

1 Department of Health

2

3 Adopted Permanent Rules Relating to Infectious Waste

4

5 Rules as Adopted

6 4610.2300 SANITARY CONDITION OF FUNERAL ESTABLISHMENTS.

7 [For text of subp 2, see M.R.]

8 Subp. 3. Removal of waste. Refuse, bandages, cotton, and
 9 other wastes shall be collected in approved receptacles as
 10 provided in the embalming and preparation room. All infectious
 11 waste and pathological waste as defined in Minnesota Statutes,
 12 section 116.76, must be handled in a sanitary manner according
 13 to parts 4622.0100 to 4622.1200 and Minnesota Statutes, sections
 14 116.76 to 116.83 and ~~145.1621~~. Embalming tables, hoppers,
 15 sinks, receptacles, instruments, positioning blocks, and other
 16 appliances used in the embalming of dead human bodies shall be
 17 thoroughly cleaned immediately upon completion of preparation
 18 and embalming. Pathological waste does not include the remains
 19 specified in Minnesota Statutes, section 145.1621 and such
 20 remains must be handled in accordance with that statute.

21 4622.0100 APPLICABILITY.

22 Subpart 1. General. Parts 4622.0100 to 4622.1200 govern
 23 the on-site management of infectious waste and pathological
 24 waste and the development of generator management plans. Parts
 25 4622.0100 to 4622.1200 apply to all generators regardless of the
 26 quantity of infectious waste and pathological waste generated.
 27 Parts 4622.0100 to 4622.1200 must be read in conjunction with
 28 Minnesota Statutes, sections 116.76 to 116.83. If a facility is
 29 a health care facility licensed under Minnesota Statutes,
 30 sections 144.50 to 144.56 or chapter 144A, but is not a
 31 generator as defined in Minnesota Statutes, section 116.76,
 32 subdivision 9, the facility is not regulated under parts
 33 4622.0100 to 4622.1200.

34 Subp. 2. Excluded waste. In accordance with Minnesota
 35 Statutes, section 116.77, parts 4622.0100 to 4622.1200 do not

1 apply to a person who generates:

- 2 A. household waste;
- 3 B. farm operation waste; or
- 4 C. agricultural business waste.

5 Subp. 3. **Excluded generators.** In accordance with
6 Minnesota Statutes, section 116.76, subdivision 9, the following
7 persons are not generators regulated by the commissioner for
8 purposes of the management of infectious waste or the submission
9 of a generator management plan:

- 10 A. an ambulance service licensed under Minnesota
11 Statutes, section 144.802;
- 12 B. an eligible board of health, community health
13 board, or public health nursing agency as defined in Minnesota
14 Statutes, section 116.78, subdivision 10;
- 15 C. a program providing school health service under
16 Minnesota Statutes, section 123.35, subdivision 17; and
- 17 D. any person acting as a "good samaritan" within the
18 context of Minnesota Statutes, section 604.05.

19 Subp. 4. **Other practices.** Parts 4622.0100 to 4622.1200 do
20 not apply to:

- 21 A. the operation of on-site incinerators; and
- 22 B. off-site waste management practices regulated by
23 the agency including persons who transport infectious waste or
24 pathological waste.

25 4622.0300 DEFINITIONS.

26 Subpart 1. **Scope.** The definitions in this part apply to
27 parts 4622.0100 to 4622.1200.

28 Subp. 2. **Agency.** "Agency" means the Minnesota Pollution
29 Control Agency.

30 Subp. 3. **Agricultural business waste.** "Agricultural
31 business waste" means waste produced by:

- 32 A. a soil preparation service;
- 33 B. a crop service;
- 34 C. a slaughtering or rendering operation;
- 35 D. an animal service except veterinary medicine;

1 E. a farm labor and management service;

2 F. a landscaping and horticultural service for
3 another on a contract or fee basis; or

4 G. a feedlot or poultry hatchery.

5 Subp. 4. Blood. "Blood" has the meaning given in
6 Minnesota Statutes, section 116.76, subdivision 3.

7 Subp. 5. Commissioner. "Commissioner" means the
8 commissioner of health.

9 Subp. 6. Decontamination. "Decontamination" has the
10 meaning given in Minnesota Statutes, section 116.76, subdivision
11 6.

12 Subp. 7. Disinfection. "Disinfection" has the meaning
13 given in part 7035.9110, subpart 7.

14 Subp. 8. Facility. "Facility" means a site under the
15 control of a generator where infectious or pathological waste is
16 generated, stored, decontaminated, incinerated, or disposed. A
17 mobile self-contained unit such as a bloodmobile, a mobile
18 veterinary vehicle, or a mobile x-ray unit are individually a
19 facility.

20 Subp. 9. Farm operation waste. "Farm operation waste"
21 means waste produced by an operation involved in the growing or
22 harvesting of crops, the raising of livestock or poultry, or
23 related activities conducted on a site such as a farm, ranch,
24 orchard, dairy farm, or similar farming operation.

25 Subp. 10. Generating employee. "Generating employee"
26 means an employee, either full- or part-time, whose activities
27 produce infectious or pathological waste. Volunteers are not
28 employees for purposes of fee payment.

29 Subp. 11. Generator. "Generator" has the meaning given in
30 Minnesota Statutes, section 116.76, subdivision 9.

31 Subp. 12. Generator management plan. "Generator
32 management plan" means a written and implemented system
33 developed by a generator for the safe on-site management of
34 infectious or pathological waste that complies with Minnesota
35 Statutes, section 116.79, subdivisions 1, 2, and 3, and parts
36 4622.0100 to 4622.1200.

1 Subp. 13. Household. "Household" has the meaning given in
2 Minnesota Statutes, section 116.76. Household includes a
3 domicile such as a student dormitory or convent where the
4 resident self-administers medication. Household does not
5 include a facility licensed as a hospital, nursing home,
6 boarding care facility, or intermediate care facility.

7 Subp. 14. Household waste. "Household waste" means waste
8 produced in a household and includes waste produced by members
9 through self-administration. Household waste does not include
10 waste produced in a household by a home care or hospice program
11 regulated under Minnesota Statutes, sections 144A.43 to 144A.49.

12 Subp. 15. Infectious agent. "Infectious agent" has the
13 meaning given in Minnesota Statutes, section 116.76, subdivision
14 11.

15 Subp. 16. Infectious waste. "Infectious waste" has the
16 meaning given in Minnesota Statutes, section 116.76, subdivision
17 12.

18 Subp. 17. Laboratory. "Laboratory" means a research,
19 analytical, or clinical facility that performs health
20 care-related analyses or services. This includes medical,
21 pathological, pharmaceutical, and other research, commercial, or
22 industrial laboratories.

23 Subp. 18. Laboratory waste. "Laboratory waste" has the
24 meaning given in Minnesota Statutes, section 116.76, subdivision
25 13.

26 Subp. 19. Off-site. "Off-site" has the meaning given in
27 part 7035.9100, subpart 13.

28 Subp. 20. On-site. "On-site" means any facility including
29 the appurtenances and vehicles at which infectious waste or
30 pathological waste is generated or decontaminated and which is
31 owned by, leased to, or under contract to the generator of the
32 waste.

33 Subp. 21. Pathological waste. "Pathological waste" has
34 the meaning given in Minnesota Statutes, section 116.76,
35 subdivision 14. Pathological waste does not include the remains
36 specified in Minnesota Statutes, section 145.1621 and such

1 remains must be handled in accordance with that statute.

2 Subp. 22. **Person.** "Person" has the meaning given in
3 Minnesota Statutes, section 116.76, subdivision 15.

4 Subp. 23. **Point of generation.** "Point of generation"
5 means the location where infectious waste or pathological waste
6 first becomes waste.

7 Subp. 24. **Regulated human body fluids.** "Regulated human
8 body fluids" has the meaning given in Minnesota Statutes,
9 section 116.76, subdivision 16.

10 Subp. 25. **Research animal waste.** "Research animal waste"
11 has the meaning given in Minnesota Statutes, section 116.76,
12 subdivision 17.

13 Subp. 26. **Satellite facility.** "Satellite facility" means
14 a facility operated by and under the control of a generator but
15 not located on the primary site of the generator.

16 Subp. 27. **Sharps.** "Sharps" has the meaning given in
17 Minnesota Statutes, section 116.76, subdivision 18.

18 Subp. 28. **Spill.** "Spill" has the meaning given in part
19 7035.9110, subpart 22.

20 Subp. 29. **Storage.** "Storage" means the on-site holding by
21 the generator of infectious waste or pathological waste:

22 A. generated on-site by the generator or by the
23 generator's satellite facility; or

24 B. stored by the generator for a party specified in
25 part 4622.0100, subpart 3.

26 Subp. 30. **Transportation.** "Transportation" means the
27 collection, transfer, or movement of infectious waste or
28 pathological waste by a generator on-site, from or between
29 satellite facilities.

30 Subp. 31. **Universal biohazard symbol.** "Universal
31 biohazard symbol" means a symbol that conforms to the design
32 shown in Code of Federal Regulations, title 29, section
33 1910.145(f)(8)(ii).

34 Subp. 32. **Waste.** "Waste" means a material discarded for
35 disposal.

1 4622.0400 GENERAL MANAGEMENT STANDARDS.

2 Subpart 1. Policies and procedures. A generator of
3 infectious waste or pathological waste must prepare, maintain,
4 and implement written policies and procedures that:

- 5 A. are consistent with parts 4622.0100 to 4622.1200;
- 6 B. identify and address the management of all
7 infectious waste and pathological waste generated; and
- 8 C. are updated as needed or required by Minnesota
9 Statutes, sections 116.76 to 116.83.

10 Subp. 2. Employee training. Employee training must be
11 provided for employees who generate and handle infectious waste
12 or pathological waste. Training must be provided for employees
13 before operating on-site compaction, decontamination,
14 incineration, or disposal systems to assure proper operation,
15 waste treatment, and safety. Employee training must include:

- 16 A. an explanation of the generator's infectious waste
17 management plan;
- 18 B. procedures to ensure the proper separation of
19 infectious waste and pathological waste from other solid waste;
20 and
- 21 C. policies and procedures applicable to the
22 employee's assigned roles and responsibilities.

23 All employees who generate and handle infectious waste and
24 pathological waste shall attend refresher training as often as
25 necessary to prevent violations.

26 Subp. 3. Segregation at point of generation; mixing wastes.
27 Infectious waste and pathological waste must be segregated by
28 container from other waste at the point of generation within the
29 facility. Any solid waste mixed with infectious waste must be
30 managed as infectious waste.

31 Subp. 4. No recycling. There must be no recycling effort
32 of infectious waste and pathological waste before the waste is
33 decontaminated.

34 Subp. 5. Labeling waste. All bags, boxes, and other
35 containers used for the collection, transportation, or storage
36 of infectious waste or pathological waste on-site must be

1 clearly and conspicuously labeled with the universal biohazard
2 symbol or with the words "Infectious Waste" written in letters
3 no less than one inch in height on a background with contrasting
4 color. If the waste requires labeling under Code of Federal
5 Regulations, title 49, section 172.432, relating to the
6 transportation of medical waste, or Code of Federal Regulations,
7 title 29, section 1910.1030, relating to bloodborne pathogens,
8 the generator shall comply with the labeling requirements
9 specified in those regulations and compliance shall satisfy the
10 labeling requirements of this subpart except that red bags or
11 red containers alone may not be substituted for labeling. Waste
12 labeled as infectious waste or with the universal biohazard
13 symbol must be managed as infectious waste. Bags that change
14 color or labels that change during decontamination are
15 acceptable. All removable bags must be labeled as well as
16 outside containers enclosing the bags.

17 Subp. 6. Packaging waste. Packaging must be appropriate
18 for the type of infectious waste and pathological waste
19 generated and the type of handling and treatment anticipated.

20 A. Infectious waste and pathological waste must be
21 packaged and contained to prevent release of the waste material.

22 B. Packages of infectious waste and pathological
23 waste must remain intact until decontamination, incineration, or
24 disposal unless a compaction system or other treatment method is
25 approved by the commissioner.

26 C. Decontaminated infectious waste and decontaminated
27 pathological waste must be repackaged or relabeled on-site
28 before it is handled and disposed of as solid waste unless:

29 (1) the waste has been shredded or has otherwise
30 been rendered nonrecognizable; or

31 (2) there has been a visible change in packaging
32 or labeling.

33 D. Except for fluid infectious waste and sharps,
34 infectious waste and pathological waste must be contained in
35 plastic bags that are impervious to moisture and of sufficient
36 strength to preclude ripping, tearing, or bursting during use,

1 storage, collection, transportation, and decontamination.

2 E. Material in a fluid state of greater than 20 cubic
3 centimeters must be packaged in a container that prevents
4 spillage. This container may be placed with bagged infectious
5 and pathological waste.

6 F. A container designed for reuse, if reused, must be
7 intact and disinfected as specified in subpart 12, if it has
8 been in contact with infectious waste or pathological waste.

9 Subp. 7. Sharps. Sharps must be segregated from other
10 waste and discarded directly into single-use or reusable sharps
11 containers.

12 A. Glass or rigid plastic vials containing infectious
13 waste must be managed as infectious waste.

14 B. Discarded sharps must be placed directly into
15 containers that are leak-resistant, puncture-resistant, and
16 burst-resistant under normal conditions of handling and use.

17 C. Sharps containers must be maintained to prevent
18 spillage and tampering.

19 Subp. 8. On-site compaction of infectious waste; on-site
20 compaction or mixing of sharps with other waste. A generator
21 must not compact infectious waste on-site with other waste
22 before decontamination, incineration, or disposal unless the
23 compaction process meets the requirements in this subpart.
24 Discarded sharps must not be compacted or mixed with other solid
25 waste on-site unless the compaction process or mixing process
26 meets the requirements in this subpart.

27 A. The compaction of infectious waste, or the
28 compaction or mixing process for sharps, must be an integral
29 part of:

30 (1) an off-site decontamination process approved
31 by the agency for the decontamination of infectious waste;

32 (2) an off-site disposal system approved by the
33 agency for the disposal of infectious waste; or

34 (3) an on-site decontamination process approved
35 by the commissioner in accordance with part 4622.0700 for the
36 on-site decontamination of infectious waste.

1 B. To obtain approval, a written request to compact
2 infectious waste, or to compact or mix sharps with other solid
3 waste, must be directed by the generator to the commissioner.

4 The request must:

5 (1) specify the reason for the request;

6 (2) describe the process proposed for use;

7 (3) if decontamination takes place on-site,

8 present evidence verifying that the proposed compaction or

9 mixing process is an integral part of the on-site

10 decontamination process that meets the requirements of part

11 4622.0700; and

12 (4) describe how the health and safety of

13 employees and the public are protected during compaction or

14 mixing, decontamination, storage, transportation, and disposal.

15 D. The commissioner shall approve the request if the

16 commissioner determines that the process meets the requirements

17 in this subpart and there is no evidence of adverse effect on

18 the health and safety of employees and the public during

19 compaction or mixing, decontamination, storage, transportation,

20 and disposal.

21 E. The commissioner shall respond to the request

22 within 60 days after receipt of all required information. A

23 generator whose compaction or mixing process is not approved by

24 the commissioner may reapply when new information or data

25 relevant to the reasons for the decision is available.

26 Subp. 9. Waste from other regulated generators. A

27 generator must not accept infectious waste or pathological waste

28 for storage, decontamination, or incineration from another

29 regulated generator unless the other generator has a card from

30 the commissioner acknowledging receipt by the commissioner of a

31 generator management plan and the fee specified in part

32 4622.1100.

33 Subp. 10. Record retention and access. All generator

34 records on the generation and management of infectious waste and

35 pathological waste must be maintained for three years and made

36 available for inspection by the commissioner on request

1 according to Minnesota Statutes, section 116.83, subdivision 3.
2 If the three-year period expires during an unresolved
3 enforcement action, the period is automatically extended until
4 resolution of the pending enforcement action.

5 Subp. 11. Spill containment, cleanup kit. Infectious
6 waste and pathological waste must be contained so there is no
7 discharge or release of any waste during collection, storage,
8 decontamination, incineration, or disposal. If a spill occurs
9 on-site, a spill cleanup kit must be readily available on-site
10 that is sufficient to contain the spill.

- 11 A. The cleanup kit must include at least:
 - 12 (1) absorbent material for spilled liquids;
 - 13 (2) detergent;
 - 14 (3) hospital grade disinfectant as specified in
15 subpart 12;
 - 16 (4) packaging and labeling, as required in this
17 part;
 - 18 (5) cleanup utensils; and
 - 19 (6) appropriate protective clothing, latex and
20 neoprene gloves, a surgical facemask, and goggles.

- 21 B. When responding to a spill:
 - 22 (1) access to the spill area by unauthorized
23 personnel must be prevented;
 - 24 (2) broken containers and spillage must be
25 packaged and labeled as required in this part;
 - 26 (3) absorbent material must be applied to surface
27 areas that have been contaminated with infectious waste; and
 - 28 (4) reusable items must be cleaned and
29 disinfected using the procedures in subpart 12.

30 Subp. 12. Spill cleanup procedures. Surfaces contaminated
31 with spilled infectious waste or pathological waste must be
32 cleaned with a detergent to remove visible soil and be
33 disinfected with a chemical germicide registered by the
34 Environmental Protection Agency as a hospital disinfectant that
35 is a tuberculocidal when used at recommended dilutions.

36 Subp. 13. Cleaning of decontamination devices. Autoclaves

1 and other decontamination devices must be maintained in a
2 sanitary condition. Work areas and loading devices must be
3 cleaned and disinfected after each use.

4 4622.0600 ON-SITE STORAGE.

5 Subpart 1. General. All on-site storage of infectious
6 waste and pathological waste must be in a designated area away
7 from general traffic flow patterns and be accessible only to
8 authorized personnel. Storage of infectious waste and
9 pathological waste must be in a manner that protects human
10 health and the environment.

11 Subp. 2. Area. An area used for the storage of infectious
12 waste and pathological waste, other than the point of
13 generation, must be constructed of smooth, easily cleanable
14 materials capable of being maintained in a sanitary condition
15 and designed to prevent the entry of vermin. The central
16 storage area must be conspicuously marked with the universal
17 biohazard symbol or with the words "Infectious Waste" on or
18 adjacent to the exterior of any entry door or access gate.

19 Subp. 3. Storage of plastic bags. Plastic bags of
20 infectious waste and pathological waste must be packaged for
21 storage by placement in corrugated cardboard boxes or equivalent
22 rigid containers such as reusable barrels, cartons, or bins.
23 Containers must be closed ~~or~~, covered, or otherwise managed to
24 preclude losing or spilling the contents and labeled according
25 to part 4622.0400, subpart 5.

26 A. Reusable storage containers for plastic bags must
27 be rigid, leak-resistant, burst-resistant, and tear-resistant
28 under normal conditions of handling and use, be constructed of
29 smooth, easily cleanable, impermeable materials, and be
30 resistant to corrosion by disinfectant chemicals.

31 B. Single-use outer containers used for the on-site
32 storage of bagged infectious waste or pathological waste must be
33 rigid, leak-resistant, burst-resistant, and tear-resistant under
34 normal conditions of handling and use.

35 4622.0700 ON-SITE DECONTAMINATION, INCINERATION, DISPOSAL.

1 Subpart 1. General. Any on-site decontamination,
2 incineration, or disposal of infectious waste or pathological
3 waste, including a generator-operated mobile decontamination
4 unit, must comply with this part.

5 Subp. 2. Procedures. A generator must develop written
6 procedures for each decontamination, incineration, and disposal
7 method used at the facility and ensure compliance with the
8 procedures.

9 Subp. 3. Loading. Loading of infectious waste and
10 pathological waste must not exceed the design capacity of the
11 decontamination device.

12 Subp. 4. Maintenance. The decontamination device must be
13 maintained according to manufacturer's instructions and a record
14 kept of the dates of calibration, repair, and service.

15 Subp. 5. Load decontamination verification. Unless the
16 decontamination device is equipped to continuously monitor and
17 record time, temperature, and pressure during the entire length
18 of the decontamination cycle, each load of infectious waste and
19 pathological waste to be decontaminated must have an indicator
20 placed in the center of the load aggregate, that verifies that
21 the waste material has been decontaminated or the
22 decontamination temperature and pressure indicated in the
23 generator's procedures has been reached. Depending on the
24 device and method used, decontamination is verified if:

25 A. a temperature of at least 250 degrees Fahrenheit
26 or 121 degrees Celsius at 15 pounds per square inch of steam
27 gauge pressure for one hour or an equivalent setting is reached;

28 B. for steam autoclaves without time, temperature,
29 and pressure monitors, a biological indicator indicates the
30 complete kill of bacillus stearothermophilus spores;

31 C. for dry heat or ethylene oxide decontamination, a
32 biological indicator indicates the complete kill of bacillus
33 subtilis spores; or

34 D. there is an equivalent spore test or laboratory
35 culture of the treatment residue prior to disposal showing that
36 infectious agents have been killed.

1 Subp. 6. Decontamination records. The following records
2 must be maintained on-site by the generator for three years:

3 A. a record with an entry for each load of infectious
4 waste or pathological waste decontaminated on-site in accordance
5 with subpart 5. The record must specify for each load the:

6 (1) date and operator;

7 (2) approximate amount of waste decontaminated;

8 and

9 (3) method of decontamination and relevant
10 parameters such as time and temperature; and

11 B. a record of the verification of the generator's
12 decontamination process in accordance with subpart 7.

13 Subp. 7. Decontamination process verification. The
14 generator's decontamination process, including all devices such
15 as autoclaves, must be monitored and verified for effectiveness
16 initially and at least once every 40 hours of operation
17 thereafter using normal operating and loading procedures to
18 ensure decontamination of the infectious waste or pathological
19 waste. A record must be maintained of the results for at least
20 three years. Using a load for testing that is comparable in
21 amount and density to that routinely decontaminated,
22 decontamination is verified if:

23 A. a biological indicator placed in the center of the
24 load aggregate shows the complete kill of bacillus
25 stearothermophilus spores or bacillus subtilis spores; or

26 B. there is an equivalent spore test or laboratory
27 culture of the treatment residue prior to disposal showing that
28 infectious agents have been killed.

29 Subp. 8. Autoclaving. The use of a steam autoclave is an
30 approved method for the decontamination of infectious waste if
31 the device and procedure used meet the standards in this part.

32 Subp. 9. Incineration. Incineration is an approved method
33 for the on-site management of infectious or pathological waste
34 if:

35 A. the incinerator complies with applicable rules of
36 the agency and the State Fire Marshal; and

1 B. the generator has an approved management plan from
2 the agency.

3 Subp. 10. Other treatment methods. Other on-site
4 treatment methods for the decontamination of infectious waste or
5 pathological waste must be reviewed and approved by the
6 commissioner before use. A written request from the generator
7 must be directed to the commissioner.

8 A. The request must:

- 9 (1) specify the reason for the request;
10 (2) describe the decontamination method proposed;
11 (3) present evidence that the proposed method
12 provides effective decontamination of the infectious waste,
13 including sharps; and
14 (4) describe how the health and safety of
15 employees and the public are protected.

16 B. The commissioner shall approve the alternative
17 method if:

- 18 (1) there is verification that the infectious
19 waste or pathological waste is decontaminated in accordance with
20 subpart 7; and
21 (2) there is no evidence of adverse effect on the
22 health and safety of employees and the public.

23 C. The commissioner shall respond to the request
24 within 60 days after receipt of all required information. The
25 commissioner shall provide written reasons for the decision. A
26 person whose alternative decontamination process is not approved
27 may reapply when new information or data relevant to the reasons
28 for the decision are available.

29 Subp. 11. Disposal by sanitary sewer. Blood or blood
30 products and other regulated human body fluids may be disposed
31 of in a sanitary sewer unless prohibited by local ordinance.

32 Subp. 12. Body tissue. Body tissue that has been
33 histologically fixed must be considered decontaminated. Tissues
34 prepared by frozen sectioning must not be considered
35 decontaminated.

1 4622.0900 GENERATOR MANAGEMENT PLAN SUBMISSION.

2 A person required by Minnesota Statutes, section 116.79,
3 subdivision 1, to have a generator management plan must comply
4 with this part.

5 A. A management plan submitted to the commissioner
6 for approval must provide the information listed in part
7 4622.1000, be signed and dated by the generator, and designate
8 the person responsible for ensuring implementation of the plan
9 at each facility.

10 B. A generator who begins to generate infectious
11 waste or pathological waste after adoption of parts 4622.0100 to
12 4622.1200 or who does not have a plan on file with the
13 commissioner must submit to the commissioner a copy of a
14 generator management plan as specified in part 4622.1000 before
15 initiating the management of or continuing to generate
16 infectious waste or pathological waste.

17 C. If a generator sells or transfers a facility to
18 another generator, the generator to whom the facility has been
19 transferred must submit a generator management plan and fee.

20 4622.1000 GENERATOR MANAGEMENT PLAN.

21 Subpart 1. General. A generator must develop and submit
22 to the commissioner for approval a generator management plan
23 covering all facilities operated by the generator. The
24 generator must ensure the implementation of the plan submitted.

25 Subp. 2. Plan contents. The generator management plan
26 must contain the information specified in this subpart.

27 A. The plan must specify the name, address, and phone
28 number of each generating facility covered by the plan and the
29 name, title, and phone number of the individual responsible for
30 the management of the infectious waste and pathological waste at
31 each facility.

32 B. The management plan must list all physicians,
33 dentists, chiropractors, podiatrists, veterinarians, certified
34 nurse practitioners, certified nurse midwives, physician
35 assistants, or the number of practitioners specified in part

1 4622.1100, item C, employed by, under contract to, or working at
2 all generating facilities, except at hospitals and laboratories.

3 (1) A management plan from a hospital or
4 long-term care facility including a nursing home, boarding care
5 facility, or intermediate care facility must list the number of
6 licensed beds.

7 (2) A management plan from a laboratory or a
8 licensed home care agency must list the number of generating
9 employees.

10 C. The generator management plan must identify the
11 types of infectious waste and pathological waste generated.

12 D. All infectious waste and pathological waste
13 generated at a hospital or nursing home must be covered by the
14 hospital or nursing home's generator management plan.

15 E. A home care provider registered and licensed under
16 Minnesota Statutes, sections 144A.43 to 144A.49, must submit a
17 generator management plan to cover all generating activity
18 provided by that generator.

19 F. All information in the generator management plan
20 must be consistent with the policies and procedures established
21 in parts 4622.0100 to 4622.1200 and must include the information
22 required in Minnesota Statutes, section 116.79.

23 G. The generator management plan must describe the
24 activities, programs, and locations at and associated with each
25 facility that generates infectious waste and pathological waste.

26 H. The plan must estimate the average monthly
27 quantity of infectious waste and pathological waste to be
28 generated by each facility. Quantities of sharps and bagged
29 infectious waste and pathological waste must be reported in
30 pounds and liquid infectious waste must be reported in gallons.

31 I. The plan must describe the procedures for
32 segregating infectious waste and pathological waste from other
33 waste material at the point of generation.

34 J. The plan must describe each facility's procedure
35 for packaging infectious waste and pathological waste.

36 K. The plan must describe each facility's procedure

1 for labeling all bags, boxes, and other containers used for
2 infectious waste and pathological waste on-site.

3 L. The plan must describe each facility's procedure
4 for collecting the infectious waste and pathological waste from
5 the point of generation to the central collection point, before
6 and after decontamination or disposal on-site, or its transport
7 off-site.

8 M. The plan must describe each facility's procedure
9 for the storage of infectious waste and pathological waste at
10 temporary collection points and at central collection points.
11 If a generator stores infectious waste or pathological waste
12 from a satellite facility or another generator, the plan must
13 identify the type of waste to be stored and the generating
14 facility.

15 N. The generator must describe the method and
16 procedures used for on-site decontamination of infectious waste
17 and pathological waste, including the estimated average monthly
18 volume in gallons and pounds of waste decontaminated.

19 (1) If a generator decontaminates infectious
20 waste or pathological waste for any other generator, the plan
21 must:

22 (a) identify all other generators;

23 (b) identify whether the waste is sharps or
24 bagged waste; and

25 (c) estimate the average monthly quantity in
26 pounds of waste decontaminated.

27 (2) If a generator puts blood or other regulated
28 human body fluids into an on-site sanitary sewer for disposal,
29 the plan must indicate that blood and regulated human body
30 fluids are disposed of in this manner and estimate the average
31 monthly total volume in gallons.

32 (3) If a generator incinerates infectious waste
33 or pathological waste on-site, the plan must:

34 (a) identify the quantity in pounds on a
35 monthly average that is generated and incinerated on-site;

36 (b) have the on-site generator management

1 plan required by the agency as an attachment; and

2 (c) require a record of each load of
3 infectious waste and pathological waste incinerated on-site.

4 The record must specify for each load the date, operator, and
5 approximate amount of waste incinerated and be retained for
6 three years.

7 O. If a generator incinerates infectious waste or
8 pathological waste for any other generator, the plan must:

9 (1) identify all other generators;

10 (2) identify whether the waste is sharps or
11 bagged infectious waste; and

12 (3) estimate the average monthly quantity in
13 pounds of waste incinerated.

14 P. If a generator has infectious waste or
15 pathological waste transported off-site for storage,
16 decontamination, or disposal by a commercial transporter as
17 defined in Minnesota Statutes, section 116.76, subdivision 4,
18 the plan must:

19 (1) list the company name, address, and phone
20 number;

21 (2) list the agency registration identification
22 number, and contact person for each commercial transporter used
23 by the facility;

24 (3) identify whether the waste is sharps or
25 bagged waste; and

26 (4) specify the average monthly quantity in
27 pounds of infectious waste and pathological waste handled by
28 each commercial transporter.

29 Q. If an intermediate facility or commercial
30 transporter is used between initial transport and final disposal
31 of infectious or pathological waste, the plan must:

32 (1) identify each intermediate facility and
33 commercial transporter used by name, address, phone number, and
34 contact person;

35 (2) estimate the average monthly quantity of
36 sharps and bagged infectious waste and pathological waste in

1 pounds handled; and

2 (3) describe the services provided.

3 R. If a generator transports the generator's own
4 waste or if the generator's waste is transported by another
5 generator off-site, the generator's management plan must
6 identify the transporting generator and all storage,
7 decontamination, and disposal facilities by name, address,
8 telephone number, contact person, and service provided. The
9 monthly quantity in pounds of sharps and bagged infectious and
10 pathological waste handled by each facility must be specified.
11 A record for each shipment must be maintained on-site for three
12 years. The shipment record must specify the:

13 (1) decontamination or disposal facility;

14 (2) weight or volume of the waste; and

15 (3) date the waste left the generator's facility.

16 S. If the generator mails sharps for storage,
17 decontamination, or disposal, the plan must specify how the
18 generator will comply with applicable federal laws and rules.
19 The plan must specify the name of the facility to which the
20 sharps are mailed, facility address, phone number, contact
21 person who receives the sharps, and the average monthly quantity
22 in pounds. If the facility to which the sharps are mailed is
23 not the disposal facility, the plan must identify the disposal
24 facility.

25 T. If a generator transports infectious waste or
26 pathological waste for another generator, the plan must list the
27 name of each generator whose waste is transported.

28 U. If a generator's infectious waste or pathological
29 waste is transported by any other generator, the plan must
30 identify all generators transporting the waste.

31 V. The plan must describe the steps taken by the
32 generator to minimize the exposure of employees to infectious
33 agents throughout the process of handling infectious waste and
34 pathological wastes.

35 W. The plan must identify a contingency system to be
36 used, if the present infectious waste and pathological waste

1 disposal system breaks down or is unavailable.

2 Subp. 3. Maintenance of plan on-site. A copy of the
3 current generator management plan must be maintained on the site
4 of each facility.

5 4622.1050 GENERATOR MANAGEMENT PLAN RENEWAL, RESUBMISSION.

6 A generator must update and resubmit a generator management
7 plan on January 1 of each even-numbered year.

8 A. A generator management plan must be submitted for
9 renewal at least 30 days before the expiration of the previous
10 generator management plan.

11 B. During the period the plan is in effect, a
12 generator must notify the commissioner if the facility ceases
13 operation.

14 C. The generator must submit a revised plan to the
15 commissioner if:

16 (1) the generator opens a satellite facility not
17 previously identified in the generator management plan; or

18 (2) the generator materially changes the
19 infectious waste management system including changes in the
20 method of waste decontamination.

21 4622.1100 FEES.

22 A generator management plan must be submitted to the
23 commissioner with the fee required by Minnesota Statutes,
24 section 116.79, subdivision 3.

25 A. If a generator management plan covers more than
26 one facility, the appropriate fee for each facility must be paid
27 pursuant to Minnesota Statutes, section 116.79, subdivision 3.

28 B. If a hospital and nursing home are a single
29 facility, the fee is determined by the total number of licensed
30 beds and based on the fee for a hospital.

31 C. The fee for a generator at a facility staffed by a
32 practitioner, other than one specified in Minnesota Statutes,
33 section 116.79, subdivision 3, paragraph (b), clause (1) or (2),
34 must be in accordance with the fee specified in Minnesota
35 Statutes, section 116.79, subdivision 3, paragraph (b), clause

1 (1) or (2), if the facility does not come under any other
2 provision of Minnesota Statutes, section 116.79, subdivision 3,
3 paragraph (b). Practitioners other than those specified in
4 Minnesota Statutes, section 116.79, subdivision 3, paragraph
5 (b), clause (1) or (2), include nurses, laboratory or blood bank
6 technologists and technicians, phlebotomists, dialysis
7 personnel, medical technicians, physical therapists, and x-ray
8 technicians.

9 D. A facility providing phlebotomy services only
10 shall pay a fee in accordance with Minnesota Statutes, section
11 116.79, subdivision 3, paragraph (b), clause (1) or (2).

12 4622.1150 GENERATOR MANAGEMENT PLAN REVIEW.

13 The commissioner shall select generator management plans
14 for review in accordance with standard procedures for random
15 sample selection.

16 A. On review of an infectious waste generator
17 management plan under Minnesota Statutes, section 116.79, the
18 commissioner may require a generator to modify the infectious
19 waste generator management plan if the commissioner determines
20 the plan does not comply with parts 4622.0100 to 4622.1200.

21 B. On determination that the plan does not comply
22 with parts 4622.0100 to 4622.1200, the commissioner shall notify
23 the generator in writing of the commissioner's determination and
24 specify the modifications necessary for compliance.

25 C. The generator must modify the plan to comply with
26 parts 4622.0100 to 4622.1200 within 20 working days after
27 receipt of the notice from the commissioner.

28 4622.1200 REMEDIES AND PENALTIES.

29 A generator who fails to submit a plan or fee or manage
30 infectious waste and pathological waste in accordance with
31 Minnesota Statutes, sections 116.76 to 116.83, and parts
32 4622.0100 to 4622.1200 is subject to the procedures, remedies,
33 and penalties specified in Minnesota Statutes, sections 115.071
34 and 116.072.

1 4655.9070 HOUSEKEEPING RULES APPLICABLE ONLY TO NURSING HOMES.

2 [For text of subpart 1, see M.R.]

3 Subp. 2. Management of special waste. Infectious waste
4 and pathological waste as defined in Minnesota Statutes, section
5 116.76, must be managed according to Minnesota Statutes,
6 sections 116.76 to 116.83, and parts 4622.0100 to 4622.1200.

7 [For text of subp 3, see M.R.]

8 4675.2205 INFECTIOUS WASTE AND PATHOLOGICAL WASTE.

9 Infectious waste and pathological waste as defined in
10 Minnesota Statutes, section 116.76, must be managed according to
11 Minnesota Statutes, sections 116.76 to 116.83 ~~and 145.1621~~ and
12 parts 4622.0100 to 4622.1200. Pathological waste does not
13 include the remains specified in Minnesota Statutes, section
14 145.1621 and such remains must be handled in accordance with
15 that statute.

16 REPEALER. Minnesota Rules, parts 4675.2200, 4675.2300,
17 4675.2400, 4675.2500, and 4675.2600, are repealed.