

**R315. Environmental Quality, Waste Management and Radiation Control, Waste Management.**

**R315-316. Infectious Waste Requirements.**

**R315-316-1. Applicability.**

- (1) The standards of Rule R315-316 apply to:
  - (a) any health facility that generates more than 200 pounds, per month, of infectious waste;
  - (b) any transporter that collects and transports more than 200 pounds of infectious waste in any one load; and
  - (c) a facility storing more than 200 pounds of infectious waste, or a facility treating or disposing of infectious waste.
- (2) The standards of Rule R315-316 do not apply to:
  - (a) any health facility that generates 200 pounds, or less, of infectious waste per month;
  - (b) any transporter that:
    - (i) collects and transports 200 pounds or less of infectious waste from all generators in any one load; or
    - (ii) collects infectious waste only from facilities that generate 200 pounds or less of infectious waste per week; and
  - (c) infectious waste generated by a household.

**R315-316-2. General Operational Requirements.**

- (1) Every owner and operator of a health facility or a transporter of infectious waste, regulated by Rule R315-316, that generates, transports, stores, treats, or disposes of infectious waste must prepare and maintain on file a management plan for the waste that identifies the:
  - (a) type and estimated quantity of waste generated or handled;
  - (b) segregation, packaging, and labeling procedures;
  - (c) collection, storage, and transportation procedures;
  - (d) treatment or disposal methods that will be used; and
  - (e) the person responsible for the management of the infectious waste.
- (2) Infectious waste consisting of recognizable human anatomical remains including human fetal remains shall be disposed by incineration or interment in a location appropriate for human remains.
- (3) For the purposes of Rule R315-316 "sharps" means any object that may be contaminated with a pathogen and that is capable of cutting or penetrating skin or a packaging material.

**R315-316-3. Storage and Containment Requirements.**

- (1) Infectious waste shall be contained in a manner and location which affords protection from animal intrusion, does not provide a breeding place or a food source for insects or rodents, and minimizes exposure to the public.
- (2) Unless all waste is considered infectious and labeled as such, infectious waste shall be segregated by separate containment from other waste during storage.
- (3) Except for sharps, infectious waste shall be contained in plastic bags or inside rigid containers. The bags shall be securely tied and the containers shall be securely sealed to prevent leakage or expulsion of solid or liquid wastes during storage or handling.
- (4) Sharps shall be contained for storage, transportation, treatment, and disposal in leak-proof, rigid, puncture-resistant containers which are taped closed or tightly lidded to preclude loss of contents.
- (5) All infectious waste containers should be red or orange and shall be clearly identified with the international biohazard sign and one of the following labels: "INFECTIOUS WASTE", "BIOMEDICAL WASTE", or "BIOHAZARD".
- (6) If other waste is placed in the same container as infectious waste, then the generator must package, label, and mark the container and its entire contents as infectious waste.
- (7) A rigid infectious waste container may be reused for infectious or non-infectious waste if it is thoroughly washed and decontaminated each time it is emptied or if the surfaces of the container have been completely protected from contamination by disposable, unpunctured, or undamaged liners, bags, or other devices that are removed with the infectious waste, the surface of the liner has not been damaged or punctured.
- (8) Storage and containment areas shall: protect infectious waste from the elements; be ventilated to the outside atmosphere; be accessible only to authorized persons; and be marked with prominent warning signs on, or adjacent to, the exterior doors or gates. The warning signs shall contain the international biohazard sign and shall state: "CAUTION -- INFECTIOUS WASTE STORAGE AREA -- UNAUTHORIZED PERSONS KEEP OUT" and must be easily read during daylight from a distance of 25 feet.
- (9) If infectious waste is stored longer than seven days, the infectious waste shall be stored at or below a temperature of 40 degrees Fahrenheit (5 degrees Celsius).
- (10) Under no conditions may infectious waste be stored for longer than 60 days.
- (11) Compactors, grinders, or similar devices shall not be used to reduce the volume of infectious waste unless the device is contained sufficiently to prevent contamination of the surrounding area.

**R315-316-4. Infectious Waste Transportation Requirements.**

- (1) Infectious waste shall not be transported in the same vehicle with other waste unless the infectious waste is contained in a separate, fully enclosed leak-proof container within the vehicle or unless all of the waste is to be treated as infectious waste in accordance with Rule R315-316.
- (2) Persons manually loading or unloading containers of infectious waste onto or from transport vehicles shall:

- (a) be trained in the proper use of protective equipment;
- (b) have available and easily accessible at all times puncture resistant gloves and shoes, shatterproof glasses, and coveralls; and
- (c) shall have face shields and respirators available.
- (d) Protective gear that becomes soiled with infectious waste shall be decontaminated or disposed as infectious waste.
- (3) Surfaces of transport vehicles that have contacted spilled or leaked infectious waste shall be decontaminated by procedures approved by the Director.
- (4) Vehicles transporting infectious waste shall meet all warning requirements of the Department of Transportation related to infectious, biohazardous or biomedical waste.
- (5) Each truck, trailer, or semitrailer, or container used for transporting infectious waste shall be designed and constructed, and its contents limited, so that under conditions normally incident to transportation, there shall be no releases of infectious waste to the environment.
- (6) Any truck, trailer, semitrailer, or container used for transporting infectious waste shall be free from leaks, and all discharge openings shall be securely closed during transportation.
- (7) No person shall transport infectious waste into the state for treatment, storage, or disposal unless the waste is packaged, contained, labeled and transported in the manner required by this section.
- (8) All transporter vehicles shall carry a spill containment and cleanup kit and the transport workers shall be trained in spill containment and cleanup procedures.

**R315-316-5. Infectious Waste Treatment and Disposal Requirements.**

- (1) Infectious waste shall be treated or disposed as soon as possible and shall be treated or disposed at a facility with a permit or other form of approval allowing the facility to treat or dispose infectious waste.
- (2)(a) Any material that has been made noninfectious through an approved treatment method may be handled as noninfectious solid waste if it is not otherwise a hazardous waste or a radioactive waste excluded from disposal in a solid waste facility by Rules R315-301 through R315-322.
- (b) Except for incineration and steam sterilization, no treatment method may be used to make materials noninfectious without receiving earlier approval from the director.
- (3) Infectious waste may be incinerated in an incinerator if the incinerator is permitted or approved under Rules R315-301 through R315-322.
- (4) Infectious waste may be sterilized by heating in a steam sterilizer to make the waste noninfectious.
- (a) The operator shall have available, and shall certify in writing that the operator understands, written operating procedures for each steam sterilizer, including time, temperature, pressure, type of waste, type of container, closure of container, pattern of loading, water content, and maximum load quantity.
- (b) Infectious waste shall be subjected to sufficient temperature, pressure and time to inactivate *Bacillus stearothermophilus* spores in the center of the waste load at a 6 Log<sub>10</sub> reduction or greater.
- (c) Unless a steam sterilizer is equipped to continuously monitor and record temperature and pressure during the entire length of each sterilization cycle, each package of infectious waste to be sterilized shall have a temperature sensitive tape or equivalent test material, such as chemical indicators, attached that will indicate if the sterilization temperature and pressure have been reached. Waste may not be considered sterilized if the tape or equivalent indicator fails to indicate that a temperature of at least 250 degrees Fahrenheit, 121 degrees Celsius, was reached and a pressure of at least 15 psi was maintained during the process.
- (d) Each sterilization unit shall be evaluated for effectiveness with spores of *B. stearothermophilus* at least once each 40 hours of operation or each week, whichever is less frequent.
- (e) A written log for each load shall be maintained for each sterilization unit that shall contain at a minimum:
  - (i) the time of day and the date of each load and the operator's name;
  - (ii) the amount and type of infectious waste placed in the sterilizer; and
  - (iii) the temperature, pressure, and duration of treatment.
- (5)(a) Alternative treatment methods may be approved on a site-specific basis if the director finds the proposed alternative treatment method makes the material noninfectious.
- (b) The determination shall be based on the results of laboratory tests, submitted by the person proposing the use of the treatment method, meeting the following requirements:
  - (i) the laboratory tests shall be conducted:
    - (A) by qualified laboratory personnel;
    - (B) using recognized microbial techniques;
    - (C) on samples that have been inoculated with the test organisms, then subjected to the proposed treatment method and processed in an identical way to the treatment process being proposed for approval; and
  - (ii) the results of the tests shall document that the proposed treatment method inactivates:
    - (A) vegetative bacteria - *Staphylococcus aureus*, ATCC 6538, or *Pseudomonas aeruginosa*, ATCC 15442, at a 6 Log<sub>10</sub> reduction or greater, a 99.9999% reduction or greater of the organism population;
    - (B) fungi - *Candida albicans*, ATCC 18804, *Penicillium chrysogenum*, ATCC 24791, or *Aspergillus niger* at a 6 Log<sub>10</sub> reduction or greater;
    - (C) viruses - Polio 2, Polio 3, or MS-2 Bacteriophage, ATCC15597-B1, at a 6 Log<sub>10</sub> reduction or greater;

- (D) parasites - *Cryptosporidium* spp. oocysts or *Giardia* spp. cysts at a 6 Log<sub>10</sub> reduction or greater;
- (E) mycobacteria - *Mycobacterium terrae* or *Mycobacterium phlei* at a 6 Log<sub>10</sub> reduction or greater; and
- (F) Bacterial spores - *Bacillus stearothermophilus* spores, ATCC 7953, or *Bacillus subtilis* spores, ATCC 19659, at a 4 Log<sub>10</sub> reduction or greater, a 99.99% reduction or greater of the organism population.

(iii) The director shall review the submitted materials and reply in writing within 30 days of the receipt of the treatment studies.

(6) Infectious waste may be discharged to a sewage treatment system that provides secondary treatment of waste but only if the waste is liquid or semi-solid and if approved by the operator of the sewage treatment system.

(7) Infectious waste may be disposed in a permitted Class I, II, or V Landfill. Upon entering the landfill, the transporter of infectious waste shall notify the landfill operator that the load contains infectious waste. The landfill operator shall abide by the following procedures in the disposition and covering of infectious waste:

- (a) place the infectious waste containers in the working face with sufficient care to avoid breaking them;
- (b) completely cover the infectious waste immediately with a minimum of 12 inches of earth or waste material containing no infectious waste; and
- (c) not compact the infectious waste until completely covered with 12 inches of earth or waste material containing no infectious waste.

**KEY: solid waste management, waste disposal**

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