1 Pollution Control Agency

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3 Adopted Permanent Rules Relating to Infectious Waste Management

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- 5 Rules as Adopted
- 6 7035.9100 SCOPE.
- 7 Parts 7035.9100 to 7035.9150 apply to owners and operators
- 8 of facilities, to commercial transporters, and to all infectious
- 9 waste without regard to quantity. They do not apply to waste
- 10 generated by households, farms, agricultural businesses, or,
- 11 except where specified, generators.
- 12 7035.9110 DEFINITIONS.
- 13 Subpart 1. Scope. As used in parts 7035.9100 to
- 14 7035.9150, the following terms have the meanings given them.
- Subp. 2. Agency. "Agency" means the Minnesota Pollution
- 16 Control Agency, its agent, or representative.
- 17 Subp. 3. Blood. "Blood" means waste human blood and blood
- 18 products in containers, or solid waste saturated and dripping
- 19 human blood or blood products. Human blood products include
- 20 serum, plasma, and other blood components.
- Subp. 4. Commercial transporter. "Commercial transporter"
- 22 means a person who transports infectious or pathological waste
- 23 for compensation.
- Subp. 5. Commissioner. "Commissioner" means the
- 25 commissioner of the Minnesota Pollution Control Agency.
- Subp. 6. Decontamination. "Decontamination" means
- 27 rendering infectious waste safe for routine handling as a solid
- 28 waste.
- 29 Subp. 7. Disinfection. "Disinfection" means the use of
- 30 chemical solutions to substantially reduce the number of
- 31 microorganisms present on surfaces of inanimate objects.
- 32 Subp. 8. Facility. "Facility" means a site where
- 33 infectious waste is stored, disposed, or decontaminated,
- 34 including incineration.
- 35 Subp. 9. Generator. "Generator" means a person whose

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- l activities produce infectious waste. Generator does not include
- 2 a person who produces sharps as a result of administering
- 3 medication to oneself, an ambulance service licensed under
- 4 Minnesota Statutes, section 144.802, an eligible board of
- 5 health, community health board, or public health nursing agency
- 6 as defined in Minnesota Statutes, section 116.78, subdivision
- 7 10, or a program providing school health service under Minnesota
- 8 Statutes, section 123.35, subdivision 17.
- 9 Subp. 10. Infectious waste. "Infectious waste" means
- 10 laboratory waste, blood, regulated body fluids, sharps, and
- 11 research animal waste that have not been decontaminated.
- 12 Subp. 11. Laboratory waste. "Laboratory waste" means
- 13 waste cultures and stocks of agents that are generated from a
- 14 laboratory and are infectious to humans; discarded contaminated
- 15 items used to inoculate, transfer, or otherwise manipulate
- 16 cultures or stocks of agents that are infectious to humans;
- 17 wastes from the production of biological agents that are
- 18 infectious to humans; and discarded live or attenuated vaccines
- 19 that are infectious to humans.
- 20 Subp. 12. Management plan. "Management plan" means a
- 21 written and implemented system, as described in part 7035.9130,
- 22 for the safe handling of infectious or pathological waste
- 23 through collection, disinfection, transport, storage, and
- 24 disposal.
- Subp. 13. Offsite. "Offsite" means a land area and
- 26 appurtenances for the decontamination, storage, or disposal of
- 27 infectious waste that is not on the generator's site.
- Subp. 14. Operator. "Operator" means the person or
- 29 persons responsible for the operation of a facility.
- 30 Subp. 15. Owner or facility owner. "Owner or facility
- 31 owner" means the person or persons who own a facility or part of
- 32 a facility.
- 33 Subp. 16. Pathological waste. "Pathological waste" means
- 34 human tissues and body parts removed accidentally or during
- 35 surgery or autopsy intended for disposal. Pathological waste
- 36 does not include teeth.

- 1 Subp. 17. Person. "Person" means an individual,
- 2 partnership, association, public or private corporation, or
- 3 other legal entity, the United States government, an interstate
- 4 body, the state, and an agency, department, or political
- 5 subdivision of the state.
- 6 Subp. 18. Putrefaction. "Putrefaction" means the
- 7 decomposition of organic matter by microorganisms, producing
- 8 foul-smelling matter.
- 9 Subp. 19. Regulated human body fluids. "Regulated human
- 10 body fluids" means cerebrospinal fluid, synovial fluid, pleural
- 11 fluid, peritoneal fluid, pericardial fluid, and amniotic fluid
- 12 that are in containers or that drip freely from body fluid
- 13 soaked solid waste items.
- 14 Subp. 20. Research animal waste. "Research animal waste"
- 15 means carcasses, body parts, and blood derived from animals
- 16 knowingly and intentionally exposed to agents that are
- 17 infectious to humans for the purpose of research, production of
- 18 biologicals, or testing of pharmaceuticals.
- 19 Subp. 21. Sharps. "Sharps" means:
- 20 A. discarded items that can induce subdermal
- 21 inoculation of infectious agents, including needles, scalpel
- 22 blades, pipettes, and other items derived from human or animal
- 23 patient care, blood banks, laboratories, mortuaries, research
- 24 facilities, and industrial operations; and
- 25 B. discarded glass or rigid plastic vials containing
- 26 infectious agents.
- 27 Subp. 22. Spill. "Spill" means the release of infectious
- 28 waste to the environment.
- 29 Subp. 23. Storage. "Storage" means the offsite holding of
- 30 infectious waste for more than 48 hours, except when such waste
- 31 is accepted on a Friday, provided that any waste so accepted
- 32 must be disposed of not later than the following Monday.
- 33 7035.9120 REQUIRED PRACTICES FOR FACILITY OWNERS AND OPERATORS
- 34 AND COMMERCIAL TRANSPORTERS.
- 35 Subpart 1. Packaging and labeling requirements. No

- 1 commercial transporter shall receive any infectious waste that
- 2 is not packaged according to items A to G. No facility owner or
- 3 operator shall receive for offsite decontamination, storage, or
- 4 disposal, any infectious waste that is not packaged according to
- 5 items A to G.
- 6 A. Sharps must be in rigid, puncture-resistant
- 7 containers that have lids or caps that are designed to preclude
- 8 loss or leakage of the contents.
- 9 B. Sharps must remain packaged throughout collection,
- 10 storage, decontamination, and any handling processes that
- 11 precede disposal, unless the sharps have been treated by a
- 12 process that renders them incapable of inducing subdermal
- 13 inoculation. This item does not prevent the use of sharps
- 14 containers that are designed to be reusable if parts 7035.9100
- 15 to 7035.9150 are complied with.
- 16 C. Sharps containers, or infectious waste containers
- 17 that include sharps containers, that will be transported to an
- 18 offsite facility must be labeled, on the outer container, with
- 19 "Sharps" in letters at least one inch high with a stroke width
- 20 of one-eighth inch and with either the international biohazard
- 21 symbol, at least three inches by three inches, or the words
- 22 "Infectious Waste" in letters at least one inch in height with a
- 23 stroke width of one-eighth inch.
- D. Infectious waste, except for sharps, must be
- 25 contained in plastic bags that are impervious to moisture, and
- 26 of sufficient strength to preclude ripping, tearing, or bursting
- 27 under normal conditions of use and handling. Each plastic bag
- 28 must be constructed of material of sufficient single thickness
- 29 and strength to pass the 165-gram dropped dart impact resistance
- 30 test as prescribed by ASTM Standard D 1709-75, which is
- 31 incorporated by reference, and is not subject to frequent
- 32 change. The standard appears in the Annual Book of ASTM
- 33 Standards, issued by the American Society of Testing and
- 34 Materials (Philadelphia, 1975), and is available at the
- 35 Minnesota State Law Library or through the statewide
- 36 interlibrary loan system. The bags must be secured to prevent

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- 1 leakage of waste during handling, decontamination, storage,
- 2 transport, or disposal.
- 3 E. Plastic bags of infectious waste that will be
- 4 shipped offsite must be packaged for storage or handling by
- 5 placement in corrugated fiberboard boxes or equivalent rigid
- 6 containers such as reusable pails, cartons, or portable bins.
- 7 Containers must have tight-fitting covers and be securely sealed.
- 8 F. Boxes and rigid containers of infectious waste
- 9 must be conspicuously labeled with the words "Infectious Waste"
- 10 in letters at least one inch high, with a stroke width of
- ll one-eighth inch, or the international biohazard symbol, at least
- 12 three inches by three inches.
- G. Containers that have been in direct contact with
- 14 infectious waste must be disinfected before further use. The
- 15 disinfection methods in subpart 6, item C, must be used.
- 16 Subp. 2. Storage requirements. Offsite facility owners
- 17 and operators must store waste according to items A to E.
- 18 A. Infectious or pathological waste must be
- 19 segregated from other wastes in a storage area designed to
- 20 prevent the entry of vermin. Storage areas for infectious or
- 21 pathological waste must be secured to deny access by
- 22 unauthorized persons and must be prominently marked with the
- 23 international biohazard symbol and with the words "Infectious
- 24 Waste" on or adjacent to the exterior of entry doors and access
- 25 gates.
- 26 B. Interior surfaces of storage areas must be
- 27 constructed of materials that are easily cleaned.
- 28 C. Offsite storage areas must be designed to contain
- 29 spills.
- 30 D. Infectious or pathological waste must not be
- 31 allowed to become putrescent during storage or at any time.
- 32 E. Storage facility owners and operators must comply
- 33 with the spill response requirements in subpart 6.
- 34 Subp. 3. Decontamination requirements. Facility owners
- 35 and operators may use incineration, autoclaving, or other
- 36 decontamination methods that have been approved by the

- 13 commissioner for the decontamination of infectious waste.
- 2 Facility owners and operators shall use handling and storage
- 3 practices that comply with subparts 1 and 2, and decontamination
- 4 methods that comply with items A to C and subpart 6.
- 5 A. Incinerators must be operated in compliance with
- 6 chapters 7001 and 7005.
- 7 B. Offsite decontamination of infectious waste by
- 8 autoclaving must be achieved in the following manner:
- 9 (1) Infectious waste must be autoclaved at 250
- 10 degrees Fahrenheit at 15 pounds per square inch of gauge
- 11 pressure for one hour or at least equivalent settings.
- 12 (2) Loading of infectious waste must not exceed
- 13 the design capacity of the autoclave.
- 14 (3) An operating log for each load of infectious
- 15 waste decontaminated must be kept onsite for three years and
- 16 must contain the date, time, temperature, pressure, and operator
- 17 name.
- 18 C. Other methods for decontaminating infectious waste
- 19 offsite, such as grinding, microwaving, or disinfecting
- 20 technologies must receive commissioner approval. To obtain
- 21 approval, the facility owner or operator proposing the
- 22 decontamination method must submit to the commissioner
- 23 information demonstrating that the proposed method
- 24 decontaminates the waste. The commissioner may request
- 25 additional information to determine whether the method is
- 26 effective. In making this decision, the commissioner shall
- 27 consult with the Centers for Disease Control and the Minnesota
- 28 Department of Health.
- 29 Subp. 4. Commercial transporter requirements.
- A. A commercial transporter must possess a valid
- 31 transporter registration as described in part 7035.9140, subpart
- 32 3.
- 33 B. The commercial transporter's management plan
- 34 required in part 7035.9130 must be kept at the address
- 35 identified as the commercial transporter's principal place of
- 36 business.

- 1 C. A commercial transporter who transports infectious
- 2 waste offsite and facilities that receive the waste must be in
- 3 compliance with subitems (1) to (9).
- 4 (1) A commercial transporter must not accept
- 5 infectious waste from a generator who does not have a management
- 6 plan acknowledgment card issued by the Minnesota Department of
- 7 Health or a storage facility or treatment facility that does not
- 8 have a management plan as described in part 7035.9130.
- 9 (2) Infectious waste must be transported in a
- 10 fully enclosed vehicle compartment.
- 11 (3) Infectious waste must be delivered for
- 12 decontamination, storage, or disposal only to a facility owner
- 13 or operator that has an approved management plan onsite or to a
- 14 facility owner or operator that is exempt from the requirements
- 15 for a management plan.
- 16 (4) A commercial transporter must not deliver
- 17 infectious waste to a facility owner or operator prohibited from
- 18 accepting the waste.
- 19 (5) Surface areas of equipment used to transport
- 20 infectious waste must be smooth and easily cleaned.
- 21 (6) Infectious waste must not be compacted during
- 22 transport. Sharps containers, or infectious waste containers
- 23 that include sharps containers, must never be compacted, whether
- 24 or not the sharps have been decontaminated. Containers must be
- 25 secured to prevent movement during transport.
- 26 (7) Infectious waste must not be allowed to
- 27 become putrescent during transportation.
- 28 (8) A person must not transport or receive for
- 29 transport infectious waste that is not packaged and labeled
- 30 according to subpart 1.
- 31 (9) Commercial transporters must comply with
- 32 subpart 6.
- D. Commercial transporter vehicles must bear labels
- 34 or placards that comply with subitems (1) and (2).
- 35 (1) Vehicles transporting infectious waste must
- 36 be identified on each side of the vehicle, and on the access

- 1 doors to any area holding infectious waste, with the name of the
- 2 transporter and the words "Infectious Waste" in letters six
- 3 inches high with a stroke width of three-fourths inch or with
- 4 the international biohazard symbol, eight inches by eight inches.
- 5 (2) The vehicle identification number that is
- 6 issued by the commissioner under part 7035.9140, subpart 3, must
- 7 be displayed on the single unit vehicle or trailer to which it
- 8 is assigned in letters and numbers at least four inches in
- 9 height with a stroke width of one-half inch.
- 10 Subp. 5. Generator transport requirements.
- 11 A. Generators who transport their own infectious
- 12 waste to an offsite decontamination, storage, or disposal
- 13 facility must comply with the packaging, labeling, and storage
- 14 requirements of subparts 1 and 2.
- B. Generators who provide not-for-compensation or at
- 16 cost infectious waste collection and transport services for
- 17 other generators or groups of generators that provide
- 18 not-for-compensation infectious waste collection and transport
- 19 service for the group must comply with the packaging, labeling,
- 20 and storage requirements of subparts 1 and 2 and the commercial
- 21 transporter requirements of subpart 4, item C.
- C. Generator transport vehicles that exceed 7,000
- 23 pounds gross vehicle weight must be identified on each side of
- 24 the vehicle, and on the access doors to any area holding
- 25 infectious waste, with the name of the transporter and the words
- 26 "Infectious Waste" in letters six inches high with a stroke
- 27 width of three-fourths inch or with the international biohazard
- 28 symbol, eight inches by eight inches. Magnetic placards that
- 29 meet these specifications are acceptable.
- 30 D. Generators who transport infectious waste in
- 31 vehicles that exceed 7,000 pounds gross vehicle weight must
- 32 comply with subpart 8, items B and C, in addition to providing
- 33 the name and title of the individual responsible for the
- 34 implementation of infectious waste activities that are
- 35 consistent with parts 7035.9100 to 7035.9150.
- 36 Subp. 6. Spill response plan. Spill response plans must

comply with items A to C. 1 2 A. A spill cleanup kit must be available for use in areas used for the transport storage, decontamination, 3 or offsite-storage disposal of infectious wastes waste and also on each transport vehicle. The cleanup kit must include at least: (1) absorbent material for spilled liquids; 7 8 (2) one gallon of hospital grade disinfectant or disinfectant made of a formula listed in item C; 9 10 (3) packaging and labeling, as required in subpart 1 in-quantities-sufficient-to-accommodate-the-quantity 11 of-waste-present; and 12 (4) scoop shovel, push brooms, and plastic 13 14 buckets; and (5) disposable coveralls, latex and neoprene 15 16 gloves, surgical type face mask, and goggles. Response to a spill must include the following 17 В. minimum procedures: 18 (1) access to the spill area by unauthorized 19 personnel must be prevented; 20 (2) broken containers and spillage must be 21 22 packaged and labeled as required in subpart 1; 23 (3) absorbent material must be applied to surface areas that have been contaminated with infectious waste; and 24 (4) reusable items must be cleaned and 25 26 disinfected using the procedures in item C. C. Procedures for disinfecting contaminated surfaces 27 include, but are not limited to, agitation to remove visible 28 soil and application of one of the following chemical sanitizers 29 for the contact time required by the manufacturer's label: 30 (1) hypochlorite solution (500 ppm available 31 32 chlorine); (2) phenolic solution (500 ppm active 33 34 ingredient); 35 (3) iodoform solution (100 ppm active 36 ingredient); or

- 1 (4) other chemical sanitizer solutions of
- 2 equivalent disinfectant strength.
- 3 Subp. 7. Financial assurance. As a condition of
- 4 management plan approval, an offsite storage facility owner or
- 5 operator shall provide to the agency evidence of financial
- 6 assurance according to items A, B, or C.
- 7 A. An offsite storage facility owner or operator may
- 8 satisfy the requirements of this subpart by depositing
- 9 acceptable securities with the state treasurer in accordance
- 10 with subitems (1) to (9). The value of the securities to be
- 11 deposited shall at least equal the estimated costs of final
- 12 waste disposal that is approved in the management plan.
- 13 (1) Acceptable securities, for the purposes of
- 14 this item, are:
- 15 (a) United States government bonds;
- 16 (b) bonds or securities that are issued by
- 17 the state of Minnesota and that are secured by the full faith
- 18 and credit of this state; and
- 19 (c) certificates of deposit issued by a bank
- 20 that has deposits insured by the Federal Deposit Insurance
- 21 Corporation.
- 22 (2) An offsite storage facility owner or operator
- 23 must send a copy of the state treasurer's receipt to the
- 24 commissioner within ten days after the deposit is made.
- 25 (3) Securities must be assigned to the state of
- 26 Minnesota. The assignment of securities must be signed by an
- 27 officer, partner, or owner of the offsite storage facility. The
- 28 assignment must state: "Assigned to the state of Minnesota for
- 29 the purpose of providing financial assurance required by
- 30 Minnesota Rules, part 7035.9120, under the Infectious Waste
- 31 Control Act."
- 32 (4) All securities shall be deposited with the
- 33 state treasurer. The commissioner and the state treasurer shall
- 34 be authorized to sell and collect, if stored wastes are allowed
- 35 to putresce, as much of the deposited securities as is needed to
- 36 pay for final waste disposal. The commissioner's order to sell

- 1 securities must be approved by the agency.
- 2 (5) Interest accruing on any securities deposited
- 3 under this item shall be collected and transmitted to the
- 4 depositor, provided that the depositor has not allowed stored
- 5 wastes to putresce.
- 6 (6) All deposits shall remain in the custody of
- 7 the state treasurer until three months after the facility
- 8 operator stops accepting infectious waste.
- 9 (7) Any securities deposited with the state
- 10 treasurer may be exchanged or replaced by the depositor with
- 11 other acceptable securities so long as the market value of the
- 12 securities equals the amount of deposit required.
- 13 (8) No securities on deposit with the state
- 14 treasurer may be released without a written order from the
- 15 commissioner. The commissioner shall refuse to release
- 16 securities on deposit if the offsite storage facility owner or
- 17 operator fails to dispose properly of any infectious wastes
- 18 remaining after the facility permanently stops accepting waste.
- 19 (9) The offsite storage facility owner or
- 20 operator may request that deposited securities be returned.
- 21 Such requests must be submitted in writing by certified mail.
- 22 The commissioner shall direct the state treasurer to return the
- 23 securities to the depositor if:
- 24 (a) the offsite storage facility owner or
- 25 operator has stopped taking waste and no wastes remain on the
- 26 site;
- 27 (b) the offsite storage facility owner or
- 28 operator has substituted other securities of equal or greater
- 29 value for the securities that are requested; or
- 30 (c) another person has received approval to
- 31 operate the offsite storage facility.
- The commissioner shall refuse to order return of the
- 33 securities if the conditions for return have not been met. The
- 34 commissioner shall have 60 days in which to determine whether to
- 35 order return of the securities. If the commissioner does not
- 36 order return of the securities, the commissioner shall, within

- 1 30 days of the decision, provide the offsite storage facility
- 2 owner or operator with written reasons for not ordering return
- 3 of the securities.
- B. An offsite storage facility owner or operator may
- 5 satisfy the requirements of this subpart by sending to the
- 6 commissioner a surety bond that conforms to the requirements of
- 7 subitems (1) to (8). The surety company issuing the bond must
- 8 be among those listed as acceptable sureties on federal bonds in
- 9 Circular 570, issued by the United States Department of the
- 10 Treasury, as published annually in the Federal Register on July
- 11 1.
- 12 (1) The penal sum of the bond shall at least
- 13 equal the estimated costs of final waste disposal that is
- 14 approved in the management plan.
- 15 (2) The wording of the surety bond must be
- 16 identical to the wording specified in part 7035.9150, subpart 1.
- 17 (3) The bond must guarantee that the offsite
- 18 storage facility owner or operator will:
- 19 (a) properly dispose of all stored wastes
- 20 after the offsite storage facility has stopped accepting wastes;
- 21 (b) provide alternate financial assurance as
- 22 specified in this subpart; and
- 23 (c) obtain the commissioner's written
- 24 approval of the assurance provided within 90 days after receipt
- 25 by the commissioner of a notice of cancellation of the bond from
- 26 the surety.
- 27 (4) Under the terms of the bond, the surety must
- 28 become liable on the bond obligation when the offsite storage
- 29 facility owner or operator fails to perform as guaranteed by the
- 30 bond. Following a determination by the commissioner that the
- 31 offsite storage facility owner or operator has failed to
- 32 properly dispose of all stored wastes after the offsite storage
- 33 facility has stopped accepting wastes or has not provided
- 34 alternate financial assurance as specified in this subpart and
- 35 obtained the commissioner's written approval of the assurance
- 36 provided, within 90 days after receipt by the commissioner of a

- 1 notice of cancellation of the bond from the surety, under the
- 2 terms of the bond the surety shall pay the amount of the penal
- 3 sum to the agency.
- 4 (5) Whenever the estimated costs of final waste
- 5 disposal become greater than the penal sum, the offsite storage
- 6 facility owner or operator, within 60 days after the increase,
- 7 shall either increase the penal sum to equal the new cost
- 8 estimate, or obtain other financial assurance as specified in
- 9 this subpart. Whenever the estimated costs of final waste
- 10 disposal decrease, the penal sum shall be reduced to equal the
- 11 new cost estimate following written approval by the commissioner.
- 12 (6) Under the terms of the bond, the surety may
- 13 cancel the bond by sending notice of cancellation by certified
- 14 mail to the offsite storage facility owner or operator and to
- 15 the commissioner. However, cancellation is not effective until
- 16 120 days after the commissioner has received the notice of
- 17 cancellation, as evidenced by the return receipt.
- 18 (7) The offsite storage facility owner or
- 19 operator may cancel the bond if the commissioner has given prior
- 20 written approval. The commissioner shall approve cancellation
- 21 if:
- 22 (a) the offsite storage facility owner or
- 23 operator properly disposes of all stored wastes after the
- 24 offsite storage facility has stopped accepting wastes; or
- 25 (b) the offsite storage facility owner or
- 26 operator provides alternate financial assurance as specified in
- 27 this subpart.
- 28 (8) The surety shall not be liable for
- 29 deficiencies in the performance of final waste disposal after
- 30 the commissioner releases the offsite storage facility owner or
- 31 operator from the requirements of this subpart.
- 32 C. An offsite storage facility owner or operator may
- 33 satisfy the requirements of this subpart by sending to the
- 34 commissioner a letter of credit that conforms to the
- 35 requirements of subitems (1) to (8). The issuing institution
- 36 must be an entity which has the authority to issue letters of

- 1 credit. Its letter-of-credit operations must be regulated and
- 2 examined by a federal or Minnesota state agency.
- 3 (1) The letter of credit must be issued in an
- 4 amount that is at least equal to the estimated costs of final
- 5 waste disposal that is approved in the management plan.
- 6 (2) The wording of the letter of credit must be
- 7 identical to the wording specified in part 7035.9150, subpart 2.
- 8 (3) The letter of credit must be accompanied by a
- 9 letter from the offsite storage facility owner or operator
- 10 referring to the letter of credit by number, issuing
- 11 institution, and date, and providing the following information:
- 12 (a) the identification number;
- (b) the name and address of the facility;
- 14 and
- 15 (c) the amount of funds assured by the
- 16 letter of credit for final disposal of wastes at the facility.
- 17 (4) The letter of credit must be irrevocable and
- 18 issued for a period of at least one year. The letter of credit
- 19 must provide that the expiration date will be extended
- 20 automatically for a period of at least one year unless, at least
- 21 120 days before the current expiration date, the issuing
- 22 institution notifies both the offsite storage facility owner or
- 23 operator and the commissioner by certified mail of a decision
- 24 not to extend the expiration date. Under the terms of the
- 25 letter of credit, the 120 days must begin on the date when the
- 26 commissioner has received the notice, as evidenced by the return
- 27 receipt.
- 28 (5) Whenever the estimated costs of final waste
- 29 disposal become greater than the amount of the letter of credit,
- 30 the offsite storage facility owner or operator, within 60 days
- 31 after the increase, shall either increase the amount of the
- 32 letter of credit to equal the new cost estimate, or obtain other
- 33 financial assurance as specified in this subpart. Whenever the
- 34 estimated costs of final waste disposal decrease, the amount of
- 35 the letter of credit shall be reduced to equal the new cost
- 36 estimate following written approval by the commissioner.

- (6) Following a determination by the commissioner 1 that the offsite storage facility owner or operator has failed 2 to properly dispose of all stored wastes after the offsite 3 storage facility has stopped accepting wastes, the commissioner shall draw on the letter of credit. 5 (7) The commissioner shall draw on the letter of 6 7 credit if the offsite storage facility owner or operator does not establish alternate financial assurance as specified in this 8 subpart and obtain written approval of the alternate financial 9 10 assurance from the commissioner within 90 days after the commissioner receives notice from the issuing institution that 11 it has decided not to extend the letter of credit beyond the 12 current expiration date. The commissioner may delay the drawing 13 if the issuing institution grants an extension of the term of 14 the credit. During the last 30 days of any extension the 15 commissioner shall draw on the letter of credit if the offsite 16 storage facility owner or operator has failed to provide 17 18 alternate financial assurance as specified in this subpart and obtain written approval of the alternate financial assurance 19 from the commissioner. 20 (8) The commissioner shall return the letter of 21 credit to the issuing institution for termination if: 22 23 (a) the offsite storage facility owner or operator properly disposes of all stored wastes after the 24 offsite storage facility has stopped accepting wastes; or 25 (b) the offsite storage facility owner or 26 operator provides alternate financial assurance as specified in 27 28 this subpart. Subp. 8. Reporting and record keeping. Facility owners 29 and operators and commercial transporters must maintain records 30
- for a minimum of three years. If the three-year period expires during an unresolved enforcement action, the period is
- 33 automatically extended until resolution of the pending
- 34 enforcement action. Facility owners and operators and
- 35 commercial transporters shall report the following information
- 36 annually to the commissioner on the anniversary date of

- 1 management plan approval:
- 2 A. the title and name of the individual responsible
- 3 for implementation of the management plan as specified in part
- 4 7035.9130, item A;
- 5 B. the incidences in which infectious waste is
- 6 released to the environment; and
- 7 C. the amounts of infectious waste managed; storage
- 8 and decontamination facility owners and operators must submit
- 9 the following information for the management of infectious waste
- 10 that is generated both in and outside of Minnesota; commercial
- 11 transporters must submit the following information only for the
- 12 transport of infectious waste that is generated in Minnesota:
- 13 (1) the weight or number and size of containers
- 14 of infectious waste transported, decontaminated, stored, and
- 15 disposed of, giving the decontamination and disposal methods
- 16 used; and
- 17 (2) the weight or number and size of containers
- 18 of sharps transported, decontaminated, stored, and disposed of,
- 19 giving the decontamination and disposal method used.
- 20 7035.9130 MANAGEMENT PLAN.
- 21 Each facility owner or operator and commercial transporter
- 22 must develop and submit to the commissioner for approval a
- 23 management plan that meets the requirements of this part. A
- 24 copy of the management plan must also be submitted to the county
- 25 solid waste officer. The management plan must be updated and
- 26 resubmitted at least once every two years to the commissioner
- 27 and to the county solid waste officer. A current copy of the
- 28 management plan must be maintained onsite. For the management
- 29 plan to be approved, all information in the management plan must
- 30 be consistent with the requirements established in part
- 31 7035.9120 and must include the information required in Minnesota
- 32 Statutes, section 116.79, and in items A to L. Storage facility
- 33 owners and operators must submit the additional information
- 34 required in item M.
- 35 A. The name and title of the individual responsible

- 1 for the implementation of the management plan.
- B. A description of packaging and identification
- 3 labels used for the packaging and offsite transport of
- 4 infectious or pathological waste as specified in part 7035.9120,
- 5 subpart 1.
- 6 C. Spill response plan, including personal
- 7 protection, cleanup, and repackaging, as specified in part
- 8 7035.9120, subpart 6.
- 9 D. Staff training and continuing education plan for
- 10 employees who handle infectious or pathological wastes.
- 11 E. For facilities that decontaminate infectious
- 12 waste, a contingency plan that identifies alternative management
- 13 methods that will be used during shutdown.
- 14 F. The length of time that waste will be stored at a
- 15 storage facility.
- 16 G. The method of receiving waste to ensure that
- 17 infectious or pathological waste is handled separately from
- 18 other waste until decontamination is completed and to prevent
- 19 unauthorized persons from having access to or contact with the
- 20 waste.
- 21 H. The method of unloading and processing infectious
- 22 or pathological waste that limits the number of employees
- 23 handling the waste and minimizes the possibility of exposure of
- 24 employees.
- I. The method of disinfecting emptied reusable
- 26 containers, surface areas of transport vehicles, and facility
- 27 equipment that has been in contact with infectious waste.
- J. The methods used to store and transport infectious
- 29 or pathological waste in a manner that prevents putrefaction.
- 30 K. The weight or number and size of containers of
- 31 infectious waste and sharps to be stored, transported,
- 32 decontaminated, or disposed of at an approved facility; storage
- 33 and decontamination facility owners and operators must list the
- 34 quantities of infectious waste and sharps managed that were
- 35 generated both in and outside of Minnesota; commercial
- 36 transporters must list quantities only for the transport of

- l infectious waste and sharps that were generated in Minnesota.
- 2 L. A list containing the name, location, and contact
- 3 persons of the decontamination, storage, or disposal facilities
- 4 that will be used.
- 5 M. An estimate of all costs that will be incurred
- 6 after the storage facility ceases to accept infectious wastes.
- 7 The estimate must include a unit cost for final disposal that is
- 8 based on material weight, the name of the waste treatment or
- 9 disposal facility to be used and a schedule of its rates, and
- 10 unit-based transport costs from the storage facility to the
- 11 waste treatment or disposal facility.
- 12 7035.9140 MANAGEMENT PLAN CERTIFICATION PROCEDURES.
- 13 Subpart 1. Management plan application. Persons required
- 14 by part 7035.9130 to have an approved management plan shall
- 15 comply with items A to E.
- 16 A. A management plan submitted to the commissioner
- 17 for approval must provide the information listed in part
- 18 7035.9130 and be signed.
- B. An existing facility owner or operator or a
- 20 commercial transporter shall submit a management plan within 45
- 21 days of the adoption of parts 7035.9100 to 7035.9150.
- 22 C. A facility owner or operator or commercial
- 23 transporter that begins the transport, storage, decontamination,
- 24 or disposal of infectious waste after adoption of parts
- 25 7035.9120 to 7035.9150 shall submit to the commissioner a copy
- 26 of the management plan before initiating the handling of the
- 27 infectious waste.
- D. A generator that also incinerates infectious waste
- 29 shall submit a management plan for incineration activities in
- 30 addition to any plan required by the Minnesota Department of
- 31 Health.
- 32 E. A facility owner or operator that has an approved
- 33 management plan shall update and resubmit a plan every two
- 34 years. The updated plan must be submitted at least 30 days
- 35 before the expiration date of the plan.

- 1 Subp. 2. Certification fees. Management plans prepared by
- 2 facility owners or operators that store, decontaminate, or
- 3 dispose of infectious waste, other than at the facility that
- 4 generates the infectious waste, or a management plan prepared by
- 5 a facility owner or operator that incinerates onsite at a
- 6 hospital must be submitted to the commissioner with the
- 7 certification fee required under Minnesota Statutes, section
- 8 116.79, subdivision 4.
- 9 Subp. 3. Commercial transporter registration. Commercial
- 10 transporters must register with the commissioner. To obtain
- 11 registration, the commercial transporter must comply with the
- 12 requirements of subpart 1. Registered transporters shall
- 13 receive registration cards to be kept in each single unit
- 14 vehicle or trailer and at the address identified as the
- 15 principal place of business. The vehicle identification number
- 16 must be displayed as required in part 7035.9120, subpart 4, item
- 17 D, subitem (1).
- 18 Subp. 4. Exemption from commercial transporter
- 19 registration. Exemption from registration does not include
- 20 exemption from the packaging and labeling requirements of part
- 21 7035.9120, subpart 1. The following are exempt from commercial
- 22 transporter registration requirements:
- 23 A. generators that transport their own infectious
- 24 waste to an approved facility;
- B. a generator that provides not-for-profit
- 26 not-for-compensation or at cost infectious waste collection and
- 27 transport services for other generators;
- C. groups of generators that provide not-for-profit
- 29 <u>not-for-compensation</u> infectious waste collection and transport
- 30 services for the group; and
- 31 D. persons who provide collection and transportation
- 32 of sharps for households as part of the feasibility study
- 33 required by Laws 1989, chapter 337, section 10.
- 34 Subp. 5. Transporter registration fees. Management plans
- 35 prepared by commercial transporters of infectious waste must be
- 36 submitted to the commissioner with the registration fee required

- 1 under Minnesota Statutes, section 116.80, subdivision 3.
- Subp. 6. Signatories to management plans. All management
- 3 plans must be signed by the following persons:
- A. for corporations, by an executive officer, or an
- 5 agent or representative of the executive officer if the agent or
- 6 representative is responsible for the implementation and
- 7 evaluation of the management plan; and
- B. for a municipality, or state, federal, or other
- 9 public agency, either an executive officer or a ranking elected
- 10 official and the individual responsible for the implementation
- 11 and evaluation of the management plan.
- Subp. 7. Duration of management plan. A management plan
- 13 is effective for two years after the date of plan approval
- 14 unless enforcement actions result in the revocation of the plan.
- Subp. 8. Review and approval or denial of management plans.
- 16 A. All management plans shall be reviewed for
- 17 completeness by the commissioner. If the management plan is
- 18 incomplete, the commissioner shall promptly advise the signatory
- 19 of the incompleteness. Further processing of the management
- 20 plan may be suspended until the necessary information is
- 21 supplied.
- B. A management plan shall be approved if the plan is
- 23 determined to be complete and consistent with these parts. A
- 24 letter of approval signed by the commissioner shall be sent to
- 25 the applicant upon approval of the plan. Part 7001.0100,
- 26 subparts 4 and 5; and 7001.0110 do not apply to these approvals.
- 27 Approval under this part is not a permit under chapter 7001.
- 28 Nothing in this part exempts facilities or generators from
- 29 applicable agency permit requirements and compliance with agency
- 30 rules.
- 31 C. Approval shall be denied if the plan does not
- 32 comply with these parts and other applicable state or federal
- 33 laws or rules.
- 34 7035.9150 FORMS.
- 35 Subpart 1. Surety bond. A surety bond as specified in

36

part 7035.9120, subpart 7, must be worded as specified in this part, except that the instructions in brackets must be replaced with the relevant information and the brackets deleted. 3 PERFORMANCE BOND 4 Date bond executed: 5 Effective date: 7 Principal: [legal name and business address of owner or operator] 8 Type of organization: [insert "individual," "joint venture," 9 "partnership," or "corporation"] 10 State of incorporation: 11 Surety(ies): [name(s) and business address(es)] 12 Identification number, name, address, and estimated costs of 13 final waste disposal for each facility guaranteed by this bond: 14 15 \$..... 16 Total penal sum of bond: \$..... Surety's bond number: 17 The Principal and Surety(ies) hereto are firmly bound to 18 the Minnesota Pollution Control Agency (hereinafter called 19 Agency), in the above penal sum for the payment of which we bind 20 ourselves, our heirs, executors, administrators, successors, and 21 22 assigns jointly and severally; provided that, where the 23 Surety(ies) are corporations acting as co-sureties, we, the Sureties, bind ourselves in the sum "jointly and severally" only 24 for the purpose of allowing a joint action or actions against 25 any or all of us and for all other purposes each Surety binds 26 itself, jointly and severally with the Principal, for the 27 payment of the sum only as is set forth opposite the name of the 28 Surety, but if no limit of liability is indicated, the limit of 29 liability shall be the full amount of the penal sum. 30 31 The Principal is required to provide financial assurance for the final disposal of wastes accepted at the facility(ies) 32 33 named above. 34 The conditions of this obligation are such that if the Principal properly disposes of all wastes accepted at the 35

facility(ies), in accordance with the Principal's approved

- l infectious waste management plan and all applicable laws,
- 2 statutes, rules, and regulations, as these laws, statutes,
- 3 rules, and regulations may be amended,
- 4 Or, if the Principal provides alternate financial assurance
- 5 as specified in Minnesota Rules, part 7035.9120, subpart 7, and
- 6 obtains the Agency Commissioner's written approval of the
- 7 financial assurance, within 90 days after the date notice of
- 8 cancellation is received by both the Principal and the Agency
- 9 Commissioner from the Surety(ies), then this obligation shall be
- 10 null and void, otherwise it is to remain in full force and
- 11 effect.
- The Surety(ies) shall become liable on this bond obligation
- 13 only when the Principal has failed to fulfill the conditions
- 14 described above.
- Upon notification by the Agency Commissioner that the
- 16 Principal has been found in violation of the requirements of
- 17 Minnesota Rules, part 7035.9120, for a facility for which this
- 18 bond guarantees proper waste disposal, the Surety(ies) shall pay
- 19 the penal sum of the bond to the Agency as directed by the
- 20 Agency Commissioner.
- 21 Upon notification by the Agency Commissioner that the
- 22 Principal has failed to provide alternate financial assurance as
- 23 specified in Minnesota Rules, part 7035.9120, subpart 7, and
- 24 obtain written approval of the financial assurance from the
- 25 Agency Commissioner during the 90 days following receipt by both
- 26 the Principal and Agency of a notice of cancellation of the
- 27 bond, the Surety(ies) shall pay the penal sum of the bond to the
- 28 Agency as directed by the Agency Commissioner.
- The Surety(ies) hereby waive(s) notification of amendments
- 30 to infectious waste management plans and applicable laws,
- 31 statutes, rules, and regulations and agree(s) that no amendment
- 32 shall in any way alleviate its (their) obligation on this bond.
- 33 The liability of the Surety(ies) shall not be discharged by
- 34 any payment or succession of payments hereunder, unless and
- 35 until the payment or payments shall amount in the aggregate to
- 36 the penal sum of the bond, but in no event shall the obligation

```
of the Surety(ies) hereunder exceed the amount of said penal sum.
 1
 2
         The Surety(ies) may cancel the bond by sending notice of
    cancellation by certified mail to the owner or operator and to
 3
    the Agency Commissioner, provided however, that cancellation
 4
    shall not occur during the 120 days beginning on the date of
 5
    receipt of the notice of cancellation by both the Principal and
 6
    the Agency Commissioner, as evidenced by the return receipts.
 7
         The Principal may terminate this bond by sending written
 8
    notice to the Surety(ies), provided, however, that no notice
 9
10
    shall become effective until the Surety(ies) receive(s) written
    authorization for termination of the bond by the Agency
11
    Commissioner.
12
         (The following paragraph is an optional rider that may be
13
    included but is not required.)
14
         Principal and Surety(ies) agree to adjust the penal sum of
15
    the bond yearly so that it guarantees a new final waste disposal
16
    cost estimate, provided that the penal sum does not increase by
17
    more than 20 percent in any one year, and no decrease in the
18
    penal sum takes place without the written permission of the
19
    Agency Commissioner.
20
         The Principal and Surety(ies) have signed this Performance
21
    Bond on the date set forth above.
22
23
         The persons whose signatures appear below hereby certify
24
    that they are authorized to execute this surety bond on behalf
    of the Principal and Surety(ies) and that the wording of this
25
    surety bond is identical to the wording in Minnesota Rules, part
26
    7035.9150, subpart 1, as the rule was constituted on the date
27
    this bond was executed.
28
29
    Principal
             [SIGNATURE(S)]
30
             [NAME(S)]
31
32
             [TITLE(S)]
33
             [CORPORATE SEAL]
34
    Corporate Surety(ies)
35
             [NAME AND ADDRESS]
36
             State of incorporation:
                                       . . . . . . . . . . . . . . . .
             Liability limit: $.....
37
38
             [SIGNATURE(S)]
39
```

[NAME(S)]

[TITLE(S)]

[CORPORATE SEAL]

40

41 42

43

- [For every co-surety, provide signature(s), corporate seal,
- 2 and other information in the same manner as for Surety above.]
- 3 Bond premium: \$......
- 5 Subp. 2. Letter of credit. A letter of credit, as
- 6 specified in part 7035.9120, subpart 7, must be worded as
- 7 specified in this part, except that the instructions in brackets
- 8 must be replaced with the relevant information and the brackets
- 9 deleted.
- 10 IRREVOCABLE STANDBY LETTER OF CREDIT
- 11 [Agency Commissioner]
- 12 Minnesota Pollution Control Agency
- 13 Dear Sir or Madam:
- 14 We hereby establish our Irrevocable Standby Letter of
- 15 Credit No. in your favor, at the request and for the
- 16 account of [owner's or operator's name and address] up to the
- 17 aggregate amount of [in words] United States dollars \$....,
- 18 available upon presentation of:
- 1. your sight draft, bearing reference to this letter of
- 20 Credit No. ...; and
- 2. your signed statement reading as follows: "I certify
- 22 that the amount of the draft is payable pursuant to the
- 23 infectious waste rules, Minnesota Rules, parts 7035.9100 to
- 24 7035.9150."
- This letter of credit is effective as of [date] and shall
- 26 expire on [date at least one year later], but the expiration
- 27 date shall be automatically extended for a period of [at least
- 28 one year] on [date] and on each successive expiration date,
- 29 unless, at least 120 days before the current expiration date, we
- 30 notify both you and [owner's or operator's name] by certified
- 31 mail that we have decided not to extend this letter of credit
- 32 beyond the current expiration date. In the event you are so
- 33 notified, any unused portion of the credit shall be available
- 34 upon presentation of your sight draft for 120 days after the
- 35 date of receipt by you, as shown on the signed return receipt.
- Whenever this letter of credit is drawn on, under, and in
- 37 compliance with the terms of this credit, we shall duly honor

- l the draft upon presentation to us and we shall deposit the
- 2 amount of the draft directly to the Minnesota Pollution Control
- 3 Agency in accordance with your instructions.
- 4 We certify that the wording of this letter of credit is
- 5 identical to the wording specified in Minnesota Rules, part
- 6 7035.9150, subpart 2, as the rules were constituted on the date
- 7 shown immediately below.
- 8 [SIGNATURE(S) AND TITLE(S) OF OFFICIAL(S) OF ISSUING
- 9 INSTITUTION]
- 10 [DATE]
- 11 This credit is subject to [insert "the most recent edition
- 12 of the Uniform Customs and Practice for Documentary Credits,
- 13 published by the International Chamber of Commerce," or "the
- 14 Uniform Commercial Code published in Minnesota Statutes, chapter
- 15 336"].