

**7035.9120 REQUIRED PRACTICES FOR FACILITY OWNERS AND OPERATORS AND COMMERCIAL TRANSPORTERS.**

Subpart 1. **Packaging and labeling requirements.** No commercial transporter shall receive any infectious waste that is not packaged according to items A to G. No facility owner or operator shall receive for offsite decontamination, storage, or disposal, any infectious waste that is not packaged according to items A to G.

A. Sharps must be in rigid, puncture-resistant containers that have lids or caps that are designed to preclude loss or leakage of the contents.

B. Sharps must remain packaged throughout collection, storage, decontamination, and any handling processes that precede disposal, unless the sharps have been treated by a process that renders them incapable of inducing subdermal inoculation. This item does not prevent the use of sharps containers that are designed to be reusable if parts 7035.9100 to 7035.9150 are complied with.

C. Sharps containers, or infectious waste containers that include sharps containers, that will be transported to an offsite facility must be labeled, on the outer container, with "Sharps" in letters at least one inch high with a stroke width of one-eighth inch and with either the international biohazard symbol, at least three inches by three inches, or the words "Infectious Waste" in letters at least one inch in height with a stroke width of one-eighth inch.

D. Infectious waste, except for sharps, must be contained in plastic bags that are impervious to moisture, and of sufficient strength to preclude ripping, tearing, or bursting under normal conditions of use and handling. Each plastic bag must be constructed of material of sufficient single thickness and strength to pass the 165-gram dropped dart impact resistance test as prescribed by ASTM Standard D 1709-75, which is incorporated by reference, and is not subject to frequent change. The standard appears in the Annual Book of ASTM Standards, issued by the American Society of Testing and Materials (Philadelphia, 1975), and is available at the Minnesota State Law Library or through the statewide interlibrary loan system. The bags must be secured to prevent leakage of waste during handling, decontamination, storage, transport, or disposal.

E. Plastic bags of infectious waste that will be shipped offsite must be packaged for storage or handling by placement in corrugated fiberboard boxes or equivalent rigid containers such as reusable pails, cartons, or portable bins. Containers must have tight-fitting covers and be securely sealed.

F. Boxes and rigid containers of infectious waste must be conspicuously labeled with the words "Infectious Waste" in letters at least one inch high, with a stroke width of one-eighth inch, or the international biohazard symbol, at least three inches by three inches.

G. Containers that have been in direct contact with infectious waste must be disinfected before further use. The disinfection methods in subpart 6, item C, must be used.

Subp. 2. **Storage requirements.** Offsite facility owners and operators must store waste according to items A to E.

A. Infectious or pathological waste must be segregated from other wastes in a storage area designed to prevent the entry of vermin. Storage areas for infectious or pathological waste must be secured to deny access by unauthorized persons and must be prominently marked with the international biohazard symbol and with the words "Infectious Waste" on or adjacent to the exterior of entry doors and access gates.

B. Interior surfaces of storage areas must be constructed of materials that are easily cleaned.

C. Offsite storage areas must be designed to contain spills.

D. Infectious or pathological waste must not be allowed to become putrescent during storage or at any time.

E. Storage facility owners and operators must comply with the spill response requirements in subpart 6.

Subp. 3. **Decontamination requirements.** Facility owners and operators may use incineration, autoclaving, or other decontamination methods that have been approved by the commissioner for the decontamination of infectious waste. Facility owners and operators shall use handling and storage practices that comply with subparts 1 and 2, and decontamination methods that comply with items A to C and subpart 6.

A. Incinerators must be operated in compliance with chapters 7001, 7005, 7007, 7009, 7011, 7017, 7019, 7021, 7023, 7025, and 7028.

B. Offsite decontamination of infectious waste by autoclaving must be achieved in the following manner:

(1) Infectious waste must be autoclaved at 250 degrees Fahrenheit at 15 pounds per square inch of gauge pressure for one hour or at least equivalent settings.

(2) Loading of infectious waste must not exceed the design capacity of the autoclave.

(3) An operating log for each load of infectious waste decontaminated must be kept onsite for three years and must contain the date, time, temperature, pressure, and operator name.

C. Other methods for decontaminating infectious waste offsite, such as grinding, microwaving, or disinfecting technologies must receive commissioner approval. To obtain approval, the facility owner or operator proposing the decontamination method must submit

to the commissioner information demonstrating that the proposed method decontaminates the waste. The commissioner may request additional information to determine whether the method is effective. In making this decision, the commissioner shall consult with the Centers for Disease Control and the Minnesota Department of Health.

**Subp. 4. Commercial transporter requirements.**

A. A commercial transporter must possess a valid transporter registration as described in part 7035.9140, subpart 3.

B. The commercial transporter's management plan required in part 7035.9130 must be kept at the address identified as the commercial transporter's principal place of business.

C. A commercial transporter who transports infectious waste offsite and facilities that receive the waste must be in compliance with subitems (1) to (9).

(1) A commercial transporter must not accept infectious waste from a generator who does not have a management plan acknowledgment card issued by the Minnesota Department of Health or a storage facility or treatment facility that does not have a management plan as described in part 7035.9130.

(2) Infectious waste must be transported in a fully enclosed vehicle compartment.

(3) Infectious waste must be delivered for decontamination, storage, or disposal only to a facility owner or operator that has an approved management plan onsite or to a facility owner or operator that is exempt from the requirements for a management plan.

(4) A commercial transporter must not deliver infectious waste to a facility owner or operator prohibited from accepting the waste.

(5) Surface areas of equipment used to transport infectious waste must be smooth and easily cleaned.

(6) Infectious waste must not be compacted during transport. Sharps containers, or infectious waste containers that include sharps containers, must never be compacted, whether or not the sharps have been decontaminated. Containers must be secured to prevent movement during transport.

(7) Infectious waste must not be allowed to become putrescent during transportation.

(8) A person must not transport or receive for transport infectious waste that is not packaged and labeled according to subpart 1.

(9) Commercial transporters must comply with subpart 6.

D. Commercial transporter vehicles must bear labels or placards that comply with subitems (1) and (2).

(1) Vehicles transporting infectious waste must be identified on each side of the vehicle, and on the access doors to any area holding infectious waste, with the name of the transporter and the words "Infectious Waste" in letters six inches high with a stroke width of three-fourths inch or with the international biohazard symbol, eight inches by eight inches.

(2) The vehicle identification number that is issued by the commissioner under part 7035.9140, subpart 3, must be displayed on the single unit vehicle or trailer to which it is assigned in letters and numbers at least four inches in height with a stroke width of one-half inch.

**Subp. 5. Generator transport requirements.**

A. Generators who transport their own infectious waste to an offsite decontamination, storage, or disposal facility must comply with the packaging, labeling, and storage requirements of subparts 1 and 2.

B. Generators who provide not-for-compensation or at cost infectious waste collection and transport services for other generators or groups of generators that provide not-for-compensation infectious waste collection and transport service for the group must comply with the packaging, labeling, and storage requirements of subparts 1 and 2 and the commercial transporter requirements of subpart 4, item C.

C. Generator transport vehicles that exceed 7,000 pounds gross vehicle weight must be identified on each side of the vehicle, and on the access doors to any area holding infectious waste, with the name of the transporter and the words "Infectious Waste" in letters six inches high with a stroke width of three-fourths inch or with the international biohazard symbol, eight inches by eight inches. Magnetic placards that meet these specifications are acceptable.

D. Generators who transport infectious waste in vehicles that exceed 7,000 pounds gross vehicle weight must comply with subpart 8, items B and C, in addition to providing the name and title of the individual responsible for the implementation of infectious waste activities that are consistent with parts 7035.9100 to 7035.9150.

**Subp. 6. Spill response plan.** Spill response plans must comply with items A to C.

A. A spill cleanup kit must be available for use in areas used for the storage, decontamination, or disposal of infectious waste and also on each transport vehicle. The cleanup kit must include at least:

(1) absorbent material for spilled liquids;

(2) one gallon of hospital grade disinfectant or disinfectant made of a formula listed in item C;

(3) packaging and labeling, as required in subpart 1;

(4) scoop shovel, push brooms, and plastic buckets; and

(5) disposable coveralls, latex and neoprene gloves, surgical type face mask, and goggles.

B. Response to a spill must include the following minimum procedures:

(1) access to the spill area by unauthorized personnel must be prevented;

(2) broken containers and spillage must be packaged and labeled as required in subpart 1;

(3) absorbent material must be applied to surface areas that have been contaminated with infectious waste; and

(4) reusable items must be cleaned and disinfected using the procedures in item C.

C. Procedures for disinfecting contaminated surfaces include, but are not limited to, agitation to remove visible soil and application of one of the following chemical sanitizers for the contact time required by the manufacturer's label:

(1) hypochlorite solution (500 ppm available chlorine);

(2) phenolic solution (500 ppm active ingredient);

(3) iodoform solution (100 ppm active ingredient); or

(4) other chemical sanitizer solutions of equivalent disinfectant strength.

Subp. 7. **Financial assurance.** As a condition of management plan approval, an offsite storage facility owner or operator shall provide to the agency evidence of financial assurance according to item A, B, or C.

A. An offsite storage facility owner or operator may satisfy the requirements of this subpart by depositing acceptable securities with the commissioner of management and budget in accordance with subitems (1) to (9). The value of the securities to be deposited shall at least equal the estimated costs of final waste disposal that is approved in the management plan.

(1) Acceptable securities, for the purposes of this item, are:

(a) United States government bonds;

(b) bonds or securities that are issued by the state of Minnesota and that are secured by the full faith and credit of this state; and

(c) certificates of deposit issued by a bank that has deposits insured by the Federal Deposit Insurance Corporation.

(2) An offsite storage facility owner or operator must send a copy of the commissioner of management and budget's receipt to the commissioner within ten days after the deposit is made.

(3) Securities must be assigned to the state of Minnesota. The assignment of securities must be signed by an officer, partner, or owner of the offsite storage facility. The assignment must state: "Assigned to the state of Minnesota for the purpose of providing financial assurance required by Minnesota Rules, part 7035.9120, under the Infectious Waste Control Act."

(4) All securities shall be deposited with the commissioner of management and budget. The commissioner and the commissioner of management and budget shall be authorized to sell and collect, if stored wastes are allowed to putresce, as much of the deposited securities as is needed to pay for final waste disposal. The commissioner's order to sell securities must be approved by the agency.

(5) Interest accruing on any securities deposited under this item shall be collected and transmitted to the depositor, provided that the depositor has not allowed stored wastes to putresce.

(6) All deposits shall remain in the custody of the commissioner of management and budget until three months after the facility operator stops accepting infectious waste.

(7) Any securities deposited with the commissioner of management and budget may be exchanged or replaced by the depositor with other acceptable securities so long as the market value of the securities equals the amount of deposit required.

(8) No securities on deposit with the commissioner of management and budget may be released without a written order from the commissioner. The commissioner shall refuse to release securities on deposit if the offsite storage facility owner or operator fails to dispose properly of any infectious wastes remaining after the facility permanently stops accepting waste.

(9) The offsite storage facility owner or operator may request that deposited securities be returned. Such requests must be submitted in writing by certified mail. The commissioner shall direct the commissioner of management and budget to return the securities to the depositor if:

(a) the offsite storage facility owner or operator has stopped taking waste and no wastes remain on the site;

(b) the offsite storage facility owner or operator has substituted other securities of equal or greater value for the securities that are requested; or

(c) another person has received approval to operate the offsite storage facility.

The commissioner shall refuse to order return of the securities if the conditions for return have not been met. The commissioner shall have 60 days in which to determine whether to order return of the securities. If the commissioner does not order return of the securities, the commissioner shall, within 30 days of the decision, provide the offsite storage facility owner or operator with written reasons for not ordering return of the securities.

B. An offsite storage facility owner or operator may satisfy the requirements of this subpart by sending to the commissioner a surety bond that conforms to the requirements of subitems (1) to (8). The surety company issuing the bond must be among those listed as acceptable sureties on federal bonds in Circular 570, issued by the United States Department of the Treasury, as published annually in the Federal Register on July 1.

(1) The penal sum of the bond shall at least equal the estimated costs of final waste disposal that is approved in the management plan.

(2) The wording of the surety bond must be identical to the wording specified in part 7035.9150, subpart 1.

(3) The bond must guarantee that the offsite storage facility owner or operator will:

(a) properly dispose of all stored wastes after the offsite storage facility has stopped accepting wastes;

(b) provide alternate financial assurance as specified in this subpart; and

(c) obtain the commissioner's written approval of the assurance provided within 90 days after receipt by the commissioner of a notice of cancellation of the bond from the surety.

(4) Under the terms of the bond, the surety must become liable on the bond obligation when the offsite storage facility owner or operator fails to perform as guaranteed by the bond. Following a determination by the commissioner that the offsite storage facility owner or operator has failed to properly dispose of all stored wastes after the offsite storage facility has stopped accepting wastes or has not provided alternate financial assurance as specified in this subpart and obtained the commissioner's written approval of the assurance provided, within 90 days after receipt by the commissioner of a notice of cancellation of the bond from the surety, under the terms of the bond the surety shall pay the amount of the penal sum to the agency.

(5) Whenever the estimated costs of final waste disposal become greater than the penal sum, the offsite storage facility owner or operator, within 60 days after the increase, shall either increase the penal sum to equal the new cost estimate, or obtain other financial assurance as specified in this subpart. Whenever the estimated costs of final waste disposal decrease, the penal sum shall be reduced to equal the new cost estimate following written approval by the commissioner.

(6) Under the terms of the bond, the surety may cancel the bond by sending notice of cancellation by certified mail to the offsite storage facility owner or operator and to the commissioner. However, cancellation is not effective until 120 days after the commissioner has received the notice of cancellation, as evidenced by the return receipt.

(7) The offsite storage facility owner or operator may cancel the bond if the commissioner has given prior written approval. The commissioner shall approve cancellation if:

(a) the offsite storage facility owner or operator properly disposes of all stored wastes after the offsite storage facility has stopped accepting wastes; or

(b) the offsite storage facility owner or operator provides alternate financial assurance as specified in this subpart.

(8) The surety shall not be liable for deficiencies in the performance of final waste disposal after the commissioner releases the offsite storage facility owner or operator from the requirements of this subpart.

C. An offsite storage facility owner or operator may satisfy the requirements of this subpart by sending to the commissioner a letter of credit that conforms to the requirements of subitems (1) to (8). The issuing institution must be an entity which has the authority to issue letters of credit. Its letter-of-credit operations must be regulated and examined by a federal or Minnesota state agency.

(1) The letter of credit must be issued in an amount that is at least equal to the estimated costs of final waste disposal that is approved in the management plan.

(2) The wording of the letter of credit must be identical to the wording specified in part 7035.9150, subpart 2.

(3) The letter of credit must be accompanied by a letter from the offsite storage facility owner or operator referring to the letter of credit by number, issuing institution, and date, and providing the following information:

(a) the identification number;

(b) the name and address of the facility; and

(c) the amount of funds assured by the letter of credit for final disposal of wastes at the facility.

(4) The letter of credit must be irrevocable and issued for a period of at least one year. The letter of credit must provide that the expiration date will be extended automatically for a period of at least one year unless, at least 120 days before the current expiration date, the issuing institution notifies both the offsite storage facility owner or operator and the commissioner by certified mail of a decision not to extend the expiration date. Under the terms of the letter of credit, the 120 days must begin on the date when the commissioner has received the notice, as evidenced by the return receipt.

(5) Whenever the estimated costs of final waste disposal become greater than the amount of the letter of credit, the offsite storage facility owner or operator, within 60 days after the increase, shall either increase the amount of the letter of credit to equal the new cost estimate, or obtain other financial assurance as specified in this subpart. Whenever the estimated costs of final waste disposal decrease, the amount of the letter of credit shall be reduced to equal the new cost estimate following written approval by the commissioner.

(6) Following a determination by the commissioner that the offsite storage facility owner or operator has failed to properly dispose of all stored wastes after the offsite storage facility has stopped accepting wastes, the commissioner shall draw on the letter of credit.

(7) The commissioner shall draw on the letter of credit if the offsite storage facility owner or operator does not establish alternate financial assurance as specified in this subpart and obtain written approval of the alternate financial assurance from the commissioner within 90 days after the commissioner receives notice from the issuing institution that it has decided not to extend the letter of credit beyond the current expiration date. The commissioner may delay the drawing if the issuing institution grants an extension of the term of the credit. During the last 30 days of any extension the commissioner shall draw on the letter of credit if the offsite storage facility owner or operator has failed to provide alternate financial assurance as specified in this subpart and obtain written approval of the alternate financial assurance from the commissioner.

(8) The commissioner shall return the letter of credit to the issuing institution for termination if:

(a) the offsite storage facility owner or operator properly disposes of all stored wastes after the offsite storage facility has stopped accepting wastes; or

(b) the offsite storage facility owner or operator provides alternate financial assurance as specified in this subpart.

Subp. 8. **Reporting and record keeping.** Facility owners and operators and commercial transporters must maintain records for a minimum of three years. If

the three-year period expires during an unresolved enforcement action, the period is automatically extended until resolution of the pending enforcement action. Facility owners and operators and commercial transporters shall report the following information annually to the commissioner on the anniversary date of management plan approval:

A. the title and name of the individual responsible for implementation of the management plan as specified in part 7035.9130, item A;

B. the incidences in which infectious waste is released to the environment; and

C. the amounts of infectious waste managed; storage and decontamination facility owners and operators must submit the following information for the management of infectious waste that is generated both in and outside of Minnesota; commercial transporters must submit the following information only for the transport of infectious waste that is generated in Minnesota:

(1) the weight or number and size of containers of infectious waste transported, decontaminated, stored, and disposed of, giving the decontamination and disposal methods used; and

(2) the weight or number and size of containers of sharps transported, decontaminated, stored, and disposed of, giving the decontamination and disposal method used.

**Statutory Authority:** *MS s 116.75*

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