunocompromised persons.

g. Unused sharps. This waste includes the following unused, discarded sharps: hypodermic needles, intravenous or other needles, hypodermic or intravenous syringes, suture needles, or scalpel blades.

2. As used in this chapter, "disinfection or disinfect" means treatment or processing of infectious waste so that it poses no risk of infection or other health risk to individuals handling or otherwise coming into contact with the waste. The term includes autoclaving, chemical disinfection, radiation and irradiation, and incineration.

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General Authority: NDCC 23.1-08-03; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-08-03; S.L. 2017, ch. 199, § 23

33.1-20-12-02. Management standards.

Every person who collects, stores, transports, treats, or disposes of regulated infectious waste shall comply with these standards of performance.

1. At the point of origin, regulated infectious waste must be separated from other wastes and placed in distinctive containers which do not leak and which are impervious, puncture resistant, and tear resistant and which contain obvious markings (for example, red or orange plastic bags or the biohazard label). Bags and containers holding regulated infectious waste must be tied, closed, or sealed securely to prevent leakage. Prior to shipment offsite, all containers must comply with all appropriate federal and state department of transportation packaging and labeling requirements.

2. At the point of origin, sharps must be:
   a. Separated from other regulated infectious waste, disinfected onsite, rendered nonsharp onsite, and then disposed; or
   b. Placed in containers that are:
      (1) Closable;
      (2) Puncture resistant;
      (3) Leak-proof on sides and bottom; and
      (4) Labeled or color-coded in accordance with 29 CFR 1910.1030
   and handled as required by subsection 5.

3. The handling and storage of regulated infectious waste, before the treatment of subsection 7, must be conducted in a manner which minimizes exposure to employees of the waste generator, the waste transporter, and the public.

4. Areas used for the storage of regulated infectious waste must be enclosed and meet the following requirements:
   a. Storage rooms, buildings, or areas must be of rodentproof construction which is readily cleanable with proper drainage.
b. Storage rooms or buildings, if not refrigerated, must be adequately vented and all openings must be screened.

5. Containers and enclosed storage areas used for regulated infectious waste must be maintained according to the following requirements:
   a. All containers and enclosed areas for storage of solid waste must be maintained in good repair and in a manner as necessary to prevent litter, nuisances, odors, insect breeding, and rodents.
   b. Containers that are broken or otherwise fail to meet requirements of this section must be replaced with complying containers.

6. Recycled containers or devices such as carts used for the handling of wastes must be disinfected after each use. The disinfectant must be either an United States environmental protection agency registered disinfectant that is also tuberculocidal, for a contact time as specified by the manufacturer, an unexpired dated stabilized bleach product that is an United States environmental protection agency registered disinfectant that is also tuberculocidal, for a contact time and as specified by the manufacturer or materials necessary to prepare a minimum ten percent sodium hypochlorite solution prepared immediately prior to use with a minimum thirty minutes of contact time with the container.

7. All regulated infectious waste must be incinerated or disinfected and sharps that are not incinerated must be rendered nonsharp before disposal. Incineration and disinfection equipment and facilities shall meet the requirements of article 33.1-15 and this article.

8. Blood and blood products can be discarded without incineration or disinfection through municipal sewage disposal systems that meet the requirements of article 33.1-16.

9. The disposal of nonviable human fetuses shall meet the requirements of section 33.1-03-02-05.

10. An infectious waste which is not regulated by this chapter may be disposed at a permitted municipal waste landfill.

11. Household waste containing regulated infectious waste in amounts normally found in household waste may be disposed of at a permitted municipal waste landfill.

12. Every person who treats or transports regulated infectious waste or operates a regulated infectious waste management unit or facility shall have a valid permit issued by the department.

13. Vehicles used for the commercial collection and transportation of regulated infectious waste must be fully leakproof and fully enclosed or covered to prevent scattering of material.
   a. Regulated infectious waste may not be subject to mechanical stress or compaction during loading, unloading, and transit.
   b. Regulated infectious waste must not be allowed to become putrescent during transportation.
   c. Any spilled material must be immediately returned to the transport vehicle or container and, if necessary, the area must be cleaned and decontaminated.

14. The owner or operator of a permitted regulated infectious waste treatment facility shall comply with these standards:
a. Regulated infectious waste must be confined to storage containers and areas specifically designed to store waste. Waste handling and storage systems must provide sufficient excess capacity to prevent nuisances, environmental impacts, or health hazards in the event of mechanical failure or unusual waste flows.

b. All residues must be controlled and stored in a manner that does not constitute a fire or safety hazard or a sanitary nuisance.

c. The regulated infectious waste management facility may not cause a violation of the ambient air quality standard or odor rules, article 33.1-15, at the facility boundary.

d. All incinerators used for regulated infectious waste must be constructed and operated in compliance with article 33.1-15.

e. The owner or operator shall demonstrate that the treatment unit renders infectious waste noninfectious. The operator shall follow a written operational manual or documented quality assurance procedures for operating the treatment unit. The treatment unit must be tested at a frequency specified by the manufacturer's instructions or after every forty hours of operation to verify disinfection. Acceptable test methods may be physical, chemical, or microbiological in nature, as appropriate for the treatment method.

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### 33.1-20-12-03. Recordkeeping requirements.

1. Regulated infectious waste generators shall keep records of the amount of regulated infectious waste sent offsite for treatment. Records may consist of any of the following: copies of regulated infectious waste manifests, invoices, records received from the regulated infectious waste treatment facility, logs, or other written documentation of the amount of regulated infectious waste sent offsite for treatment. These records shall be kept for at least three years after they were created.

2. Permitted regulated infectious waste treatment facilities receiving regulated infectious waste from others for treatment shall maintain a log indicating the approximate quantities of regulated infectious waste received; the date of receipt; and the name and address of the generator from whom the waste was received, operating parameters, and results of any tests run to verify disinfection. The logs shall be maintained for a period of three years.

3. Permitted regulated infectious waste treatment facilities shall prepare and submit a copy of an annual report to the department by March first of each year. The annual report must cover facility activities during the previous calendar year and must include the following information:

   a. Name and address of the facility;
   
   b. Calendar period covered by the report;
   
   c. Annual quantity for each category of solid waste in tons or volume;
   
   d. Identification of occurrence and conditions that prevented compliance with the permit and this article; and
   
   e. Other items identified in the facility plans and permit.

4. The owner or operator of a regulated infectious waste treatment facility shall prepare and implement a plan of operation approved by the department as part of the permit. The plan
must describe the facility's operation to operating personnel, and the facility must be operated in accordance with the plan. The plan of operation must be available for inspection at the request of the department. Each plan of operation must include, where applicable:

a. A description of waste acceptance procedures, including categories of solid waste to be accepted and waste rejection;

b. A description of waste handling procedures;

c. A description of contingency actions for the following:
   (1) Fire or explosion;
   (2) Leaks;
   (3) Other releases (for example, spills); and
   (4) Any other issues pertinent to the facility.

d. Safety procedures; and

e. A description of facility inspection activities required by subsection 5 including frequency of inspections.

5. The owner or operator shall inspect the facility to ensure compliance with this article, a permit, and approved plans. The owner or operator shall keep an inspection log including information, such as the date of inspection, the name of the inspector, a notation of observations made, and the date and nature of any repairs or corrective action taken.

History: Effective July 1, 2020.
General Authority: NDCC 23.1-08-03; S.L. 2017, ch. 199, § 1
Law Implemented: NDCC 23.1-08-03; S.L. 2017, ch. 199, § 23