

WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Form #7

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: Department of Health and Human Resources TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code §§20-5J-6(a) and 20-5E-7(d)

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES _____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED _____

IF NO, SERIES NUMBER OF RULE BEING FILED AS AN EMERGENCY: 56

TITLE OF RULE BEING FILED AS AN EMERGENCY: Infectious Medical Waste

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 35TH DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

W. Va. Code §20-5J-5(b) states that: "On or after the first day of October, one thousand nine hundred ninety-one, no person may own, construct, modify, operate or close any facility or site for the treatment, storage or disposal of infectious medical waste, nor shall any person store, treat or dispose of any such infectious medical waste without first obtaining a permit from the secretary, unless specifically excluded or exempted by rules promulgated by the secretary."

Tanja Willis Miller

Tanja Willis Miller, Secretary

Use Additional Sheets If Necessary.

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Furthermore, W. Va. Code §20-5J-6(a) requires that the Secretary of Health and Human Resources promulgate rules necessary to effectuate the "findings and purposes" of W. Va. Code §20-5J-1 et seq. Two specific dates for particular rules are given, August 1, 1991 for rules giving terms and conditions of permits; September 5, 1991 for rules to effectuate the purposes of the legislative findings and determinations. The Secretary of the Department of Health and Human Resources therefore hereby files the attached proposed rule, Infectious Medical Waste, 64 CSR 56, on an emergency basis and requests your approval of this emergency filing, in order to comply with a time limit set by the State Legislature as cited above. The rule is also being filed for a public hearing on October 3, 1991.

DATE: September 3, 1991
TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE
FROM: Department of Health and Human Resources
EMERGENCY RULE TITLE: Infectious Medical Waste

1. Date of filing: September 3, 1991
2. Statutory authority for promulgating the emergency rule:
W. Va. Code §§20-5J-6(a) and 20-5E-7(d)
3. Date of filing of proposed legislative rule: Sept. 3, 1991
4. Does the emergency rule adopt new language or does it amend or repeal a current legislative rule?
Adopts new language.

5. Has the same or similar emergency rule previously been filed and expired?
No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the immediate preservation of public peace, health, safety or welfare.
See attached Notice

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

See attached Notice

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

See attached Notice

[EMERGENCY]

TITLE 64

WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

INFECTIOUS MEDICAL WASTE

SERIES 56

1991

[EMERGENCY]
WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
INFECTIOUS MEDICAL WASTE
64 CSR 56

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[EMERGENCY]
TITLE 64
WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
SERIES 56
INFECTIOUS MEDICAL WASTE

§64-56-1. General.

1.1. Preamble.

It is the intent of the department of health and human resources to provide effective controls for the management of infectious medical waste to ensure the protection of public health, safety and welfare and the environment, consistent with legislative policy stated as follows in W. Va. Code §20-5J-2:

"The Legislature finds that the proper and environmentally-sound disposal of medical waste and infectious and noninfectious medical waste is an important issue facing all West Virginians.

The Legislature further finds that effective controls for the management of medical waste are necessary to ensure the protection of the public health, safety and welfare, and the environment.

The Legislature further finds that regulation of the generation, handling, storage, transportation, treatment and disposal of medical waste is an important and necessary function of state government.

The Legislature further finds that toxic pollutants emitted by medical waste incinerators are an important public health hazard.

The Legislature further finds that commercial incineration of medical waste, and its transportation in the infectious state, pose a potentially serious threat to the health, safety and welfare of West Virginians.

The Legislature further finds that safe and cost-effective alternatives to the incineration of infectious and noninfectious medical waste should be encouraged.

The Legislature further finds that the public interest is best served by:

(1) Efforts to reduce the volume of medical waste generated at all levels;

(2) On-site separation and treatment of infectious medical waste;

(3) Treatment and disposal of infectious medical waste in local infectious medical waste management facilities; and

(4) Treatment and disposal in approved regional infectious waste management facilities when administrative proceedings result in a finding that on-site or local treatment of infectious medical waste is not feasible.

The Legislature further finds that local responsibility for the minimization in volume, and for the treatment and disposal of infectious and noninfectious medical waste is an important part of a sound and rational waste management program.

The Legislature further finds that small quantity generators of infectious medical waste should either render such waste noninfectious on-site, or properly label and package the waste for transportation to a local infectious waste management facility for proper treatment and disposal.

The Legislature further finds that generators of medical waste should be informed and educated in its management; that training should be provided to all workers likely to come in contact with medical waste, including in-home health care workers; and that relevant information on the potential for infection and disease related to medical waste should be made available to the general public, including in-home health care patients.

The Legislature further finds that the necessity for transporting infectious medical waste be minimized, and that any infectious medical waste transported be safely packaged and identified by source and content:

The Legislature further finds that public policy favors a reduction in the volume of infectious and noninfectious medical waste, the separation of infectious medical waste from noninfectious medical waste, and that efforts to reduce medical waste should be fostered and strongly encouraged at all levels of generation.

The Legislature further finds that noninfectious medical waste is solid waste.

The Legislature further finds that noninfectious medical waste should be handled by environmentally sound disposal technologies, and that alternative disposal technologies promoting safe recycling and limiting the need for incineration should be emphasized, developed and utilized.

Therefore, it is the policy of the State of West Virginia to prohibit commercial infectious medical waste facilities; to regulate and control the generation,

handling, storage, transportation, treatment and disposal of infectious and noninfectious medical waste; to reduce the generation of infectious and noninfectious medical waste; to encourage local responsibility for the minimization, management and disposal of infectious and noninfectious medical waste; and to authorize the department of health and human resources to promulgate rules and regulations necessary to carry out the purposes of this article."

1.2. Scope.

This legislative rule establishes requirements regarding the generation, handling, storage, transportation, treatment and disposal of infectious medical waste.

1.3. Authority.

W. Va. Code §§20-5J-6(a) and 20-5E-7(d). Related - W. Va. Code §§20-5J-1 et seq. and 20-5E-11, 12, 13, 14, 15, 16 and 17.

1.4. Filing Date - September 3, 1991.

1.5. Effective Date -

§64-56-2. Applicability; Exemptions; Enforcement.

2.1. Applicability.

This rule applies to any person who generates, handles, stores, transports, treats or disposes of infectious medical waste except as specified in Section 2.2 of this rule.

2.2. Exemptions.

2.2.1. Individual households in which infectious medical waste is generated by a member of the household during self health care or by the provision of health care services within the residence shall be exempt from the requirements of this rule, except that the householder shall place sharps in a container with a high degree of puncture resistance prior to discarding them.

2.2.2. Ambulance or rescue services shall be exempt from the requirements of this rule, except that all infectious medical waste generated in an ambulance or rescue vehicle shall be packaged as required by Section 6.2 of this rule and delivered to a permitted infectious medical waste management facility.

2.3. Enforcement.

This rule is enforced by the secretary of the State department of health and human resources.

§64-56-3. Definitions.

3.1. **Animal Carcasses, Body Parts, Bedding and Related Wastes** - Contaminated animal carcasses, body parts, and bedding of animals that are known to have been exposed to infectious agents during research, production of biologicals, testing of pharmaceuticals, or for any other reason.

3.2. **Blood and Blood Products** - Liquid waste human blood and blood products in a free-flowing or unabsorbed state.

3.3. **Commercial Infectious Medical Waste Facility** - Any infectious medical waste management facility at which thirty-five per cent (35%) or more by weight of the total infectious medical waste stored, treated, or disposed of by said facility in any calendar year is generated off-site.

3.4. **Cultures and Stocks of Microorganisms and Biologicals** - Discarded cultures, stocks, specimens, vaccines and associated items likely to have been contaminated by an infectious agent. Discarded etiologic agents are infectious medical waste. Wastes from the production of biologicals and antibiotics likely to have been contaminated by an infectious agent are infectious medical waste.

3.5. **Disposal** - The discharge, deposit, injection, dumping, spilling, leaking or placing of any infectious medical waste into or on any land or water so that such infectious medical waste, or any constituent thereof, may be emitted into the air, discharged into any waters, including groundwater, or otherwise enter into the environment. (See Section 5.7 of this rule.)

3.6. **Generator** - Any person, by site location, whose act or process produces infectious medical waste.

3.7. **Hospital** - An institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic and therapeutic services for medical diagnosis, treatment and care of injured, disabled or sick persons or services for the rehabilitation of injured, disabled or sick persons. This term also includes psychiatric and tuberculosis hospitals.

3.8. **Infectious Agent** - Any organism such as a virus or a bacteria that is in such quantity that it is capable of being communicated by invasion of and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.

3.9. **Infectious Medical Waste.**

3.9.1. Infectious medical waste is medical waste which is capable of producing an infectious disease. Infectious medical waste shall be considered capable of producing an infectious disease if it has been, or is likely to have been, contaminated by

an organism likely to be pathogenic to healthy humans, if such organism is not routinely and freely available in the community, and such organism has a significant probability of being present in sufficient quantities and with sufficient virulence to transmit disease.

3.9.2. For the purposes of this rule, infectious medical waste includes the following materials:

3.9.2.1. Cultures and stock of microorganisms and biologicals;

3.9.2.2. Blood and blood products;

3.9.2.3. Pathological wastes;

3.9.2.4. Sharps;

3.9.2.5. Animal carcasses, body parts, bedding and related wastes;

3.9.2.6. Isolation wastes;

3.9.2.7. Any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any infectious medical waste; and

3.9.2.8. Waste contaminated by or mixed with infectious medical waste.

3.9.3. For the purposes of this rule, infectious medical waste does not include the following materials:

3.9.3.1. Human remains and body parts being used or examined for medical purposes which are under the control of a licensed physician or dentist and are not abandoned materials;

3.9.3.2. Human remains lawfully interred in a cemetery or in preparation by a licensed mortician for such interment or cremation;

3.9.3.3. Used personal hygiene products, such as diapers, facial tissues and sanitary napkins;

3.9.3.4. Gauze and dressing material, containing small amounts of blood or other body secretions with no free flowing or unabsorbed liquid;

3.9.3.5. Hair, nails, and extracted teeth; and

3.9.3.6. Waste generated by veterinary hospitals, except for waste meeting the criteria found in Sections 3.9.1, 3.9.4, or 3.9.5 of this rule.

3.9.4. Infectious medical waste contaminated with radioactive waste is considered to be radioactive waste and is subject to State and federal law and regulation as radioactive waste.

3.9.5. Infectious waste contaminated with hazardous chemical waste is considered to be hazardous chemical waste and is subject to State and federal law and regulation as hazardous chemical waste.

3.10. Infectious Medical Waste Management Facility - An infectious medical waste facility which generates, handles, processes, stores, treats or disposes of infectious medical waste, including all land and structures, other appurtenances, and improvements thereon, used for infectious medical waste.

3.11. Isolation Wastes - Wastes generated from the care of a patient who has or is suspected of having any disease listed as Class IV in "Classification of Etiologic Agents on the Basis of Hazard," published by the United States Centers for Disease Control.

3.12. Medical Waste - Infectious and noninfectious solid waste generated in the course of the diagnosis, treatment or immunization of human beings or animals, or in research pertaining thereto, or in the production or testing of biologicals. Such term does not include low-level radioactive waste, any hazardous waste identified or listed under Subtitle C, or any household waste as defined in the regulations promulgated pursuant to Subtitle C.

3.13. Manifest - The form used for identifying the quantity, composition, and the origin, routing, and destination of infectious medical waste during its transportation from the point of generation to the point of off-site treatment or disposal.

3.14. Non-commercial Infectious Medical Waste Facility - Any infectious medical waste facility at which less than thirty-five per cent (35%) by weight of the total infectious medical waste stored, treated or disposed of by said facility in any calendar year is generated off-site.

3.15. Noninfectious Medical Waste - Any medical waste not capable of producing an infectious disease or infectious medical waste which has been rendered noninfectious. Noninfectious medical waste is considered solid waste for purposes of this rule.

3.16. Off-Site - A facility or area for the collection, storage, transfer, processing, treatment, or disposal of infectious medical waste which is not on the generator's site, or a facility or area that receives infectious medical waste for storage or treatment that has not been generated on-site at that facility or area.

3.17. On-Site - The same or geographically contiguous prop-

erty which may be divided by a public or private right-of-way, provided the entrance and exit between the properties is at a cross-roads intersection, and access is by crossing, as opposed to going along, the right-of-way. Non-contiguous properties owned by the same person but connected by a right-of-way controlled by said person and to which the public does not have access, is also considered on-site property. Hospitals with more than one (1) facility located in the same county shall be considered one (1) site.

3.18. **Pathological Waste** - Human pathological wastes, including tissues, organs, body parts, and containers of body fluids, exclusive of those fixed in formaldehyde or another fixative.

3.19. **Person** - Individual, partnership, corporation or other legal entity.

3.20. **Secretary** - The secretary of the department of health and human resources or his or her designee.

3.21. **Sharps** - Discarded articles that may cause punctures or cuts and that have been used in animal or human patient care or treatment, or in pharmacies or medical, research or industrial laboratories, including, but not limited to, hypodermic needles, syringes with attached needles, scalpel blades, lancets and broken glassware.

3.22. **Small Quantity Generator** - Any generator of infectious medical waste who generates fifty (50) pounds or less during a one (1) month period.

3.23. **Storage** - The containment of infectious medical waste on a temporary basis. Storage shall not constitute disposal of the waste. The containment of infectious medical waste during off-site transport is considered to be a form of storage.

3.24. **Subtitle C** - Subtitle C of the federal Resource Conservation and Recovery Act of 1976, 90 Stat. 2806, as amended.

3.25. **Transport** - The movement of infectious medical waste from one location to another, except for on-site movement of infectious medical waste.

3.26. **Transporter** - A person engaged in the off-site transportation of infectious medical waste.

3.27. **Transport Vehicle** - A motor vehicle, aircraft, boat, barge or rail car used for the transportation of cargo by any mode. Each cargo-carrying body shall be considered a separate transport vehicle.

3.28. **Treatment** - Any method, technique or process, including neutralization, designed to change the physical, chemical or

biological character or composition of any infectious medical waste so as to render such waste noninfectious.

§64-56-4. General Permit Application and Approval Procedures.

4.1. On or after the first day of October, one thousand nine hundred ninety-one, no person may own, construct, modify or operate an infectious medical waste management facility, nor shall any person store, treat or dispose of any infectious medical waste without first obtaining a permit for such facility from the secretary, unless exempted by Sections 2.1, 2.2 or 4.15 of this rule.

4.2. No person shall begin physical construction of a new infectious waste management facility without having received a permit.

4.3. The owner of an infectious medical waste management facility shall be responsible for insuring that the facility has a permit.

4.4. An application for a permit shall be submitted to the secretary in duplicate on forms prescribed by the secretary and shall include the following:

4.4.1. The name, mailing address, and location of the facility for which the application is submitted;

4.4.2. The name, address and telephone number of the owner of the facility;

4.4.3. The name, address, and telephone number of the manager of the facility, if different from the owner; and

4.4.4. A proposed infectious medical waste management plan as required by Section 5 of this rule.

4.5. For new infectious medical waste management facilities, the application shall be accompanied by two (2) copies of a topographic map showing the facility and the area one thousand (1,000) feet around the facility site, which clearly shows the following:

4.5.1. The map scale and date;

4.5.2. Land uses (e.g., residential, commercial, agricultural, recreational);

4.5.3. The orientation of the map (north arrow);

4.5.4. The legal boundaries of the facility site;

4.5.5. Access control (fences, gates); and

4.5.6. Buildings to be used for treatment, storage, and disposal operations and other structures (e.g. recreation areas, run-off control systems, access and internal roads, storm, sanitary, and process sewerage systems, loading and unloading areas, fire control facilities).

4.6. Infectious medical waste management facilities in operation at the time this rule becomes effective shall submit an application for a permit which shall contain the information required in Section 4.4 of this rule and an infectious medical waste management plan as required by Section 5 of this rule. An application from an existing facility which is complete except for the infectious medical waste management plan may be used by the secretary to grant an interim permit for a period no longer than one hundred twenty (120) days for the facility to develop and submit its infectious medical waste management plan for review and approval. A decision to grant an interim permit shall be based on the size and complexity of the plan required.

4.7. The secretary shall not begin the evaluation of a permit before receiving a complete application, including any supplemental information requested under Section 4.9 of this rule. The completeness of a permit application shall be judged independently of the status of any other permit application or permit for the same facility or activity.

4.8. The secretary shall not issue a permit before receiving a complete application.

4.9. The secretary shall have the authority to request supplemental information needed to demonstrate that the facility will be operated in compliance with this rule.

4.10. Permits shall be renewed annually prior to expiration. An application for permit renewal shall be submitted forty-five (45) days prior to the expiration date of the previous permit.

4.11. An application for an original or renewal permit shall be accompanied by a non-refundable application fee according to the schedule shown in Table 64-56A found at the end of this rule.

4.12. A permit shall be issued if the facility is, or in the case of a projected facility, is planned to be, in compliance with the applicable provisions of this rule and has submitted the application fee.

4.13. The secretary may refuse to grant or renew a permit if an applicant or permittee has attempted to obtain a permit by means of fraud, deceit or material misrepresentation.

4.14. A permittee shall submit an application for approval of a major change in the permittee's infectious medical waste management plan before implementing the change. Minor changes in

the infectious medical waste plan may be made without notifying the secretary and shall be included in the next application for permit renewal. All major changes shall be approved prior to implementation. An application for approval of any change in conditions described in the permittee's infectious medical waste management plan which is beyond the permittee's control shall be submitted to the secretary within fifteen (15) days of its occurrence.

4.15. Small quantity generators who generate infectious medical waste in the provision of health care services in their own office are not required to obtain a permit. Small quantity generators shall keep their infectious medical waste management plan on file and shall make a copy available to the secretary on request.

§64-56-5. Infectious Medical Waste Management Plan.

5.1. All infectious medical waste management facilities shall develop an infectious medical waste management plan.

5.2. The infectious medical waste management plan shall set forth policies and procedures for managing infectious medical waste which are consistent with this rule and shall include, at a minimum, the following:

5.2.1. A projection of the weight of the infectious medical waste which will be generated monthly;

5.2.2. A description of infectious and noninfectious medical waste handling, storage, separation and volume-reduction procedures;

5.2.3. The methods which will be used to treat the infectious medical waste;

5.2.4. Transportation method;

5.2.5. Manifest systems and labeling;

5.2.6. Disposal methods consistent with Section 10.4 of this rule;

5.2.7. The name, address, telephone number, and public service commission or other permit or license number of any infectious medical waste transporter, if applicable;

5.2.8. Personnel training procedures, including an outline of training programs, in-service training, refresher training, and other training, including procedures for the certification of personnel at infectious medical waste management facilities or sites;

5.2.9. The name, address, and telephone number of the person

responsible for infectious medical waste management at the generator or the facility, and the name, address and telephone number of an alternate person to contact in the event the manager is not available;

5.2.10. Policies requiring that no infectious medical waste will be knowingly transported or knowingly received by the generator or facility without being packaged and labeled in accordance with this rule;

5.2.11. Contingency plans for effective action to minimize damage from any interruption in treatment, storage or disposal of infectious medical waste;

5.2.12. A description of the procedures used to:

5.2.12.1. Prevent hazards in unloading operations;

5.2.12.2. Prevent run-off from infectious medical waste handling areas to other areas of the facility or environment;

5.2.12.3. Prevent contamination of water supplies;

5.2.12.4. Mitigate effects of equipment failure and power outages; and

5.2.12.5. Prevent exposure of personnel to infectious medical waste;

5.2.13. Procedures for continuity of operations during a change of ownership;

5.2.14. Any other information pertinent to the evaluation of compliance with this rule.

5.3. Infectious medical waste management facilities which are willing to accept infectious medical waste generated off-site for treatment shall also include the following in their infectious medical waste management plan:

5.3.1. Procedures for receiving off-site infectious medical waste which are consistent with this rule;

5.3.2. A statement that in any calendar year the facility will not knowingly receive from off-site more than thirty-five (35) percent by weight of the total amount of infectious medical waste treated at the facility;

5.3.3. A statement that the facility will not knowingly accept any infectious medical waste which is not properly packaged and labeled in accordance with Section 6 of this rule;

5.3.4. Procedures for keeping records in accordance with

Section 13 of this rule;

5.3.5. Procedures for returning manifests to the generator after treatment of the infectious medical waste;

5.3.6. Procedures for reporting to the secretary as required by this rule; and

5.3.7. Procedures to be followed for closure of the facility including, but not limited to, notification of all facilities using the treatment service thirty (30) days prior to closure.

5.4. The secretary may grant a period of no more than two (2) years for an infectious medical waste management facility in existence as of the effective date of this rule to develop a proposal to modify or upgrade the treatment process being used. Such plans shall be considered to be part of the facility's infectious medical waste management plan.

5.5. The infectious medical waste management plan shall comply with this rule.

5.6. Infectious medical waste management facilities shall operate in compliance with their infectious medical waste management plan as approved by the secretary.

5.7. Disposal of infectious medical waste in this State is prohibited, except as described in Section 10.4 of this rule.

§64-56-6. Packaging and Labeling.

6.1. General.

6.1.1. The generator of infectious medical waste shall be responsible for ensuring that the packaging and labeling of infectious medical waste is in compliance with this rule and any other applicable state or federal laws or regulations.

6.1.2. Contractors or other agents may provide services to the generator, including packaging and labeling of infectious medical waste: Provided, however, That no contract or other relationship shall relieve the generator of the responsibility for packaging and labeling the infectious medical waste as required by this rule.

6.1.3. No person shall knowingly accept for transportation, storage, treatment or disposal any infectious medical waste that is not packaged and labeled in accordance with this rule. Contractors or other agents may package or repackage infectious medical waste to comply with this rule, if the packaging or repackaging is performed on-site where the infectious medical waste was generated and if no storage or treatment occurs prior to the packaging or repackaging. Nothing in this section shall prevent the proper

repackaging and further transportation of infectious medical waste that has spilled during transportation.

6.2. Packaging.

6.2.1. All infectious medical waste shall be packaged as required by this rule prior to storage, treatment, or transport.

6.2.2. Infectious medical waste shall be contained and sealed on-site in leak-proof, plastic bags capable of passing the American Society for Testing and Materials drop weight test (ASTM-D-959-80) or, in three (3) mil plastic bags or containers with equivalent containment properties. Free liquids shall be contained in break-resistant, tightly stoppered containers. Heavier materials shall be supported in double-walled corrugated fiberboard boxes or equivalent rigid containers.

6.2.3. Sharps shall be collected at the point of generation in rigid, leak-proof and puncture-resistant containers clearly marked as infectious medical waste. Containers shall be compatible with selected treatment processes to preclude contact with waste materials, and sealed before handling. Sharps containers shall not be completely filled.

6.2.3.1. If the sharps are to be stored or treated off-site, such containers shall be placed inside a plastic bag as specified in Section 6.2.2 of this rule. Prior to storage, the plastic bags shall be bound at the gathered open end with tape or another closing device such that prevents leakage of liquids.

6.2.3.2. Sharps which are rendered noninfectious and encapsulated in a solid state on-site may be discarded as solid waste. The encapsulated container shall be labeled in accordance with Section 6.3.2 of this rule.

6.2.4. All bags containing infectious medical waste shall be red in color except that infectious medical waste that is to be steam treated shall be contained in orange bags and marked with autoclave tape or other heat-activated ink which will indicate whether or not the appropriate temperature, as required by this rule, has been reached. Both red and orange bags shall be imprinted with the international biohazard symbol and the words "infectious medical waste" or "biomedical waste" or "biohazard". Waste contained in red bags shall be considered infectious medical waste and managed as infectious medical waste. Waste contained in orange bags shall be managed as infectious medical waste prior to steam treatment and as solid waste after steam treatment, but shall not be removed from the orange bags.

6.2.5. In addition to other packaging, all infectious medical waste which is to be transported off-site shall also be packaged in double-wall corrugated fiberboard boxes or equivalent rigid containers. The boxes or containers shall be leak-resistant or

lined with a tear-resistant leak-proof plastic bag.

6.2.6. Reusable containers shall be leak-proof and vermin-proof, shall have tight-fitting covers, and shall be kept clean and in good repair. Reusable containers shall be thoroughly washed and disinfected if they are contaminated by or come in contact with improperly contained medical waste items, unless the surfaces of the containers have been protected from contamination by disposable liners, bags or other devices. Such disposable liners, bags or other devices shall be removed and handled as infectious medical waste. Red or orange bags may not be enclosed in a bags of different colors.

6.2.7. Disinfection of the container shall be accomplished by one of the following methods:

6.2.7.1. Immersion in hot water at a temperature of at least one hundred and eighty degrees Fahrenheit (180° F) for a minimum of thirty (30) seconds;

6.2.7.2. Exposure to a chemical sanitizer by immersion in one of the following for a minimum of thirty (30) seconds: hypochlorite solution of one hundred parts per million (100 ppm) available chlorine; iodoform solution of twenty-five parts per million (25 ppm) available iodine; or quaternary ammonium solution of two hundred parts per million (200 ppm) active agent; or

6.2.7.3. Swabbing or rinsing the container with a chemical sanitizer double the strength specified in Section 6.2.7.2 of this rule or a chemical with equivalent sanitizing capabilities.

6.2.8. Individuals packaging infectious medical waste shall use protection as specified in the Personnel Protection Equipment section of the Occupational Safety and Health Administration Bloodborne Pathogen Standards and found at 29 CFR PART 1910.1030.

6.3. Labeling Requirements.

6.3.1. Infectious medical waste shall be labeled prior to being stored on-site or transported off-site. The label shall be securely attached to the outer layer of packaging and shall be clearly legible. The label may be a tag securely affixed to the package. Indelible ink shall be used to complete the information on the label, and the label shall be at least three (3) inches by five (5) inches in size. The following information shall be included on the label:

6.3.1.1. The name, address and business telephone number of the generator;

6.3.1.2. "Infectious medical waste" or "bio-medical waste" or "bio-hazard";

6.3.1.3. The name, address and business telephone number of all transporters, treatment facilities, or other persons to whose control the infectious medical waste is being transferred and the permit numbers of transporters, if applicable;

6.3.1.4. The date on which the infectious medical waste was packaged; and

6.3.1.5. The weight of the infectious medical waste.

6.3.2. Recognizable treated noninfectious medical waste shall be labeled prior to being transported off-site. The label shall be sized and attached as required by Section 6.3.1 of this rule. The following information shall be included on the label:

6.3.2.1. The name, address and business telephone number of the generator;

6.3.2.2. The name, address, and business telephone numbers of the facility at which the waste was rendered noninfectious;

6.3.2.3. The weight of the treated noninfectious medical waste and the method of treatment;

6.3.2.4. A signed and dated certification by the facility at which the waste was rendered noninfectious which states: "I hereby certify under penalty of law that this waste is not infectious medical waste, as defined in Solid Waste Management, 47 CSR 38, Section 2.28, or has been rendered noninfectious in accordance with procedures required by Infectious Medical Waste, 64 CSR 56."

§64-56-7. Management of Spills of Infectious Medical Waste.

7.1. All infectious medical waste management facilities shall keep a spill containment and cleanup kit within the vicinity of any area where infectious medical waste is managed on a bulk storage basis. The location of the kit shall provide for rapid and efficient cleanup of spills anywhere within the area. All vehicles transporting infectious medical waste shall carry a spill containment and cleanup kit in the vehicle whenever infectious medical waste is conveyed.

7.1.1. For facilities, the kit shall contain an amount of absorbent material sufficient to have a rated capacity of one (1) gallon of liquid for every cubic foot of infectious medical waste that is normally managed in the area for which the kit is provided or ten (10) gallons, whichever is less. For vehicles transporting infectious medical waste, the amount of absorbent material contained in the kit shall be sufficient to have a rated capacity to absorb ten (10) gallons of liquid for every cubic foot of infectious medical waste that is transported.

7.1.2. The kit shall contain one (1) gallon of hospital grade

disinfectant in a sprayer capable of dispersing its charge in a mist or in a stream at a distance. The disinfectant shall be hospital-grade and effective against myco bacteria.

7.1.3. The kit shall contain enough red plastic bags to enclose one hundred and fifty percent (150%) of the maximum load accumulated or transported. The bags shall meet the American Society for Testing and Materials drop weight test (ASTM-D-959-80) or shall be three (3) mils thick or the equivalent and shall be accompanied by sealing tape or devices and labels or tags. These bags shall be large enough to enclose any box or other container normally used for infectious medical waste management by that facility or carried by a transport vehicle.

7.1.4. The kit shall contain two (2) new sets of overalls, gloves, boots, caps and protective eye and breathing devices and tape for sealing wrists and ankles. The overalls, boots and caps shall be oversized or fitted to the infectious medical waste workers or transporters, and shall be made of materials impermeable to liquids. Boots may be of thick rubber and gloves shall be of heavy neoprene or equivalent material. Boots, gloves and breathing devices may be reused if disinfected between uses.

7.1.5. The kit shall contain an adequate first aid kit and one hundred (100) feet of boundary marking tape.

7.2. Immediately following a spill of infectious medical waste or its discovery, all individuals present shall leave the area until any aerosol settles.

7.3. The cleanup crew shall implement the following procedures for cleaning up a spill:

7.3.1. Put on cleanup outfits as described in Section 7.1.4 of this rule and secure the spill area from entry by unauthorized persons;

7.3.2. Spray all broken containers of infectious medical waste with disinfectant;

7.3.3. Place broken containers and spillage in the packing bags in the kit;

7.3.4. Disinfect and take other steps necessary to clean up the area;

7.3.5. Clean and disinfect non-disposable items;

7.3.6. Remove cleanup outfits and place disposable items in a cleanup bag; and

7.3.7. Take prompt steps to initiate procedures for the replenishment of the containment and cleanup kit.

7.4. When a spill involves a single container of infectious medical waste with a weight of less than fifty (50) lbs. and a volume of spilled liquid of less than one (1) quart, the individual responsible for the cleanup may elect to use dress and procedures other than those required by Section 7.1.4 of this rule. Any proposed alternate procedures for small quantity spills shall be specified in the infectious medical waste management plan and shall provide protection to the health of workers and the public equivalent to that provided by the procedures specified in Section 7.2 of this rule.

§64-56-8. Storage of Infectious Medical Waste.

8.1. This section is applicable to the storage of infectious medical waste at any time after packaging, including time spent during transportation and at all treatment and disposal sites or facilities.

8.2. Infectious medical waste other than sharps shall not be stored for more than thirty (30) days, even if refrigerated.

8.3. Infectious medical waste shall be stored in a specifically designated area located at or near the treatment site, or at the pickup point if it is to be transported off-site for treatment.

8.4. The manner of storage shall maintain the integrity of the containers; prevent the leakage of waste from the container; provide protection from water, rain and wind, and maintain the waste in a non-putrescent state.

8.5. All storage areas shall be constructed of materials which are durable, easily cleanable, impermeable to liquids, and vermin-proof.

8.6. Carpets and floor coverings with seams shall not be used in storage areas. All floor drains shall discharge directly to a sanitary sewage disposal system which is in compliance with Sewage System Rules, 64 CSR 9.

8.7. All storage areas shall be kept clean and in good repair.

8.8. All storage areas shall have access control that limits access to those persons specifically designated to manage infectious medical waste. Such areas shall be posted prominently with the international biohazard symbol and with warning signs located adjacent to the exterior of entry doors, gates or lids which indicate the use of the area for storage of infectious medical waste and that entry to unauthorized persons is denied.

8.9. Infectious medical waste shall not be placed in chutes at any time.

8.10. Compaction of infectious medical waste or subjecting infectious medical waste to violent mechanical action is prohibited unless as a part of a specific treatment process approved by the secretary.

§64-56-9. Transportation.

9.1. This section applies to all transportation of infectious medical waste over roads or highways within West Virginia, regardless of point of origin or intended disposal, except as specified in Sections 9.2 and 9.3 of this rule.

9.2. A small quantity generator may transport his or her infectious medical waste to a permitted infectious medical waste management facility or may arrange for transport by his or her employee as follows:

9.2.1. An employee who transports the infectious medical waste shall be trained in the proper handling of infectious medical waste as required by this rule; and

9.2.2. The infectious medical waste shall be delivered within forty-five (45) days of its generation.

9.3. A generator that transfers infectious medical waste on-site shall be exempt from Sections 9.9, 9.10, 9.11 and 9.12 of this rule: Provided, That:

9.3.1. On-site transfer of infectious medical waste is covered in the infectious medical waste management plan; and

9.3.2. No off-site infectious medical waste is knowingly and routinely accepted for on-site transfer.

9.4. No person shall knowingly receive for transportation any infectious medical waste that is not packaged and labeled in accordance with Section 6 of this rule.

9.5. A transporter shall deliver infectious medical waste in West Virginia only to a permitted infectious medical waste management facility. Transporters of infectious medical waste out of state shall transport it to a facility permitted by the receiving jurisdiction.

9.6. All vehicles transporting infectious medical waste shall be prominently identified while transporting such infectious medical waste with the following, except for vehicles used as specified in Sections 9.2 and 9.3 of this rule:

9.6.1. The international biohazard symbol;

9.6.2. The words "infectious medical waste", or "biomedical waste", or "biohazard";

9.6.3. The number of the transporter's permit issued by the secretary; and

9.6.4. If applicable, a placard in accordance with United States Department of Transportation requirements. Removable signs are acceptable.

9.7. Vehicles that transport infectious medical waste:

9.7.1. Shall include a cargo-carrying portion that shall be closed and secured except when loading or unloading infectious medical waste to prevent unauthorized access and exposure to wind and precipitation;

9.7.2. Shall be designed and constructed so as to contain any spillage;

9.7.3. Shall be cleaned and disinfected following leakage or spills as provided in Section 6.2.7.3 of this rule;

9.7.4. Shall be cleaned and disinfected prior to using the conveyance for any other purpose as provided in Section 6.2.7.3 of this rule; and

9.7.5. Shall not be used to transport food, foodstuffs, food additives, food containers or any substances to be ingested by people or animals or applied to food or feed.

9.8. All vehicles transporting infectious medical waste shall carry a spill containment and cleanup kit as required by Section 7 of this rule in the vehicle whenever infectious medical waste is conveyed. Spills of infectious medical waste during transportation shall be managed as required by Sections 7.2 and 7.3 of this rule. Direct physical contact of the transport vehicle or equipment with infectious medical waste shall be considered and managed as a spill.

9.9. No person shall transport infectious medical waste in West Virginia for another who does not possess a permit issued by the secretary, and, if applicable, valid authority issued by the public service commission. Permits issued by the secretary shall not be transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation.

9.10. An application for a permit to transport infectious medical waste shall be made in writing to the secretary on a form prescribed by the secretary. The application form shall be signed by the applicant or his or her authorized representative. The application shall contain at a minimum the following:

9.10.1. The applicant's name;

9.10.2. The business address and telephone number of the applicant, including both headquarters and local office;

9.10.3. The make, model and license number of each vehicle to be used to transport infectious medical waste within West Virginia;

9.10.4. The counties and cities in West Virginia in which the transporter will operate;

9.10.5. The name of any person or firm other than reported in Section 9.10.1 of this rule that is associated with the applicant or any other name under which that person or firm does business;

9.10.6. The name of any other person or firm using any of the same vehicles and operators;

9.10.7. The name and telephone number of a person who may be contacted in the event of an accident or spill;

9.10.8. Verification that the applicant has established a program of training for employees involved in the transportation of infectious medical waste as required by this rule; and

9.10.9. Designation of the treatment facilities to be used.

9.11. The application shall be accompanied by a fee per transport vehicle according to the fee schedule shown in Table 64-56A found at the end of this rule. An application for renewal shall be submitted with the fee forty-five (45) days prior to the expiration date of an existing permit.

9.12. Once the application has been approved by the secretary, and upon verification that the applicant has been duly authorized by the public service commission, if applicable, a permit shall be issued to the applicant. All transport vehicles shall display the decal provided by the public service commission as required by the commission.

9.13. Upon request, the transporter shall provide the secretary with information needed for the investigation of the handling of particular infectious medical waste including, but not limited to, the names, addresses and telephone numbers of transporters from or to whom the transporter has received or transferred infectious medical waste and infectious medical waste management facilities and generators with which the transporter has a contract or agreement for services.

9.14. All infectious medical waste transport vehicles shall be subject to inspection by the secretary without prior notice to evaluate compliance with this rule.

§64-56-10. Methods of Treatment.

10.1. General.

10.1.1. All infectious medical waste shall be treated by one of the following methods:

10.1.1.1. Incineration as described in Section 10.2 of this rule;

10.1.1.2. Steam treatment as described in Section 10.3 of this rule;

10.1.1.3. Discharge to a sanitary sewer as described in Section 10.4 of this rule; or

10.1.1.4. Any other alternative method approved in writing and permitted by the secretary according to the provisions of Section 10.5 of this rule.

10.1.2. The residue or ash remaining after the treatment of infectious medical waste in accordance with this rule becomes noninfectious medical waste and may be disposed of as solid waste.

10.2. Incineration.

10.2.1. All incinerators of infectious medical waste are required to comply with applicable State laws and with rules of the West Virginia Air Pollution Control Commission.

10.2.2. Whenever infectious medical waste is introduced into an incinerator, all the waste shall be subjected to a burn temperature of not less than one thousand four hundred degrees Fahrenheit (1400° F) for a period not less than one (1) hour. Gases generated by the combustion shall be subjected to a temperature of not less than one thousand eight hundred degrees Fahrenheit (1800° F) for a period of one (1) second or more.

10.2.3. An incinerator used for treatment of infectious medical waste shall have interlocks or other process control devices to prevent feeding of the incinerator until the conditions specified in Section 10.2.2 of this rule can be achieved. Such devices may have an override for start-up. In the event low temperatures occur, facilities shall have automatic auxiliary burners which are capable, excluding the heat content of the waste, of independently maintaining the secondary chamber temperature at the minimum of one thousand eight hundred degrees Fahrenheit (1800° F).

10.2.4. There shall be continuous monitoring and recording of primary and secondary chamber temperatures. Monitoring data shall be maintained for a period of three (3) years.

10.2.5. All combustible waste shall be converted by the incineration process into ash that is not recognizably in its pre-

incineration form. Incinerator ash shall be tested at least monthly for total organic carbon content and annually for the contaminants: lead; mercury; cadmium; and other heavy metals. A maximum of five percent (5%) fixed carbon shall be permitted (minimum ninety-five percent (95%) burnout).

10.2.6. Two (2) years following the effective date of this rule, all individuals who operate infectious medical waste incinerators shall be registered with the secretary. The secretary shall issue a registration number to individuals who complete a course of study approved by the secretary; obtain a passing score on a written examination; and pay the fee shown in Table 64-56A found at the end of this rule.

10.2.7. Incinerators in operation at the time this rule becomes effective may apply to the secretary for a waiver to Sections 10.2.2 through 10.2.4 of this rule. The waiver, if granted, shall be in effect for a maximum of three years and shall be contingent upon submission of plans to upgrade the facility so as to be in full compliance with Sections 10.2.2 through 10.2.4 of this rule. Such plans shall be submitted as part of the infectious medical waste facility management plan required in Section 6 of this rule and shall be subject to approval by the secretary.

10.3. Steam Treatment.

10.3.1. A steam treatment process for infectious medical waste shall at all times maintain:

10.3.1.1. A temperature of not less than two hundred and fifty degrees Fahrenheit (250° F) for ninety (90) minutes at fifteen (15) pounds per square inch of gauge pressure; or

10.3.1.2. A temperature of two hundred and seventy-two degrees Fahrenheit (272° F) for forty-five (45) minutes at twenty-seven (27) pounds per square inch; or

10.3.1.3. A temperature of two hundred and fifty degrees Fahrenheit (250° F) for twenty-eight (28) minutes at eighty (80) pounds per square inch; or

10.3.1.4. A temperature of two hundred and seventy degrees Fahrenheit (270° F) for sixteen (16) minutes at eighty (80) pounds per square inch; or

10.3.1.5. A temperature of two hundred and seventy degrees Fahrenheit (270° F) for thirty (30) minutes at thirty-two (32) pounds per square inch; or

10.3.1.6. Other combinations of operational temperatures, pressure and time approved by the secretary. Such other combinations may be approved if the installed equipment has been proved to achieve a reliable kill of all infectious microorganisms in

infectious medical waste at design capacity. Complete and thorough testing of such other combinations of temperature and pressure shall be fully documented, including tests of the capacity to kill *Bacillus stearothermophilus*. Longer steam treatment times are required when a load contains a large quantity of liquid.

10.3.2. Each package of infectious medical waste to be treated with steam shall have a tape attached that will indicate if the steam treatment temperature has been reached. The infectious medical waste shall not be considered satisfactorily treated if the indicator does not indicate that the treatment temperature was reached during the process. Each package shall also be labeled according to the requirements of Section 6.3.2 of this rule after treatment if recognizable.

10.3.3. Steam treatment units shall be evaluated under full loading for effectiveness with spores of *Bacillus stearothermophilus* no less than once per every forty (40) hours of operation.

10.3.4. A log shall be kept at each steam treatment unit that is complete for the preceding three (3) year period. The log shall record:

10.3.4.1. The date, time and operator of each usage;

10.3.4.2. The type and approximate amount of waste treated;

10.3.4.3. The post-treatment reading of the temperature sensitive tape;

10.3.4.4. The dates and results of calibration; and

10.3.4.5. The results of the testing required by Section 10.3.3 of this rule.

Where multiple steam treatment units are used, a working log can be maintained at each unit and such logs periodically consolidated at a central location. The consolidated logs shall be retained for three (3) years and be available for review.

10.4. Sanitary Sewer.

Infectious medical waste may be discharged to a sanitary sewer through a drainage fixture of a size and type adequate to discharge the waste in a sanitary manner to a sewer system approved by the department according to Sewage System Rules, 64 CSR 9. The use of a grinder to reduce infectious solid matter to a size or consistency which can be discharged to a sewer is prohibited.

10.5. Alternative Methods.

10.5.1. The secretary may approve an alternative method of treatment not described in this rule if the secretary determines

that the proposed process will render infectious medical waste noninfectious and will provide protection to the health and safety of the public and workers at least the equivalent to the methods found at Sections 10.2, 10.3 and 10.4 of this rule.

10.5.2. The secretary may issue provisional approval to any alternate method until an appropriate trial period can validate performance. Alternate methods employing disinfection must have the disinfectant registered for that purpose in accordance with the federal Insecticide, Fungicide, and Rodenticide Act as amended. If the process fails to provide adequate treatment when operated according to manufacturer's instructions, the provisional approval shall be revoked.

10.5.3. In addition to complying with other sections of this rule, an application for approval of an alternate method shall include:

10.5.3.1. A listing of the classes and amounts of infectious medical waste the method could be employed to treat;

10.5.3.2. A copy of the detailed plans for the device used in the method;

10.5.3.3. A written summary of the proper operation of the method and device;

10.5.3.4. A copy of the operation and maintenance manual for the process or device;

10.5.3.5. Copies of approval and denial letters from other states where the process has been evaluated; and

10.5.3.6. A copy of an evaluation report provided by an independent testing firm that used the latest United States Environmental Protection Agency testing protocols confirming the efficacy of the treatment process and that the process does not produce a hazardous waste, discharge or air emission.

§64-56-11. Commercial Infectious Medical Waste Management Facilities.

11.1. This section of this rule applies only to commercial infectious medical waste management facilities.

11.2. A commercial infectious medical waste management facility may not utilize incineration technology in any form, including the manufacture or burning of refuse-derived fuel in any form.

11.3. A commercial infectious medical waste management facility shall have effective controls for the management of infectious medical waste to ensure the protection of public health,

safety, welfare and the environment.

11.4. The secretary shall conduct an investigation of the infectious medical waste stream in the region affected by the proposed facility and determine that programs have been established to minimize and reduce the infectious medical waste stream the facility will serve prior to issuing a permit.

11.5. No person may establish, construct, operate, maintain, or allow the use of property for a commercial infectious medical waste management facility within an area where there is a reasonable probability, as determined by the secretary after consultation with relevant State and federal agencies, that the facility will cause:

11.5.1. A significant adverse impact upon wetlands;

11.5.2. A significant adverse impact upon any endangered or threatened species of animal or plant;

11.5.3. A statistically significant adverse impact upon any surface water;

11.5.4. A statistically significant adverse impact upon groundwater quality;

11.5.5. A violation of surface water quality standard found in Requirements Governing Water Quality Standards, 46 CSR 1; or

11.5.6. The emission of any air contaminant exceeding the limitations for those substances established by the West Virginia Air Pollution Control Commission.

11.6. A proposed infectious medical waste management facility shall provide evidence of financial capability suitable to the scope of the facility to the secretary.

11.7. To obtain a permit to construct a commercial infectious medical waste management facility, a person shall publish a Class II legal advertisement in a qualified newspaper as defined in W. Va. Code, §59-3-1 which serves the county in which the proposed facility is to be located. The advertisement shall include:

11.7.1.1. A description of the location or locations at which the proposed facility may be sited;

11.7.1.2. Information concerning the anticipated size of the proposed facility; and

11.7.1.3. An estimate of the volume, type, and origin of the infectious medical waste to be handled at the proposed facility.

11.8. A pre-siting notice shall be filed with the secretary

within five (5) days of the publication of the legal advertisement required under Section 11.7 of this rule. The pre-siting notice shall include a certification of publication of the legal advertisement required under Section 11.7 of this rule from the newspaper in which such advertisement was published with a copy of the advertisement.

11.9. A person proposing to operate a commercial infectious medical waste management facility shall conduct a public hearing in the county where the proposed facility is to be located in accordance with the following guidelines:

11.9.1. A transcript of the hearing shall be available to the public and the secretary.

11.9.2. Any person may submit oral or written statements and data concerning the proposed facility. Reasonable limits may be set on the time allowed for oral statements, and the written statements shall be submitted no later than ten (10) days after the close of public hearings.

11.10. If any data, information or arguments submitted during the public comment period raise substantial new questions concerning the proposed facility, the secretary shall:

11.10.1. Reopen or extend the public comment period to give interested persons an opportunity to comment on the information or argument submitted; or

11.10.2. Require an additional public hearing.

11.11. The applicant for a permit for a commercial infectious medical waste management facility shall maintain a public participation file. This file shall contain all the written comments received during the public comment period, copies of transcripts of all meetings held by the applicant and a copy of the applicant's written response to all written comment letters received during the response period. This file shall be submitted to the Secretary by the applicant as a part of the application package.

11.12. The applicant shall arrange for a permitted facility to receive all treated waste.

11.13. A commercial infectious medical waste management facility shall employ a treatment technology approved according to the provisions of Sections 10 of this rule.

11.14. The applicant shall provide financial assurance in the form of a collateral bond, an escrow account or a letter of credit equal to the proposed cost of the project.

11.15. Based on comments received at the public hearing or upon written recommendations received, the secretary may within

thirty (30) days after their receipt of the pre-siting notice, require the person who submitted that notice to furnish additional information on the siting of the proposed facility as it relates to the impacts that siting may have upon wetlands, endangered or threatened species of plant and animals, surface waters, underground waters and air quality.

11.16. A retailer of sharps to be used by individuals in their own medical treatment may establish a small commercial infectious medical waste management facility to be used solely for the treatment of sharps sold by and returned to the retailer for treatment. Such small commercial infectious medical waste management facility shall apply for and obtain a permit according to the provisions of Section 4 of this rule. In addition to the requirements of Section 4, the application shall include a letter describing the location and estimated volume of sharps to be treated and a certified letter from an approved small facility agreeing to accept the treated wastes. Such commercial infectious medical waste management facility shall comply with Sections 6 and 10 of this rule, and shall be exempt from the requirements of Sections 11.2 through 11.15 of this rule.

§64-56-12. Requirements Related to Manifests.

12.1. Except as specified in Section 12.9 of this rule, the generator of infectious medical waste that is to be transported off-site for storage or treatment shall initiate a four-part manifest which is available from the secretary. Copy three (3) of the manifest shall be retained by the generator after acceptance by the transporter. Copy two (2) of the manifest shall be retained by the transporter after acceptance by the treatment facility. Copy one (1) of the manifest shall be retained by the treatment facility: The treatment facility shall forward the original to the generator as required by Section 12.8 of this rule. A transporter who commingles loads shall initiate a new manifest as a generator. He or she shall submit the first copy of the original manifest back to the actual generator after receiving the first copy of the manifest for the commingled infectious medical waste from the treatment facility, along with a photocopy of the commingled load manifest.

12.2. If the generator does not receive the completed manifest from the treatment facility within fifty (50) days after the date the medical waste was accepted by the transporter, the generator shall report this fact to the secretary.

12.3. A transporter shall not accept infectious medical waste from a generator unless the waste is accompanied by a manifest with the generator portion completed, signed, and dated by the generator.

12.4. A transporter shall in the presence of the generator or, in the event of multiple transporters, in the presence of the

previous transporter, complete the transporter portion of the manifest, including a handwritten acceptance signature and date of acceptance, and shall immediately give a signed copy of the manifest to the generator or previous transporter, with any discrepancies in manifest information noted on the manifest copy.

12.5. An infectious medical waste management facility shall not accept more than fifty (50) pounds of infectious medical waste from a generator per month or any quantity of infectious medical waste from a transporter unless it is accompanied by a properly completed manifest.

12.6. An infectious medical waste management facility shall, in the presence of the generator or transporter, complete the appropriate transport or storage, treatment or disposal facility portion of the manifest, including a handwritten acceptance signature and date of acceptance, and immediately give a signed copy of the manifest to the generator or transporter, with any discrepancies in manifest information noted on the manifest copy.

12.7. The treatment facility shall record on the manifest the date on which the shipment was received and accepted by the facility.

12.8. The treatment facility shall keep one (1) copy of the completed manifest as part of the facility operating record and shall forward the original to the generator within seven (7) days after treatment.

12.9. Small quantity generators who elect to transport their own infectious medical waste are not required to use a manifest.

12.10. In instances when an infectious medical waste management facility accepts less than fifty (50) pounds of infectious medical waste from a small quantity generator, the facility shall maintain a log of such receipts which includes, at a minimum, the following:

- 12.10.1. The name and address of the generator;
- 12.10.2. The weight of such waste received;
- 12.10.3. The date of receipt of such waste; and
- 12.10.4. The signature of the person receiving such waste.

12.11. Manifests and logs shall be retained by all parties for a period of not less than three (3) years. The period of retention of records is extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the secretary. These records shall be available for inspection by the secretary upon request.

§64-56-13. Record Keeping and Reporting.

13.1. All pertinent records required by this rule shall be retained for a period of not less than three (3) years.

13.2. The period of retention established in Section 13.1 of this rule shall extend automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the secretary.

13.3. All records shall be made available for inspection and or duplication by the secretary or his or her duly authorized representative upon request.

13.4. All generators, except those listed in Section 2 of this rule, transporters, storage facilities and treatment facilities shall submit a report covering the calendar year 1991 to the secretary in a format specified by the secretary by the twentieth day of January, 1992 and additional reports at such times the secretary judges necessary setting out the quantity of waste generated during a particular time period and the disposition of such infectious medical waste.

§64-56-14. Inspections; Right of Entry; Sampling; Reports and Analyses; Subpoenas.

Inspections and other monitoring activities are required to be conducted according to the provisions of W. Va. Code §§20-5E-12 and 20-5J-7 which are outlined in this section.

14.1. Upon the presentation of proper credentials and at reasonable times, the secretary has the authority to enter any building, property, premises, place, vehicle or permitted facility where infectious medical waste is or has been generated, handled, treated, stored, transported or disposed of for the purpose of promptly investigating any person's compliance with the provisions of relevant State law, this rule or permits issued under this rule.

14.2. The secretary is required to make periodic inspections of every permitted facility as necessary to effectively implement and enforce the requirements of relevant State law, this rule or permits issued in accordance with this rule. After an inspection is made, a report is to be prepared and filed with the secretary. A copy of the inspection report is required to be promptly furnished to the person in charge of the building, property, premises, place, vehicle or facility. All inspection reports are available to the public in accordance with the provisions of W.Va. Code §§29B-1-1 et seq.

14.3. Whenever the secretary has cause to believe that any person is in violation of any provision of relevant State law, this rule, any condition of a permit issued by the secretary, or any order issued under this rule, he or she is required to immediately

order an inspection of the building, property, premises, place, vehicle or permitted facility at which the alleged violation is occurring.

14.4. Upon presentation of proper credentials and at reasonable times, the secretary has the authority to enter any establishment, building, property, premises, vehicle or other place maintained by any person where infectious medical waste is being or has been generated, transported, stored, treated or disposed of to inspect and take samples of wastes and the contents of any containers or labeling for such wastes. A receipt describing such samples, and, if requested, a portion of such sample equal in volume or weight to the portion retained is to be given to the owner, operator or agent in charge prior to the sample being taken from the premises. The secretary is required to provide a copy of any analysis to the owner, operator or agent in charge promptly.

14.5. Upon presentation of proper credentials and at reasonable times, the secretary is to be given access to all records relating to the generation, transportation, storage, treatment or disposal of infectious medical waste in the possession of any person who generates, stores, treats, transports, disposes of, or otherwise handles or has handled such waste. The secretary is to be furnished with copies of all such records or given the records for the purpose of making copies. If the secretary, upon inspection, investigation or through other means, observes or learns of a violation or probable violation of relevant State law or this rule, he or she is authorized to issue subpoenas and subpoenas duces tecum and to order the attendance and testimony of witnesses and to compel the production of any books, papers, documents, manifests and other physical evidence pertinent to such investigation or inspection.

§64-56-15. Enforcement Orders; Related Hearings; Permit Reinstatement.

Enforcement orders and related hearings are required to be conducted according to the provisions of W. Va. Code §§20-5E-14, 20-5J-8 and 29A-5-1 et seq. as outlined in Sections 15.1 and 15.2 of this rule.

15.1. If the secretary, upon inspection, investigation or through other means observes, discovers or learns of a violation of the provisions of this rule or relevant State law or of any order or permit issued under this rule or such law by the Secretary, he or she may:

15.1.1. Issue an order stating with reasonable specificity the nature of the violation and requiring compliance immediately or within a specified time. An order under this section includes, but is not limited to, any or all of the following: orders suspending, modifying or revoking permits, orders requiring a person to take remedial action, or cease and desist orders;

15.1.2. Seek an injunction in accordance with W.Va. Code §20-5J-9(b);

15.1.3. Institute a civil action in accordance with W. Va. Code §20-5J-9(a); or

15.1.4. Request the attorney general or the prosecuting attorney of the county in which the alleged violation occurred to bring a criminal action in accordance with W. Va. Code §20-5E-15.

15.2. Any person issued a cease and desist order may file a notice of request for reconsideration with the secretary not more than seven (7) days from the issuance of such order and shall have a hearing before the secretary contesting the terms and conditions of such order within ten (10) days of the filing of such notice of a request for reconsideration. The hearing is conducted as required by State law and Section 19 of this rule. The filing of a notice of request for reconsideration shall not stay or suspend the execution or enforcement of such cease and desist order.

15.3. Any person whose permit issued under this rule has been suspended or revoked may, at any time, make application for reinstatement of the permit. After receipt of a written request, including a signed statement by the applicant that in his or her opinion the conditions causing the suspension of the permit have been corrected, the secretary shall make an inspection or investigation of the applicant's operation. If the applicant complies with the provisions of this rule, the permit shall be reinstated.

15.4. The secretary may suspend or revoke a permit if the permit has been obtained by means of fraud, deceit or material misrepresentation.

§64-56-16. Criminal Penalties.

Criminal penalties are applied according to the provisions of W. Va. Code §16-5E-15 as described in this Section.

16.1. If any person knowingly: (1) transports any infectious medical waste identified or listed under this rule to a facility which does not have a permit required by this rule; or (2) treats, stores or disposes of any such infectious medical waste either (A) without having obtained a permit required by this rule or (B) in knowing violation of a material condition or requirement of such permit, he or she is guilty of a felony, and, upon conviction thereof, is required to be fined not to exceed fifty thousand dollars (\$50,000) for each day of violation or to be confined in the penitentiary not less than one (1) nor more than two (2) years, or to receive both such fine and imprisonment or, in the discretion of the court, be confined in jail not more than one (1) year in addition to the above fine.

16.2. If any person knowingly: (1) makes any false material

statement or representation in any application, label, manifest, record, report, permit or other document filed, maintained or used for purposes of compliance with this rule; or (2) generates, stores, treats, transports, disposes of or otherwise handles any infectious medical waste identified or listed under this rule and who knowingly destroys, alters or conceals any record required to be maintained under this rule, he or she is guilty of a misdemeanor, and, upon conviction thereof, is required to be fined not to exceed twenty-five thousand dollars (\$25,000), or sentenced to imprisonment for a period not to exceed one (1) year, or both fined and sentenced to imprisonment for each violation.

16.3. Any person convicted of a second or subsequent violation of Sections 16.1 and 16.2 of this rule, is guilty of a felony, and, upon such conviction, shall be confined in the penitentiary not less than one (1) nor more than three (3) years, or fined not more than fifty thousand dollars (\$50,000) for each day of violation, or both such fine and imprisonment.

16.4. Any person who knowingly transports, treats, stores or disposes of any infectious medical waste identified or listed pursuant to this rule in violation of Section 16.1 of this rule, or having applied for a permit pursuant to this rule and knowingly fails to include in a permit application any material information required pursuant to this rule and who thereby exhibits an unjustified and inexcusable disregard for human life or the safety of others and thereby places another person in imminent danger of death or serious bodily injury, is guilty of a felony, and, upon conviction thereof, is required to be fined not more than two hundred fifty thousand dollars (\$250,000) or imprisoned not less than one (1) year not more than four (4) years or to receive both such fine and imprisonment.

16.5. As used in Section 16.4 of this rule, the term "serious bodily injury" means:

- 16.5.1. Bodily injury which involves a substantial risk of death;
- 16.5.2. Unconsciousness;
- 16.5.3. Extreme physical pain;
- 16.5.4. Protracted and obvious disfigurement; or
- 16.5.5. Protracted loss or impairment of the function of a bodily member, organ or mental faculty.

§64-56-17. Civil Penalties.

Civil penalties are to be assessed according to the provisions of W. Va. Code §§20-5E-16 and 20-5J-9 which are outlined in this section.

17.1. Any person who violates any provision of this rule or an order issued pursuant to this rule is subject to a civil administrative penalty, to be levied by the secretary, of not more than seventy-five hundred dollars (\$7,500) for each day of such violation, not to exceed a maximum of twenty-five thousand dollars (\$25,000).

17.2. In assessing any such penalty, the secretary is required to take into account the seriousness of the violation and any good faith efforts to comply with applicable requirements as well as any other appropriate factors, such as: (1) the severity of serious physical harm most likely to result, and if applicable, that did result, from the violation; (2) the extent to which the provisions of this rule were violated; and (3) any previous violations committed by the alleged violator. No assessment is to be levied pursuant to this subsection until after the alleged violator has been notified by certified mail or personal service.

17.2.1. The notice is required to include a reference to the section of the statute, rule, regulation, order or statement of permit conditions that was allegedly violated, a concise statement of the facts alleged to constitute the violation, a statement of the amount of the administrative penalty to be imposed and a statement of the alleged violator's right to an informal hearing.

17.2.2. The alleged violator has twenty (20) calendar days from receipt of the notice within which to deliver to the secretary a written request for an informal hearing. If no hearing is requested, the notice becomes a final order after the expiration of the twenty-day period. If a hearing is requested, the secretary is required to inform the alleged violator of the time and place of the hearing. The secretary may appoint an assessment officer to conduct the informal hearing and then make a written recommendation to the secretary concerning the assessment of a civil administrative penalty.

17.2.3. Within thirty (30) days following the informal hearing, the secretary is required to issue and furnish to the violator a written decision, and the reasons therefore, concerning the assessment of a civil penalty.

17.2.4. Within thirty (30) days after notification of the secretary's decision, the alleged violator may request a formal hearing in accordance with the provisions of W. Va. Code §20-5E-19 and Section 19 of this rule.

17.3. The authority to levy an administrative penalty is in addition to all other enforcement provisions of State law or this rule and the payment of any assessment is not deemed to affect the availability of any other enforcement provision in connection with the violation for which the assessment is levied: Provided, that no combination of assessments against a violator under this rule are to exceed twenty-five thousand dollars (\$25,000) per day of

each such violation: Provided however, that any violation for which the violator has paid a civil administrative penalty assessed under this section may not be the subject of a separate civil penalty action under State law to the extent of the amount of the civil administrative penalty paid.

17.4. No assessment levied pursuant to Section 17.1 of this rule is due and payable until the procedures for review of such assessment as set out herein and in State law have been completed.

17.5. Any person who violates any provision of this rule, or order issued pursuant to this rule is subject to a civil penalty not to exceed twenty-five thousand dollars (\$25,000) for each day of such violation, which penalty is to be recovered in a civil action either in the circuit court wherein the violation occurs or in the circuit court of Kanawha County.

17.6. The secretary may seek an injunction, or may institute a civil action against any person in violation of any provisions of this rule, or order issued pursuant to this rule. In seeking an injunction, it is not necessary for the secretary to post bond nor to allege or prove at any stage of the proceeding that irreparable damage will occur if the injunction is not issued or that the remedy at law is inadequate. An application for injunctive relief or a civil penalty action under this section may be filed and relief granted notwithstanding the fact that all administrative remedies provided for in this rule have not been exhausted or invoked against the person or persons against whom such relief is sought.

§64-56-18. Imminent and Substantial Hazards; Orders; Penalties; Hearings.

18.1. Notwithstanding any provision of this rule to the contrary, the secretary, upon receipt of information, or upon observation or discovery that the handling, storage, transportation, treatment or disposal of any infectious medical waste may present an imminent and substantial endangerment to public health, safety or the environment, has the authority to:

18.1.1. Request the attorney general or the appropriate prosecuting attorney to commence an action in the circuit court of the county in which the hazardous condition exists to immediately restrain any person contributing to such handling, storage, transportation, treatment or disposal to stop such handling, storage, transportation, treatment or disposal or to take such other action as may be necessary; or

18.1.2. Take other action under this section including, but not limited to issuing such orders as may be necessary to protect public health and the environment.

18.2. Any person who willfully violates, or fails or refuses

to comply with, any order of the secretary under Section 18.1 of this rule may, in an action brought in the appropriate circuit court to enforce such orders, be fined not more than five thousand dollars (\$5,000) for each day in which such violation occurs or such failure to comply continues.

§64-56-19. Administrative Due Process

Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.

§64-56-20. Severability.

The provisions of this rule are declared to be severable. If any provision of this rule shall be held invalid, the remaining provisions shall remain in effect.

TABLE 64-56A. ANNUAL INFECTIOUS MEDICAL WASTE MANAGEMENT FACILITY PERMIT FEES

<u>Type of Facility</u>	<u>Fee</u>
A. Hospitals (Non Commercial Treatment Facilities)	
1 to 50 Beds	\$ 500.00
51 to 149 Beds	1,750.00
150 or More Beds	2,500.00
B. Commercial Infectious Medical Waste Management Facility	5,000.00
Small Commercial Infectious Medical Waste Management Facility for Sharps Only (As defined in Section 11.16 of this rule)	150.00
C. Transportation Vehicles (each)	250.00
D. Commercial Storage and Transfer Facility	250.00
E. Other (generate more that 50#/mo.)	
1. Health Care Professionals	250.00
2. Independent Dialysis Centers	250.00
3. Independent Laboratories	250.00
4. Independent Rural Clinics	250.00
5. Nursing Homes	250.00
6. Other Long Term Care Facilities	250.00
7. Outpatient Surgery Centers	250.00
F. Incinerator Operator Registration	25.00



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Building 3, Capitol Complex
Charleston, WV 25305

Gaston Caperton
Governor

October 4, 1991

1001-1-1221
=11/17/91

The Honorable Ken Hechler
Secretary of State
State Capitol
Charleston, West Virginia 25305

Dear Secretary Hechler:

The Department of Health and Human Resources hereby withdraws the emergency filing of the proposed rule, Infectious Medical Waste, 64 CSR 56. As you are aware, the Department conducted a public hearing concerning this rule on October 3, 1991. In response to comments made concerning the rule, the Department intends to make some modifications to the proposed rule for purposes of clarification. The Department believes that the various parties interested in and affected by the proposed rule and the general public will be better served by taking additional time to improve the rule prior to putting it into effect.

Sincerely,

A handwritten signature in cursive script that reads "Taunja Willis Miller".

Taunja Willis Miller,
Secretary

KH:pg