

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

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1003 NOV 17 AM 9 23
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF PUBLIC HEARING ON A PROPOSED RULE

AGENCY: Division of Public Health TITLE NUMBER: 64

RULE TYPE: Legislative; CITE AUTHORITY W. Va. Code, §20-5E-7(d)

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 56

TITLE OF RULE BEING PROPOSED: Infectious Waste

DATE OF PUBLIC HEARING: December 21, 1989 TIME: 1:00 p.m.

LOCATION OF PUBLIC HEARING: Conference Room C

Conference Center

Capitol Complex

Charleston, WV 25305

COMMENTS LIMITED TO: ORAL , WRITTEN , BOTH

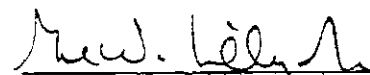
COMMENTS MAY ALSO BE MAILED TO THE FOLLOWING ADDRESS: Kay Howard
Regulatory Development
Department of Health and
Human Resources

The Department requests that persons wishing to make comments at the hearing make an effort to submit written comments in order to facilitate the review of these comments.

Capitol Complex, Bldg. 3
Charleston, WV 25305

The issues to be heard shall be limited to the proposed rule.

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL


George W. Lilley, Jr., Ed.D.
Acting Senior Administrator



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STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Building 6, Capitol Complex
Charleston, WV 25305

NOV 29 PM 12:46
SECRETARY OF STATE

Gaston Caperton
Governor

M E M O R A N D U M

DATE: November 3, 1989
TO: George W. Lilley, Jr., Ed.D.
Acting Administrator
Division of Health
FROM: Taunja Willis Miller, Secretary *jm*
Department of Health and Human Resources
SUBJECT: Approval of Proposed Rule for Public Comment

You are hereby authorized to conduct a public hearing on the proposed Infectious Waste Rule.

TWM/kpg

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Infectious Waste 64 CSR 56

FILED

Type of Rule: X Legislative Interpretive Procedural

1989 NOV 17 AM 9:24
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

Agency Health Division Address Building No. 3
Capitol Complex
Charleston, W. Va. 25305

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$	\$135,380	\$136,000
Personal Services				90,380	94,800
Current Expense				40,000	40,000
Repairs and Alterations					
Equipment				5,000	1,200
Other					
Revenue				136,000	136,000

2. Explanation of above estimates.

One program manager, two technical field personnel with vehicles and travel allowance, one secretary with office equipment to process an average of 1,300+ license applications each year plus necessary enforcement communications, office space and utilities. Supervisory duties will be assumed by existing division director at no additional cost.

3. Objectives of these rules:

Regulation of the storage, treatment, and disposal of hazardous waste with infectious characteristics in compliance with §20-5E-7 of the Code, including standards for generators of such waste.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

The rule creates a new program in which, in the minimum form proposed, cost is balanced by revenue.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of citizens.

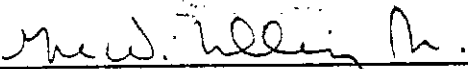
Laboratory and medical facilities covered by the proposed rule would pay approximately \$50 to \$500 per year in license fees depending on the size and nature of the facility. Additional costs would depend on how infectious waste is currently handled at such facilities. Cost to these types of facilities may increase due to: cost of packaging materials and storage requirements; cost of new equipment to comply with treatment requirements; and more costly transport services. Facilities that store or treat infectious waste on a commercial basis would pay \$300 to \$3,000 per year depending on size.

C. Economic Impact on Citizens/Public at Large.

If medical cost increases are significant, they are likely to lead to increased costs to the public for medical care.

Date October 10, 1989

Signature of Agency Head or Authorized Representative



George W. Lilley, Jr., Ed.D.
Acting Administrator
Division of Health

{PROPOSED}

TITLE 64

LEGISLATIVE RULES
DIVISION OF HEALTH

INFECTIOUS WASTE

SERIES 56

199_

For Board of Health Review
October 20, 1989

WEST VIRGINIA BOARD OF HEALTH
RULE ABSTRACT

FILED

1989 NOV 17 AM 9 23

Title: Infectious Waste

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

CSR Title and Series: 64 CSR 56

Type: Legislative

Abstract: This proposed new rule establishes licensure requirements regarding the generation, storage, treatment and disposal of infectious waste. The rule includes definitions, general administrative procedures, licensure fees, standards for packaging, storage and containment of infectious waste, methods of treatment and disposal, enforcement orders and hearings, and procedures for assessing civil penalties.

Infectious waste must be rendered non-infectious prior to disposal. The rule does not apply to infectious waste generated on the premises of a single-family residence or dwelling unit, or generated by an individual for the purposes of self-care or self-treatment.

For further information contact: Regulatory Development Section, telephone 348-3223 or Robert Paul, Office of Environmental Health, Division of Health, Building 3, Capitol Complex, Charleston, West Virginia, 25305, telephone 348-2981.

10/6/89

[PROPOSED]
WEST VIRGINIA LEGISLATIVE RULES
DIVISION OF HEALTH

INFECTIOUS WASTE

64 CSR 56

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[PROPOSED]
TITLE 64
WEST VIRGINIA LEGISLATIVE RULES
DIVISION OF HEALTH
SERIES 56
INFECTIOUS WASTE

FILED
1988 NOV 17 AM 9:24
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

§64-56-1. General

1.1. **Scope** - This rule establishes requirements regarding the generation, storage, treatment and disposal of infectious waste.

1.2. **Authority** - §20-5E-7(d) of the West Virginia Code. Related - §20-5E-1 et seq. of the West Virginia Code.

1.3. **Filing Date** -

1.4. **Effective Date** -

1.5. **Notice of Public Hearing** -

1.6. **Public Hearing** -

1.7. **Final Approval** - This rule was approved by the West Virginia Board of Health on _____.

§64-56-2. Application and Enforcement

2.1. **Application** - This rule applies to any person who generates, treats, stores or disposes of infectious waste: Provided, however, That this rule does not apply to infectious waste generated on the premises of a single-family residence or dwelling unit, or generated by an individual for the purposes of self-care or self-treatment.

2.2. **Enforcement** - This rule shall be enforced by the administrator of the division of health of the State department of health and human resources.

§64-56-3. Definitions

3.1. **Administrator** - The administrator of the division of health of the State department of health and human resources or his or her designee.

3.2. **Animal Waste** - Contaminated animal carcasses, body parts, and bedding of animals that are known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals or testing of pharmaceuticals.

3.3. **Biologicals** - Preparations made from living organisms and their products, including vaccines, cultures, and similar such products, intended for use in diagnosing, immunizing or treating humans or animals or in research pertaining thereto.

3.4. **Bulk Human Blood and Blood Products** - Liquid waste human blood and blood products in a free-flowing or unabsorbed

state, including but not limited to blood plasma, serum, platelets, red or white blood corpuscles, and other derived licensed products, such as interferon. Absorbent material containing blood or blood products with no free-flowing or unabsorbed liquid is not infectious waste.

3.5. **Disposal** - The discharge, deposit, injection, dumping, spilling, leaking or placing of any hazardous waste into or on any land or water so that such hazardous waste or any constituent thereof may enter into the environment or be emitted into the air, or discharged into any waters, including groundwaters.

3.6. **Generation** - The act or process of producing infectious waste materials.

3.7. **Hazardous Waste** - A waste or combination of wastes which, because of its quantity, concentration or physical, chemical or infectious characteristics, may (A) cause, or significantly contribute to, an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of or otherwise managed.

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

3.9. **Infectious Waste** - Waste with infectious characteristics, including: animal waste; bulk human blood and blood products; laboratory waste; pathological waste which is known to be or suspected of being contaminated by an infectious agent; sharps.

3.10. **Infectious Waste Facility** - Any facility which generates, treats, stores or disposes of infectious waste.

3.11. **Infectious Waste Incinerator** - An enclosed device using flame combustion to treat infectious wastes.

3.12. **Laboratory Waste** - Cultures and stocks of infectious agents and associated biologicals including but not limited to: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; and discarded live and attenuated vaccines.

3.13. **Land Disposal** - Any placement of hazardous waste in a landfill, surface impoundment, waste pile, injection well, land treatment facility, salt dome formation, salt bed formation, or underground mine or cave.

3.14. **Pathological Waste** - Human pathological wastes, in-

cluding tissues, organs, and body parts exclusive of those fixed in formaldehyde or another fixative. Human corpses, remains and anatomical parts that are intended for interment or cremation are not infectious waste.

3.15. **Person** - Any individual, trust, firm, joint stock company, public, private or government corporation, partnership, association, state or federal agency, the United States government, this State or any other state, municipality, county commission or any other political subdivision of a state or any interstate body.

3.16. **Sharps** - Discarded articles that may cause punctures or cuts and that have been used in animal or human patient care or treatment or in medical, research or industrial laboratories, including hypodermic needles, syringes with attached needles, scalpel blades, and broken glassware that was in contact with infectious agents.

3.17. **Storage** - Containment of infectious waste either on a temporary basis or for a period of years, in such a manner as not to constitute disposal of such hazardous waste.

3.18. **Treatment** - Any method, technique or process, including neutralization, designed to change the physical, chemical or biological character or composition of any hazardous waste so as to neutralize such waste or so as to render such waste nonhazardous, safer for transport, amenable to recovery, amenable to storage or reduced in volume. Such term includes any activity or processing designed to change the physical form or chemical composition of hazardous waste so as to render it nonhazardous.

§64-56-4. General Licensure and Inspection Provisions

4.1. No person may own, construct, modify, or operate an infectious waste facility without first obtaining a license for such facility from the administrator.

4.2. Each infectious waste facility that is physically or operationally distinct shall apply for initial licensure by the administrator within ninety (90) days of the effective date of this rule.

4.3. The application for licensure shall be submitted to the administrator and shall include the following information:

4.3.1. A description of the methods used to treat infectious wastes if any;

4.3.2. The source, amount and type of infectious waste generated, stored, and treated;

4.3.3. The name and address of any infectious waste facility storing or treating the waste if waste is transported

off the premises for treatment;

4.3.4. If an autoclave is utilized, a detailed description of the current procedure used to render wastes noninfectious, including the specific types of infectious wastes subjected to autoclaving; and

4.3.5. Any other information required by the administrator.

4.4. Licenses shall be renewed annually prior to expiration.

4.5. The administrator shall require payment of a license fee according to the schedule shown in Table 64-56A found at the end of the rule.

4.6. All infectious waste facilities shall be subject to inspection by the administrator without prior notice to assure compliance with this rule.

4.7. The administrator may refuse to grant a license if the applicant has attempted to obtain the license by means of fraud, deceit, or material misrepresentation.

4.8. The administrator may suspend or revoke a license if the license has been obtained by means of fraud, deceit, or material misrepresentation.

4.9. At least fifteen (15) days before the implementation of a proposed change of conditions described on an application submitted in compliance with §4.3 of this rule, the licensee shall submit an application amendment to the administrator. Changes in procedures shall be subject to approval by the administrator.

4.10. Within fifteen (15) days of any unintended change, beyond the control of the licensee, of conditions described on an application submitted in compliance with §4.3 of this rule, an infectious waste facility shall submit an application amendment to the administrator. Changes in procedures shall be subject to approval by the administrator.

§64-56-5. Packaging, Storage and Containment of Infectious Waste

5.1. Infectious waste shall be segregated from other waste at the point of origin in the generating facility.

5.2. Solid and semi-solid infectious wastes, except for sharps, shall be contained for storage or transportation in double impermeable plastic bags which are at least one and one half (1.5) mils in thickness or in similar single bags which are at least two (2) mils in thickness to preclude ripping, tearing, or bursting under normal conditions of usage and handling. The bags shall be securely tied so as to prevent leakage or expulsion

of solid or liquid wastes during storage, handling or transport. Bags penetrated or contaminated on their exterior surfaces shall be enclosed in an additional bag. Other types of packaging are acceptable if specifically approved in writing by the administrator.

5.3. Sharps shall be placed directly into impervious, rigid and puncture-resistant containers. Containers shall be compatible with selected treatment processes to preclude contact with waste materials, and sealed before handling.

5.4. Except where §6.3 of this rule applies, liquid infectious waste shall be placed in capped or tightly stoppered bottles or flasks. Containment tanks may be used for large quantities of liquid waste.

5.5. All bags and containers used for storage of infectious waste shall be conspicuously color coded red indicating the presence of infectious waste, or conspicuously marked with the universal biological hazard symbol shown in Figure 64-56A at the end of this rule, or other appropriate symbol if approved in writing by the administrator.

5.6. Infectious waste contained in non-reusable bags shall be placed in rigid reusable metal, plastic or fiberglass pails, drums or portable bins or rigid non-reusable cartons for transport to a separate infectious waste facility. Rigid containers shall be sealed during transport.

5.7. Reusable containers shall be leakproof, insect-proof, rodent-proof, have tight-fitting covers, and be kept clean and in good repair. Reusable containers shall be constructed to allow drainage of liquids and complete cleaning and sanitizing.

5.8. Before being reused, rigid containers for infectious waste shall be decontaminated by agitation to remove visible soil combined with one of the following procedures:

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

5.8.2. Exposure to a chemical sanitizer by rinsing with or 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 if immersed or of two hundred parts per million (200 ppm) if rinsed; iodoform solution of twenty-five parts per million (25 ppm) available iodine if immersed or fifty parts per million (50 ppm) if rinsed; or quaternary ammonium solution of two hundred parts per million (200 ppm) active agent if immersed or four hundred parts per million (400 ppm) if rinsed.

5.8.3. Any other method approved in writing by the

administrator.

5.9. Reusable pails, drums or bins used for containment of infectious waste shall not be used for containment of non-infectious waste or for any other purposes.

5.10. Infectious waste shall not be stored for more than eight (8) days unless approved by the administrator.

5.11. Storage of infectious waste shall be in a specifically designated area located at or near the treatment site, or at the pickup point if it must be transported off site for treatment. Storage of infectious waste shall be separate from other wastes unless otherwise approved in writing by the administrator. Access to the area shall be restricted and entry to unauthorized personnel shall be denied. The area shall be posted prominently with the biohazard symbol shown in Figure 64-56A (found at the end of this rule) or other appropriate symbol if approved in writing by the administrator and also with warning signs located adjacent to the exterior of entry doors, gates or lids indicating use of the area for storage of infectious waste and denying entry to unauthorized persons. The manner of storage shall afford protection from all threats to the integrity of the packaging and the area shall be kept free from rodents and vermin which may act as vectors in disease transmission.

5.12. Garbage chutes shall not be used to transfer infectious waste.

5.13. Compaction of infectious waste is prohibited.

§64-56-6. Treatment and Disposal of Infectious Waste

6.1. Treatment of infectious waste shall be by one (1) or more of the following methods:

6.1.1. Incineration as described in §6.2 of this rule;

6.1.2. Discharge to a sanitary sewer as described in §6.3 of this rule;

6.1.3. Treatment in an autoclave as described in §6.4 of this rule; or

6.1.4. Any other method approved in writing by the administrator.

6.2. Infectious waste may be treated to render it non-infectious by incineration in an infectious waste incinerator.

6.2.1. The use of heating plant fire boxes for incineration of infectious waste is prohibited.

6.2.2. The following design specifications shall apply to

all infectious waste incinerators installed after the effective date of this rule and to all infectious waste incinerators within two (2) years of the effective date of this rule:

6.2.2.1. Incinerators shall provide a minimum temperature of one thousand two hundred degrees Fahrenheit (1,200° F) in the primary chamber and shall be equipped with an auxiliary fueled secondary chamber providing a minimum retention time of one (1) second at a minimum temperature of one thousand six hundred degrees Fahrenheit (1,600° F). Process control devices shall prevent operation of the incinerator until these conditions are achieved.

6.2.2.2. Incinerators with a capacity of five hundred (500) pounds per hour or more shall be equipped with a continuous temperature monitoring and recording device.

6.2.3. Incinerator ash shall be tested at least once per month to determine the percentage of fixed carbon. A maximum of five percent (5%) fixed carbon is permitted (minimum ninety-five percent (95%) burnout).

6.3. Infectious 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 with secondary treatment, if the infectious waste is liquid or semi-liquid. The use of a grinder to reduce infectious solid matter to a size or consistency which can be discharged to a sewer is prohibited.

6.4. Autoclave operating procedures shall include, but not be limited to, the following:

6.4.1. Adoption of the manufacturer's written operating procedures for each autoclave including duration of treatment process, temperature, pressure, and maximum load quantity.

6.4.2. Examination of recording or indicating thermometers after and during each complete cycle to ensure the attainment of a temperature of two hundred fifty degrees Fahrenheit (250° F) for approximately thirty (30) minutes (depending on quantity and dispersal of load) in order to achieve sterilization of the entire load.

6.4.3. Use of heat sensitive tape or other device for each container that is processed to indicate the attainment of adequate sterilization conditions. The tape or other device shall accompany the container to the landfill or other final disposal site.

6.4.4. Use of bacteriological spore test culture (*Bacillus stearothermophilus*) placed at the center of a load processed under standard operating conditions at least weekly to confirm the attainment of adequate sterilization conditions.

6.4.5. Maintenance of records of procedures on-site for a period of not less than three (3) years. Records shall include, but not be limited to, the date, the temperature achieved during autoclaving and the duration of treatment.

6.5. Ashes resulting from the incineration of infectious waste shall be disposable as noninfectious waste.

6.6. Infectious waste sterilized by heating in an autoclave shall be disposable as noninfectious waste, however, it shall be placed in a container that bears a label or similar device indicating that the waste has been treated and specifying the treatment facility.

§64-56-7. Enforcement orders; hearings.

7.1. If the administrator, upon inspection, investigation or through other means observes, discovers or learns of a violation of the provisions of this rule or any order issued hereunder, he or she may:

7.1.1. 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, revoking or modifying licenses, orders requiring a person to take remedial action or cease and desist orders;

7.1.2. Seek an injunction in accordance with §20-5E-16(c) of the W. Va. Code;

7.1.3. Institute a civil action in accordance with §20-5E-16(c) of the W. Va. Code; or

7.1.4. 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 §20-5E-15 of the W. Va. Code.

7.2. Any person issued a cease and desist order may file a notice of request for reconsideration with the administrator not more than seven (7) days from the issuance of such order and shall have a hearing before the administrator contesting the terms and conditions of such order within ten (10) days of the filing of such notice of a request for reconsideration. The filing of a notice of request for reconsideration shall not stay or suspend the execution or enforcement of such cease and desist order.

§64-56-8. Civil penalties

8.1. Any person who violates any provision of this rule or an order issued pursuant to this rule shall be subject to a civil administrative penalty, to be levied by the administrator, of not

more than seventy-five hundred dollars (\$7,500) for each day of such violation, not to exceed a maximum of twenty-two thousand five hundred dollars (\$22,500).

8.2. In assessing any such penalty, the administrator shall 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 degree of substantial probability that death or serious physical harm will result and, if applicable, did result from the violation; (2) the severity of serious physical harm most likely to result, and if applicable, that did result, from the violation; (3) the extent to which the provisions of this rule were violated; and (4) any previous violations committed by the alleged violator. No assessment shall be levied pursuant to this subsection until after the alleged violator has been notified by certified mail or personal service.

8.2.1. The notice shall 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.

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

8.2.3. Within thirty (30) days following the informal hearing, the administrator shall issue and furnish to the violator a written decision, and the reasons therefore, concerning the assessment of a civil administrative penalty.

8.3. The authority to levy an administrative penalty shall be in addition to all other enforcement provisions of State law or this rule and the payment of any assessment shall not be 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 shall 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 shall 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.

8.4. No assessment levied pursuant to §9.1 of this rule shall become due and payable until the procedures for review of such assessment as set out herein and in State law have been completed.

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

8.6. The administrator 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 administrator 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.

§64-56-9. 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.

Figure 64-56A. The Biological Hazard Symbol



The symbol is fluorescent orange or orange-red. The background may be any color that provides sufficient contrast for the symbol to be clearly defined.

Table 64-56A. License Fee Schedule

Type of Facility	Fee
Hospitals	
1 to 49 beds	\$125
50 to 149 beds	250
150 to 249 beds	375
250 beds or more	500
Laboratories	\$100
Other Generating Facilities	\$ 50
Infectious Waste Storage/ Treatment Facilities (No Generation)	
1 to 500 lb/hr	\$ 300
501 to 1000 lb/h	600
1001 to 2000 lb/hr	1000
2001 to 3000 lb/hr	1500
3001 to 4000 lb/hr	2000
4001 lb/hr or more	3000

WEST VIRGINIA HOSPITAL ASSOCIATION

December 4, 1990

Mr. Tony Minard
Vice President
Camden Clark Memorial Hospital
800 Garfield Avenue
Parkersburg, WV 26101

Draft
~~_____~~
received 12/90 TJC
Lawyer.

Dear Mr. Minard:

Per our telephone discussion of Monday, December 3, 1990 please find enclosed a DRAFT copy of a proposed infectious waste rule. Please be advised that this enclosed DRAFT will be modified in some respects prior to our meeting on Tuesday, December 11, 1990 at 9:30 a.m. at the Hospital Association. The modified draft will be available Tuesday, December 11.

Our purpose in meeting is to:

- A. Review and discuss draft rules as they exist 12/22/90
- B. Participate in question/answer/clarification session with Mr. Joe Schock, M.P.H., P.E. of the West Virginia Division of Health.
- C. Identify any problem areas of the proposed draft.

I hope to see you December 11, 1990 at 9:30 at the Hospital Association.

Sincerely,



Gil DeLaura
Vice President/General Counsel

GD/dsm

Enclosure

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(Proposed)
TITLE 64
WEST VIRGINIA LEGISLATIVE RULES
BUREAU OF PUBLIC HEALTH
SERIES 56
INFECTIOUS WASTE

Draft

64-56-1.0 GENERAL

- 1.1. Scope - This rule establishes requirements regarding the handling, storage, transportation, treatment and disposal of infectious waste.
- 1.2. Authority - 20-5E-7(d) of the West Virginia Code. Related - 20-5E-1 et seq. of the West Virginia Code.
- 1.3. Filing Date -
- 1.4. Effective Date -
- 1.5. Notice of Public Hearing -
- 1.6. Public Hearing -
- 1.7. Final Approval - This rule was approved by the West Virginia Board of Health on _____.

64-56-2.0 APPLICATION AND ENFORCEMENT

- 2.1. Application - This rule applies to any person who generates, handles, stores, transports, treats or disposes of infectious waste except as specifically exempted or excluded in this rule.
- 2.2. Enforcement - This rule shall be enforced by the administrator of the Bureau of Public Health of the State Department of Health and Human Resources or his or her authorized designee.

64-56-3.0 DEFINITIONS

- 3.1. Administrator - The administrator of the Bureau of Public Health of the State Department of Health and Human Resources or his or her authorized designee.
- 3.2. Commercial Infectious Waste Management Facility - All contiguous land and structures, other appurtenances, and improvements thereon used for the systematic collection, storage, transfer, processing, treatment, or disposal of infectious waste of which more than 25% by weight in a calendar year is generated off-site.
- 3.2. Generator - any person, by site location, whose act or process produces waste identified or listed in section _____ of this rule or whose act first causes a waste to become subject to this rule.

- 3.3. Infectious agent - Any organism such as a virus or a bacteria that is capable of being communicated by invasion and multiplication in body tissues and capable of causing disease or adverse health impacts in humans.
- 3.4. Infectious Waste - Waste identified by the health care professional in charge as capable of producing an infectious disease. A waste shall be considered to be 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, 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.

For the purposes of this rule, infectious waste shall include the following unless specifically excluded or exempted in this section or section _____.

- a. Cultures and stock 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 waste. Wastes from the production of biologicals and antibiotics likely to have been contaminated by an infectious agent are infectious waste.
- b. Blood and blood products - Liquid waste human blood and blood products in a free-flowing or unabsorbed state.
- c. Pathological wastes - Human pathological wastes, including tissues, organs, and body parts, exclusive of those fixed in formaldehyde or another fixative.
- d. 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. Includes hypodermic needles, syringes with attached needles, scalpel blades, and broken glassware.
- e. 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.
- f. Isolation wastes - Biological wastes and discarded materials contaminated with blood, excretion, exudates or secretions from humans who are isolated to protect others from highly communicable diseases or from isolated animals known or suspected to be infected with zoonotic infectious agents.

- g. Any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any infectious waste.
 - h. Any waste contaminated by or mixed with infectious waste.
- 3.5 Infectious waste management facility - all contiguous land and structures, other appurtenances, and improvements thereon used for the systematic collection, storage, transfer, processing, treatment, or disposal of infectious waste.
- 3.7. Non-commercial Infectious Waste Management Facility - all contiguous land and structures, other appurtenances, and improvements thereon used for the systematic collection, storage, transfer, processing, treatment, or disposal of infectious waste of which 75% or more by weight in a calendar year is generated on-site.
- 3.8. Off-site - a facility or area for the collection, storage, transfer, processing, treatment, or disposal of infectious waste which is not on the generator's site (i.e. "on-site") or a facility or area which received infectious waste for storage or treatment which has not been generated on-site at that facility.
- 3.9. On-site - the land area and appurtenances thereon and thereto used for infectious waste management on the same geographically contiguous property at which infectious waste is generated. Two or more pieces of property which are geographically contiguous but which are divided by public or private right(s)-of-way are a single site for the purposes of this rule.
- 3.10. Person - Any individual, trust, firm, joint stock company, public, private or government corporation, partnership, association, state or federal agency, the United States government, this State or any other state, municipality, county commission or any other political subdivision of a state or any interstate body.
- 3.11. Transport - the movement of infectious waste by air, rail, highway, or water.
- 3.12. Transporter - a person engaged in the off-site transportation of waste by air, rail, highway, or water.
- 3.13. Transport vehicle - a motor vehicle, or rail car used for the transportation of cargo by any mode. Each cargo-carrying body (trailer, railroad freight car, etc.) is a separate transport vehicle.

4.1. Exclusions - The following are not subject to the requirements of this rule:

- a. Human remains and body parts under the control of a licensed physician or dentist, when the remains are being used or examined for medical purposes and are not abandoned materials.
- b. Human remains properly interred in a cemetery or in preparation by a licensed mortician for such interment or cremation.
- c. Used products for personal hygiene, such as diapers, facial tissues and sanitary napkins.
- d. Material, except for sharps, containing small amounts of blood with no free flowing or unabsorbed blood.
- e. Hair, nails, and extracted teeth.

4.2. Exemptions

4.2.1. These rules shall not apply to infectious waste from single or multiple residences or hotels, motels, or boarding homes provided:

- a. waste was not generated by the provision of health care services on the premises and
- b. sharps are placed in a container with a high degree of puncture-resistance before being mixed with other wastes or disposed.

4.2.2. These rules shall not apply to health care professionals who generate infectious waste in the provision of health care services in their own office or in the private home of a patient, provided:

- a. With respect to infectious waste other than sharps, the office or the patient's home generates or accumulates no more than 64 gallons in 14 days, (second option = 50 lbs./month) the waste is packaged and labeled in accordance with section _____, and the waste is delivered within 45 days to a permitted infectious waste treatment or storage facility.
- b. Sharps are packaged in rigid, leak-proof and puncture-resistant containers, labeled in accordance with section _____, and delivered to a permitted infectious waste treatment or storage facility.
- c. The health care professional transports or arranges for the transport of the infectious waste to a permitted infectious waste treatment or storage facility.

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d. The health care professional prepares and maintains an up-to-date written infectious waste management plan. A copy shall be submitted to the administrator upon request and shall also be available on the premises for inspection by the administrator. The infectious waste management plan shall include, at a minimum:

- 1) a description of the infectious waste generated by the facility including type and volume of waste;
- 2) a description of infectious waste handling and storage procedures;
- 3) the treatment/disposal methods for each type of infectious waste;
- 4) transportation method;
- 5) name, address, telephone number, and infectious waste licensed transporter number, if applicable;
- 6) personnel training procedures; and
- 7) name, address, and telephone number of the person(s) responsible for infectious waste management at the facility.

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- 5.1 No person may own, construct, modify, or operate an infectious waste management facility without first obtaining a permit for such facility from the administrator, unless specifically excluded or exempted in this rule or under a permit by rule as defined in 5.2.
- 5.2 Permit By Rule - Qualifying non-commercial facilities are deemed to operate under a permit for an infectious waste management facility and their owners or operators are not required to comply with the permit application procedures of section 12.0 of this rule. Only those non-commercial facilities that are in complete compliance with all the following conditions are qualified and considered to be under a permit by rule for their operation, and the permit by rule shall be immediately terminated when the facility fails to fulfill any of the following conditions:
- a. The facility and all infectious waste activities are in compliance with all parts of this rule except section 12.0.
 - b. More than seventy-five percent (75%) by weight in a calendar year of all infectious waste that is stored, treated or disposed of by the facility is generated on-site.
 - c. No infectious waste is transported or received by the facility without being properly packaged and labeled in accordance with this rule.
 - d. The owner or operator of the facility has notified the administrator in writing that the facility is operating under a permit by rule. The notice shall give the name, mailing address, and location address of the facility, and the type of business the facility serves. The notice shall also include a written infectious waste management plan appropriate for the size and type of facility. Such plan shall set forth policies and procedures consistent with this rule for managing infectious waste and shall include, at a minimum, the following:
 - 1) a description of the infectious waste generated by the facility including type and volume of waste.
 - 2) a detailed description of infectious waste handling and storage procedures.
 - 3) a description of the treatment and disposal methods for each type of infectious waste.
 - 4) transportation method, if applicable.

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- 5) name, address, telephone number, and licensed transporter number, if applicable.
- 6) personnel training procedures.
- 7) names, addresses and telephone numbers of the principal corporate officer and the person(s) responsible for infectious waste management at the facility.

5.2.1. While persons who own or operate qualifying facilities are not subject to section 12.0 or required to have a written permit from the administrator for those qualifying facilities, they are subject to this rule and all other parts thereof.

5.2.2. If a person owns or operates an infectious waste management facility that does not qualify for a permit by rule, that person must comply with section 12.0 and all other parts of this rule for those facilities, without regard to the presence of any other facilities on the site that are operated under a permit by rule.

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- 6.1. Responsibility for packaging and labeling - The generator of infectious waste is responsible for the packaging and labeling of infectious wastes.
- 6.1.1. Contractors or other agents may provide services to the generator, including packaging and labeling of infectious waste; however, no contract or other relationship shall relieve the generator of the responsibility for packaging and labeling the infectious waste as required by this rule.
- 6.1.2. No person shall receive for transportation, storage, treatment or disposal any infectious waste that is not packaged in accordance with this rule. Contractors or other agents may package or repackage infectious wastes to comply with this rule, if the packaging or repackaging is performed on-site where the infectious waste was generated and no transportation, storage, treatment or disposal occurs prior to the packaging or repackaging. Nothing in this section shall prevent the proper repackaging and further transportation of infectious waste that has spilled during transportation.
- 6.2. Packaging prior to storage, treatment, transport or disposal - All infectious waste shall be packaged as follows before it is stored, treated, transported or disposed of:
- 6.2.1. Infectious wastes shall be contained and sealed on-site in leak-proof, plastic bags capable of passing the ASTM 125 pound drop weight test. Free liquids shall be contained in break-resistant, tightly stoppered containers. Heavy materials must be supported in double-walled corrugated fiberboard boxes or equivalent rigid containers. Sharps shall be collected at the point of generation in puncture resistant containers, and those containers placed inside a plastic bag prior to storage or transport. All bags shall be sealed by lapping the gathered open end and binding with tape or closing device such that no liquid can leak.
- 6.2.2. All bags containing infectious waste shall be red in color except that infectious waste that is to be sterilized shall be contained in orange bags and marked with autoclave tape. Both red and orange bags shall be imprinted with the international biohazard symbol and the words "infectious waste" or "biomedical waste" or "biohazard". Waste contained in red bags shall be considered infectious waste and managed as infectious waste. Wastes in orange bags shall be managed as infectious wastes prior to steam sterilization and as solid waste after steam sterilization. Waste in orange bags shall be sterilized before disposal and shall not be treated or disposed of by incineration or any other method prior to steam sterilization.

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6.2.3. All infectious waste which is to be transported off-site or in a motor vehicle on a street or highway must also be packaged in double-wall corrugated fiberboard boxes or equivalent rigid containers. The box or container shall be leak-resistant or lined with a tear-resistant, leakproof plastic bag.

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6.2.4. Reusable containers shall be leakproof, vermin proof, have tight-fitting covers, and be kept clean and in good repair. Reusable containers shall be thoroughly washed and disinfected each time they are emptied unless the surfaces of the containers have been effectively protected from contamination by disposable liners, bags or other devices which are removed and disposed of with the waste; however, a red bag may not be enclosed in a bag of another color. Disinfection of the container shall be accomplished by one of the following methods:

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

6.2.4.2. 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; iodoforn 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. Instead of immersion, the container may be swabbed or rinsed with the chemical sanitizer provided the strength of the chemical sanitizer is double that required in this section.

6.2.5. Persons packaging infectious waste shall wear heavy gloves of neoprene or equivalent materials.

6.3. Labeling Requirements

6.3.1. Infectious waste to be transported off-site shall be labeled immediately after packaging. The label shall be securely attached to the outer layer of packaging and 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 inches by five inches in size. The following information shall be included:

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

b. "Infectious Waste" in large print.

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c. The name, address and business telephone number of all transporters, treatment facilities, or other persons to whose control the infectious waste is transferred. License number of transporters shall be provided if applicable.

d. The date upon which the infectious waste was packaged.

6.3.2. Treated infectious waste shall be labeled immediately after treatment. The label shall be sized and attached as required in section 6.3.1. The following information shall be included on the label:

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

b. The date upon which the infectious waste was treated.

c. Treatment method utilized.

d. Statement indicating that the waste has been treated and is no longer infectious waste.

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7.1. Spill containment and cleanup kit - All infectious waste management facilities are required to keep a spill containment and cleanup kit within the vicinity of any area where infectious wastes are managed, and the location of the kit shall provide for rapid and efficient cleanup of spills anywhere within the area. All vehicles transporting infectious wastes are required to carry a spill containment and cleanup kit in the vehicle whenever infectious wastes are conveyed. The kit shall consist of at least the following items:

7.1.1. Material designed to absorb spilled liquids. The amount of absorbent material shall be that having a rated capacity of one gallon of liquid for every cubic foot of infectious waste that is normally managed in the area for which the kit is provided or ten gallons, whichever is less. For vehicles transporting infectious waste, the amount of absorbent material shall be rated to absorb ten gallons.

7.1.2. One gallon of hospital grade disinfectant in a sprayer capable of dispersing its charge in a mist and in a stream at a distance. The disinfectant should be hospital grade and effective against mycobacteria.

7.1.3. Enough red plastic bags to double enclose 150 percent of the maximum load accumulated or transported, that meet the ASTM 125 pound drop weight test and are accompanied by sealing tape or devices and labels or tags. These bags shall be large enough to overpack any box or other container normally used for infectious waste management by that facility.

7.1.4. Two new sets of liquid impermeable and disposable overalls, gloves, boots, caps and protective breathing devices. Overalls, boots and caps shall be oversized or fitted to infectious waste workers and be made of materials impermeable to liquids. Boots may be of thick rubber and gloves shall be of heavy neoprene or equivalent. Boots, gloves and breathing devices may be reused if fully disinfected between uses. Tape for sealing wrists and ankles shall also be in the kit.

7.1.5. A first aid kit and boundary marking tape.

7.2. Containment and cleanup procedures - Following a spill of infectious waste or its discovery, the following procedures shall be implemented:

7.2.1. Leave the area until the aerosol settles (no more than a few minutes delay).

7.2.2. The cleanup crew will don the cleanup outfits described in section 7.1.4. and secure the spill area.

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- 7.2.3. Spray the broken containers of infectious waste with disinfectant.
 - 7.2.4. Place broken containers and spillage inside overpack bags in the kit, minimizing exposure.
 - 7.2.5. Disinfect the area and take other cleanup steps deemed appropriate.
 - 7.2.6. Clean and disinfect nondisposable items.
 - 7.2.7. Clean and disinfect cleanup outfits before removing.
 - 7.2.8. Remove cleanup outfits and place disposable items in cleanup bag.
 - 7.2.9. Take necessary steps to replenish containment and cleanup kit with items used.

7.3. Exceptions for small quantity spills - When a spill involves only a single container of waste whose volume is less than 32 gallons and spilled liquid whose volume is less than one quart, the individual responsible for the cleanup may elect to use alternate appropriate dress and procedures than those described in section 7.2. Such alternate dress or procedures shall provide an equal protection of the health of workers and the public.

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- 8.1. The requirements of this section apply only to areas of storage where more than 64 gallons of infectious waste are accumulated in 14 days (second option = more than 50 lbs. of infectious waste are accumulated in one month).
- 8.2. This section is applicable to the storage of infectious waste at any time after packaging including during transportation and at incinerator, steam sterilization and other treatment and disposal sites or facilities.
- 8.3. Excluding sharps, infectious waste stored for more than 72 hours after generation must be refrigerated at 45°F or below.
- 8.4. No infectious waste shall be stored for more than thirty (30) days, even if refrigerated.
- 8.5. Storage of infectious waste shall be in a specifically designated area located at or near the treatment site, or at the pickup point if it must be transported off site for treatment.
- 8.5. 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 nonputrescent, odorless state.
- 8.6. All areas used to store infectious waste shall be durable, easily cleanable, impermeable to liquids, and vermin proof.
- 8.7. Carpets and floor coverings with seams shall not be used in storage areas. All floor drains shall discharge directly to an approved sanitary sewage disposal system.
- 8.8. All storage areas shall be kept clean and in good repair.
- 8.9. All areas used to store infectious waste must have access control that limits access to those persons specifically designated to manage infectious 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 indicating use of the area for storage of infectious waste and denying entry to unauthorized persons.
- 8.10. Infectious wastes shall not be placed in chutes at any time.
- 8.11. Compaction of infectious waste or subjecting infectious waste to violent mechanical action is prohibited unless a part of a treatment or disposal process approved by the administrator.

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- 9.1. The requirements of this part apply to all transportation of infectious waste over roads or highways, by railroad or by water conveyance. It specifically includes all motor vehicle transportation.
- 9.2. Time in transport shall be accounted as time in storage. At all times during transportation, the storage requirements of sections 8.3 through 8.11 shall be applicable.
- 9.3. No person shall receive for transportation any infectious waste that is not packaged and labeled in accordance with section 6.0 of this rule.
- 9.4. A transporter shall deliver infectious waste in the State of West Virginia only to a permitted infectious waste management facility.
- 9.4. Identification of vehicles - All vehicles transporting infectious waste shall be prominently identified on the two sides and the back of the cargo compartment with the following:
- the international biohazard symbol,
 - the words "infectious waste", "biomedical waste", or "biohazard", and
 - the transporter's license number issued by the administrator as required in section 9.7. of this rule.
- 9.5. Spills - All vehicles transporting infectious waste shall carry a spill containment and cleanup kit in the vehicle whenever infectious wastes are conveyed as required by section 7.1 of this rule. Spills of infectious waste during transportation shall be managed as required in sections 7.2 and 7.3 of this rule. Direct physical contact of the transport vehicle or equipment with infectious waste shall be considered and managed as a spill.
- 9.6. Disinfection - All transport vehicles and equipment used to transport infectious waste must be thoroughly cleaned and disinfected weekly or as required in section 9.5; before being used for any other purpose; and prior to any transfer of ownership.
- Draft** 9.7. License Required - No person shall transport infectious waste in West Virginia who does not possess a valid license issued to him by the administrator, unless specifically exempted in section ___.
- 9.8. Application - An application for a license to transport infectious waste shall be made in writing to the administrator on a form prescribed by the administrator and signed by the applicant or his authorized representative. The application shall contain at a minimum the following:
- Name of the person or firm.

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- b. Business address and telephone number of person or firm, including headquarters and local office.
 - c. Make, model and license number of each vehicle to be used to transport infectious waste within West Virginia.
 - d. Name, business address and telephone number of each driver who will operate in West Virginia.
 - e. Area (counties and cities) in West Virginia in which the transporter will operate.
 - f. Any person or firm other than reported in 9.8.a. that is associated with the applicant firm or any other name under which that person or firm does business.
 - g. Any other person or firm using any of the same vehicles and operators.
 - h. The name and telephone number of a person who may be contacted in the event of an accident or release.
 - i. Detailed description of the methods to be utilized to clean and disinfect the transport vehicles and equipment as required in sections 9.5 and 9.6 of this rule.
 - j. Verification that the applicant and all his or her employees involved in the transportation of infectious waste are familiar with the provisions of this rule and agree to comply in full with said provisions.
- 9.9. Application Fee - The application shall be accompanied by a fee per transport vehicle according to the fee schedule in section _____ of this rule.
- 9.10. Once the application has been approved by the administrator, a license will be issued to the applicant. All transport vehicles shall display a license decal provided by the administrator in a prominent position on the driver's side.
- 9.11. Licenses shall not be transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation.
- 9.12. Licenses shall expire two years from the date of issuance. Application for renewal shall be submitted to the administrator at least 45 days prior to the expiration date and shall be accompanied by a fee per vehicle according to the fee schedule in section ____ of this rule.
- 9.13. The administrator may without warning, notice, or hearing suspend a license to transport infectious waste if the holder of the license does not comply with the requirements of this rule, or if the transportation procedures do not comply with the requirements of this rule, or if the transporter's operation constitutes a substantial hazard to public health. When a license is suspended, the transportation of infectious waste shall immediately cease.

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9.14. The administrator may revoke a license to transport infectious waste for repeated or serious violations of any of the requirements of this rule or for the interference with the administrator in the performance of his duties.

9.15. Upon request the transporter shall provide the administrator with the names, addresses, and telephone numbers of the infectious waste management facilities and generators with which the transporter has a contract or agreement for services.

9.16. Any person whose license has been suspended or revoked may, at any time, make application for reinstatement of the license. Within ten (10) days following receipt of a written request, including a signed statement by the applicant that in his opinion the conditions causing the suspension of the license have been corrected, the administrator shall make an inspection or investigation of the applicant's operation. If the applicant complies with the provisions of these regulations, the license shall be reinstated.

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10.1. All infectious waste must be treated by one of the following methods:

- a. incineration as described in section _____
- b. steam sterilization as described in section _____
- c. discharge to a sanitary sewer as described in section _____.
- d. any other method approved in writing by the administrator.

10.1.1. Upon treatment in accordance with this rule, the waste or its ash is not infectious waste and may be disposed of as non-infectious waste.

10.2 Incineration - All incinerators for infectious waste shall maintain the following level of operational performance at all times:

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- 10.2.1. Operational temperature and retention time - whenever infectious wastes are introduced into an incinerator, all the waste shall be subjected to a burn temperature of not less than 1400°F for a period not less than one hour. Gases generated by the combustion shall be subjected to a temperature of not less than 1800°F for a period of one second or more. Except at start-up, interlocks or other process control devices shall prevent feeding of the incinerator unless these conditions can be achieved.
 - 10.2.2. Loading and operating controls - The incinerator shall have interlocks or other process control devices to prevent feeding of the incinerator until the conditions in section 10.2.1. 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 wastes, of independently maintaining the secondary chamber temperature at the minimum of 1800°F.
 - 10.2.3. Monitoring - There shall be continuous monitoring and recording of primary and secondary chamber temperatures. Monitoring data shall be maintained for a period of three years.
 - 10.2.4. Ash testing - All combustible waste shall be converted by the incineration process into ash that is not recognizable as to its former character. Incinerator ash shall be tested at least monthly for total organic carbon content. A maximum of 5% fixed carbon is permitted (minimum 95% burnout).

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10.2.5. The incinerator shall be permitted by the Air Pollution Control Commission and be in compliance with the regulations of that agency.

10.2.6. No person shall operate an infectious waste incinerator unless he or she has a valid certificate issued by the administrator. Certification shall be dependent upon the applicant completing a course of study approved by the administrator. Obtaining a passing score of 70% on a written examination may be required by the administrator.

10.3. Steam Sterilization - All sterilizers for infectious waste shall maintain the following level of operational performance at all times:

10.3.1. Operational temperature and detention - All the waste shall be subjected to the following operational standards:

a. Temperature of not less than:

250°F for 90 minutes at 15 pounds per square inch of gauge pressure (psi),

272°F for 45 minutes at 27 psi,

250°F for 28 minutes at 80 psi, or

270°F for 16 minutes at 80 psi.

NOTE

Other combinations of operational temperatures, pressure and time may be approved by the administrator if the installed equipment has been proved to achieve a reliable and complete kill of all microorganisms in waste at design capacity. Complete and thorough testing shall be fully documented, including tests of the capacity to kill *B. stearothermophilus*. Longer steam sterilization times are required when a load contains a large quantity of liquid.

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10.3.2. Each package of waste to be sterilized shall have a tape attached that will indicate if the steam sterilization temperature has been reached and waste will not be considered satisfactorily sterilized if the indicator fails to indicate that temperature was reached during the process. Each package shall also be labeled according to section 6.3.2.

10.3.3. Steam sterilization units shall be evaluated under full loading for effectiveness with spores of *B. stearothermophilus* no less than once per every 40 hours of operation.

10.3.4.

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A log shall be kept at each steam sterilization unit that is complete for the preceding three year period. The log shall record the date, time and operator of each usage; the type and approximate amount of waste treated; the post-sterilization reading of the temperature sensitive tape; the dates and results of calibration; and the results of effective testing described in section 10.3.3. Where multiple steam sterilization 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 years and be available for review.

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11.1. All generators and transporters of infectious waste and all infectious waste management facilities shall maintain the following records, if applicable, and assure that they are accurate and current:

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- a. A log of infectious waste received from off-site, the generator, the amount, the generation and receipt dates, and the treatment/disposal date.
- b. A log of infectious waste transported off-site, the transporter, the destination, the amount and the generation and transport dates.
- c. The date, persons involved and short description of events in each spill of infectious wastes involving more than 32 gallons of waste or one quart of free liquid.

11.2. Records shall be maintained for a period of three years and shall be available to the administrator upon request. 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 administrator.

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11.1. The generator of infectious waste that is to be transported off-site for storage, treatment, or disposal shall initiate a 5 part manifest available from the administrator. Copy 4 of the manifest is to be retained by the generator; copy 3, by the transporter(s); copy 2, by the storage, treatment or disposal facility; and copy 1 is to be returned to the generator.

11.2. If the generator does not receive the completed manifest from the treatment or disposal facility within 35 days after the date the waste was accepted by the transporter, the generator shall report this fact to the administrator.

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

11.4. A transporter shall in the presence of the generator or, for subsequent transporters, the prior transporter, complete the appropriate transporter portion of the manifest, including handwritten acceptance signature and date of acceptance, and immediately give a signed copy of the manifest to the generator or prior transporter, noting any discrepancies in manifest information.

11.5. An infectious waste management facility shall not accept more than 50 pounds (or 64 gallons, depending on option selected) of infectious waste from a generator or any quantity of infectious waste from a transporter unless it is accompanied by a properly completed manifest.

11.6. The infectious waste management facility shall, in the presence of the generator or transporter, complete the appropriate storage, transfer, treatment or disposal facility portion of the manifest, including handwritten acceptance signature and date of acceptance, and immediately give a signed copy of the manifest to the generator or transporter, noting any discrepancies in manifest information.

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

11.8. The facility shall keep a copy of the completed manifest as part of the facility operating record and shall forward a completed copy to the generator within 35 days after the waste was accepted by the transporter.

11.9. In instances where an infectious waste management facility accepts less than 50 pounds (or 64 gallons) of infectious waste from a generator, the facility shall maintain a log of such receipts which includes, at a minimum, the following:

- a. The name and address of the generator.
- b. The type and volume of waste received.

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c. The date of receipt of such waste.

d. The signature of the person receiving the waste.

11.10. Manifests and related records and logs shall be retained by all parties for a period of not less than 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 administrator. These records shall be available for inspection by the administrator upon request.

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PART IX
PERMIT APPLICATION AND ISSUANCE
PROCEDURES

§ 9.1. Scope of Part IX.

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This part of the regulations requires a permit for the treatment, storage or disposal of any infectious waste unless specifically excluded by these regulations or under a permit by rule as defined in § 4.1. of these regulations owners and operators of infectious waste management units shall have permits during the active life (including the closure periods) of the unit. The Executive Director may issue or deny a permit for one or more units at a facility without simultaneously issuing or denying a permit to all of the units at the facility.

§ 9.2. Application for Permit.

- A. **Permit application.** Any person who is required to have a permit (including new applicants and permittees with expiring permits) shall complete, sign, and submit an application to the Executive Director, including the form contained in the appendix. Persons covered by permits by rule need not apply, but must notify the Department in accord with Part IV. Procedures for application, issuance and administration of emergency permits are found exclusively in § 9.7.A. Procedures for application, issuance and administration of research, development, and demonstration permits are found exclusively in § 9.7.B.
- B. When a facility or activity is owned by one person but is operated by another person, it is the operator's duty to obtain a permit; however, the owner shall also sign the permit application.
- C. **Completeness of Application.**
1. The Executive Director shall not begin the processing of a permit until the applicant has fully complied with the application requirements for that permit contained in § 9.3. and the signature requirements of § 9.6.
 2. The Executive Director shall not issue a permit before receiving a complete application except permits by rule or emergency permits. An application for a permit is complete when the Executive Director receives an application form and any supplemental information which are completed to his satisfaction. The completeness of any application for a permit shall be judged independently of the status of any other permit application or permit for the same facility or activity.
 3. All applicants for infectious waste management permits shall provide information set forth in § 9.3. and applicable portions of § 9.4. to the Executive Director.

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- D. Existing facilities qualifications. Owners and operators of existing and permitted infectious waste management facilities are not required to submit an application for a new permit at the time these regulations become effective. Existing permits will remain valid, except that conditions or waivers in existing permits in conflict with these regulations are void and operators of existing facilities are required to comply with these regulations.
- E. New facilities. No person shall begin physical construction of a new facility without having submitted the permit application and having received a final effective permit.

§ 9.3. Contents of The Application.

The application shall include the following information:

- A. The activities conducted by the applicant which require him to obtain a permit.
- B. Name, mailing address, and location of the facility for which the application is submitted.
- C. The latitude and longitude of the facility.
- D. The name, address and telephone number of the owner or the facility.
- E. An indication of whether the facility is new or existing.
- F. For existing facilities, a scale drawing of the facility showing the location of all past, present, and future treatment, storage, and disposal areas.
- G. For existing facilities, photographs of the facility clearly delineating all existing structures; existing treatment, storage, and disposal areas; and sites of future treatment, storage, and disposal areas.
- H. The operator's name, address, telephone number, ownership status, and status as federal, state, private, public, or other entity.
- I. A listing of all permits or construction approvals received or applied for under any of the following programs and their counterpart programs administered by the Commonwealth:
 - 1. Hazardous waste management program under RCRA;
 - 2. NPDES program under CWA;
 - 3. Prevention of Significant Deterioration (PSD) program under the Clean Air Act;
 - 4. Nonattainment program under the Clean Air Act;
 - 5. Other relevant environmental permits, including local permits.

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- J. A topographic map (or other map if a topographic map is unavailable) extending one mile beyond the property boundaries of the source, depicting the facility and each of its intake and discharge structures; each of its infectious waste treatment, storage, or disposal facilities; and those wells, springs, other surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant within the quarter-mile of the facility property boundary.
- K. A brief description of the nature of the business.
- L. A description of the processes to be used for treating, storing, transporting and disposing of infectious waste, and the design capacity of these items;
- N. A description of the type of the infectious wastes to be treated, stored, transported or disposed at the facility, an estimate of the quantity of such wastes to be treated, stored, transported or disposed annually.
- M. A certification from the governing body of the city, county or town in which the facility is to be located that the location and operation of the facility are consistent with all applicable ordinances (In accordance with § 10.1-1408.1.B. of the Code of Virginia).

§ 9.4. Detailed Submittal.

The following information is required for all facilities, however, its submittal may be delayed pending a preliminary evaluation by the Department of the concept of the application based on the information above.

- A. Conceptual review. The applicant may request in writing that the Department perform a conceptual review. The evaluation of the concept is not a commitment on the part of the Department to issue a permit, nor is it a commitment by the applicant to proceed with the permitting process.
- B. Final review. No final permit will be considered or issued until the following information is submitted and is complete (Note: If owners and operators of facilities can demonstrate that the information prescribed cannot be provided to the extent required, the Executive Director may take allowance for submission of such information on a case by case basis.):
 1. A description of procedures, structures, or equipment used at the facility to:
 - a. Prevent hazards in unloading operations.
 - b. Prevent run-off from infectious waste handling areas to other areas of the facility or environment.
 - c. Prevent contamination of water supplies.
 - d. Mitigate effects of equipment failure and power outages.
 - e. Prevent exposure of personnel to infectious waste.

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Traffic pattern, estimated volume (number, types of vehicles) and control; describe access road surfacing and load bearing capacity; show traffic control signals.

3. Owners and operators of all facilities shall provide an identification of whether the facility is located within a 100-year flood plain. This identification shall indicate the source of data for such determination and include a copy of the relevant Federal Insurance Administration (FIA) flood map, if used, or the calculations and maps used where a FIA map is not available. Information shall also be provided identifying the 100-year flood level and any other special flooding factors (e.g., wave action) which shall be considered in designing, constructing, operating, or maintaining the facility to withstand washout from a 100-year flood.
4. An outline of both the introductory and continuing training programs by owners and operators to prepare persons to operate or maintain the facility in a safe manner as required. A brief description of how training will be designed to meet actual job tasks.
5. A copy of the closure plan.
6. Closure cost documentation. The most recent closure cost and post-closure cost estimates for the facility and a copy of the documentation required to demonstrate financial assurance under.
7. A topographic map showing a distance of 1,000 feet around the facility at a scale of 2.5 centimeters (1 inch) equal to not more than 61.0 meters (200 feet). Contours shall be shown on the map. The contour interval shall be sufficient to clearly show the pattern of surface water flow in the vicinity of and from each operational unit of the facility. For example, contours with an interval of 1.5 meters (5 feet), if relief is greater than 6.1 meters (20 feet) or an interval of 0.6 meters (2 feet), if relief is less than 6.1 meters (20 feet). Owners and operators of facilities located in mountainous areas should use larger contour intervals to adequately show topographic profiles of facilities. The map shall clearly show the following:
 - a. Map scale and date.
 - b. 100-year flood plain area.
 - c. Surface waters including intermittent streams.
 - d. Surrounding land uses (residential, commercial, agricultural, recreational).
 - e. A wind rose (i.e., prevailing wind speed and direction).
 - f. Orientation of the map (north arrow).
 - g. Legal boundaries of the facility site.
 - h. Access control (fences, gates).

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- i. Injection and withdrawal wells both on-site and off-site.
 - j. Buildings; treatment, storage, or disposal operations; or other structures (recreation areas, run-off control systems, access and internal roads, storm, sanitary, and process sewerage systems, loading and unloading areas, fire control facilities, etc.).
 - k. Barriers for drainage or flood control.
 - l. Location of operational units within the facility site, where infectious waste is (or will be) treated, stored, or disposed (including equipment cleanup areas).
 - m. Applicants may be required to submit such information as may be necessary to enable the Executive Director to carry out his duties as required.
8. From owners or operators of facilities that are used or to be used for storage or treatment, a description of the containment and refrigeration system.
 9. For facilities that incinerate infectious waste.
 - a. An analysis of each waste or mixture of wastes to be burned.
 - b. Estimated heat value of the waste in the form and composition in which it will be burned.
 - c. A detailed engineering description of the incinerator, including:
 - (1) Manufacturer's name and model number of incinerator.
 - (2) Type of incinerator.
 - (3) Linear dimension of incinerator unit including cross sectional area of combustion chamber.
 - (4) Description of auxiliary fuel system (type/feed).
 - (5) Capacity of prime mover.
 - (6) Description of automatic waste feed cutoff system(s).
 - (7) Stack gas monitoring and pollution control monitoring system.
 - (8) Nozzle and burner design.
 - (9) Construction materials.
 - (10) Location and description of temperature, pressure, flow indication and control devices.
 - (11) Feed-minimum temperature interlock system.
 - d. The expected incinerator operation information, including:
 - (1) Gas zone temperatures and detention time;

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- (2) Waste feed rate;
 - (3) Combustion zone temperature;
 - (4) Indication of combustion gas velocity;
 - (5) Expected stack gas volume, flow rate, and temperature;
 - (6) Computed residence time for waste in the combustion zone;
 - (7) Proposed waste feed cutoff limits based on the identification significant operating parameters.
 - (8) Operation of feed-temperature maintenance interlock system.
- e. Such supplemental information as the Executive Director finds necessary to achieve the purposes of this paragraph.

§ 9.5. Recordkeeping.

Applicants shall keep records of all data used to complete permit applications and any supplemental information submitted for a period of at least 3 years from the date the application is signed.

§ 9.6. Signatories to Permit Applications and Reports.

- A. Applications. All permit applications shall be signed as follows:
1. For a corporation: By a principal corporate officer as defined in Part I.
 2. For a partnership or sole proprietorship: By a general partner or the proprietor, respectively; or
 3. For a municipality, state, federal, or other public agency: By either a principal executive officer (see Part I) or ranking elected official.
- B. Reports. All reports required by permits and other information requested by the Executive Director shall be signed by a person described in § 9.6.A. above or by a duly authorized representative of that person. A person is a duly authorized representative only if:
1. The authorization is made in writing by a person described in § 9.6.A.;
 2. The authorization specifies either an individual or a position having responsibility for the overall operation of the regulated facility or activity; and
 3. The written authorization is submitted to the Executive Director.
- C. Changes to authorization. If an authorization is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, a new authorization satisfying the requirements shall be submitted to the

Executive Director prior to or together with any reports, information or applications to be signed by an authorized representative.

- D. **Certification.** Any person signing a document under § 9.6.A. or 9.6.B. shall make the following certification:

"I certify under penalty of law that this document and all attachments are prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

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§ 9.7. Special Infectious Waste Management Permits.

- A. **Emergency permits.** Notwithstanding any other provision of Part IX, in the event the Executive Director finds an imminent and substantial endangerment to human health or the environment, the Executive Director may issue a temporary emergency permit to a facility to allow treatment, storage, transportation or disposal of infectious waste for a nonpermitted facility or infectious waste not covered by the permit for a facility with an effective permit. Such permits:
1. May be oral or written. If oral, it shall be followed within five days by a written emergency permit;
 2. Shall not exceed 90 days in duration;
 3. Shall clearly specify the infectious wastes to be received, and the manner and location of their treatment, storage, transportation or disposal;
 4. May be terminated by the Executive Director at any time without process if it is determined that termination is appropriate to protect human health or the environment; and
 5. Shall be accompanied by a public notice as required by the Virginia Administrative Process Act, including:
 - a. Name and address of the office granting the emergency authorization;
 - b. Name and location of the permitted facility;
 - c. A brief description of the wastes involved;
 - d. A brief description of the action authorized and reasons for authorizing it;
 - e. Duration of the emergency permit; and

6. Shall incorporate, to the extent possible and not inconsistent with the emergency situation, all applicable requirements of these regulations.

Research, development and demonstration permits.

1. The Executive Director may issue a research, development and demonstration permit for any infectious waste treatment facility which proposes to utilize an innovative and experimental infectious waste treatment technology or process for which permit standards for such experimental activity have not been promulgated. Any such permit shall include such terms and conditions as will assure protection of human health and the environment. Such permits:
 - a. Shall provide for the construction of such facilities as necessary, and for operation of the facility for no longer than one year unless renewed as provided in § 9.7.B.4., and
 - b. Shall provide for the receipt and treatment by the facility of only those types and quantities of infectious waste which the Executive Director deems necessary for purposes of determining the efficiency and performance capabilities of the technology or process and the effects of such technology or process on human health and the environment, and
 - c. Shall include such requirements as the Executive Director deems necessary to protect human health and the environment (including, but not limited to, requirements regarding monitoring, operation, financial responsibility, closure and remedial action), and such requirements as the Executive Director deems necessary regarding testing and providing of information to the Executive Director with respect to the operation of the facility.
2. For the purpose of expediting review and issuance of permits under this section, the Executive Director may, consistent with the protection of human health and the environment, modify or waive permit application and permit issuance requirements in Parts IX.
3. The Executive Director may order an immediate termination of all operations at the facility at any time he determines that termination is necessary to protect human health and the environment.
4. Any permit issued under § 9.7.B. may be renewed not more than three times. Each such renewal shall be for a period of not more than one year.

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§ 9.8. Conditions Applicable to All Permits.

The following conditions apply to all infectious waste management permits. All conditions applicable to all permits shall be incorporated into the permits either expressly or by reference. If incorporated by reference, a specific citation to these regulations shall be given in the permit.

- A. Duty to comply.** The permittee shall comply with all conditions of the permit, except that permittee need not comply with the conditions of this permit to the

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- extent and for the duration such noncompliance is authorized in an emergency permit (see § 9.7:A). Any permit noncompliance, except under the terms of an emergency permit, constitutes a violation of Title 10.1, Code of Virginia (1950) as amended, and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or for denial of a permit renewal application.
- B. Duty to reapply. If the permittee wishes to continue a regulated activity after the expiration date of his permit, he shall apply for and obtain a new permit.
 - C. Need to halt or reduce activity not a defense. It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.
 - D. Duty to mitigate. In the event of noncompliance with the permit, the permittee shall take all reasonable steps to minimize releases to the environment, and shall carry out such measures as are reasonable to prevent significant adverse impacts on human health or the environment.
 - E. Proper operation and maintenance. The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control which are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance includes effective performance, adequate funding, adequate operator staffing and training, and adequate laboratory and process controls, including quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems only when necessary to achieve compliance with permit conditions.
 - F. Permit actions. The permit may be modified, revoked, and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation, and reissuance, or termination, or a notification of planned changes or anticipated noncompliance does not stay any permit condition.
 - G. Property rights. The permit does not convey any property rights of any sort, or any exclusive privilege. Possession of a permit does not authorize any injury to persons or property or invasion of other private rights, or any infringement of Commonwealth or local law or regulations.
 - H. Duty to provide information. The permittee shall furnish to the Commonwealth within a reasonable time, any pertinent information which the Executive Director may request to determine whether cause exists for modifying, revoking, and reissuing, or terminating this permit or to determine compliance with this permit. The permittee shall also furnish to the Executive Director, upon request, copies of records required to be kept by the permit.
 - I. Inspection and entry. The permittee shall allow the Executive Director or an authorized representative, upon the presentation of credential and other documents as may be required by law, to:

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1. Enter at reasonable times upon the permittee's premises where a regulated facility or activity is located or conducted, or where records shall be kept under the conditions of the permit;
2. Have access to and copy, at reasonable times, any records that shall be kept under the conditions of the permit;
3. Inspect at reasonable times any facilities, equipment practices, or operations regulated or required under the permit; and
4. Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the regulations, any substances or parameters at any location.

J. Monitoring and records.

1. Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity. The permittee shall retain records of all monitoring information, including all calibrations and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit and records of all data used to complete the application for this permit, for a period of at least three years from the date of the sample, measurement, report, certification or application. This period may be extended by request of the Executive Director at any time.
- 2.⁴ Records of monitoring information shall include:
 - a. The date, exact place, and time of sampling or measurements;
 - b. The individual(s) who performed the sampling or measurements;
 - c. The date(s) analyses were performed;
 - d. The individual(s) who performed the analyses;
 - e. The analytical techniques or methods used; and
 - f. The results of such analyses.

K. **Signatory requirement.** All applications, reports, or information submitted to the Executive Director shall be signed and certified as specified as § 9.6.

⁴ Typographical correction has been made from officially registered text, "3"

L Reporting requirements.

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1. Planned changes. The permittee shall give written notice to the Executive Director as soon as possible of any planned physical alterations or conditions to the permitted facility.
2. Anticipated noncompliance. The permittee shall give advance written notice to the Executive Director of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements. For a new facility, the permittee may not commence treatment, storage or disposal of infectious waste; and for a facility being modified the permittee may not treat, store or dispose of infectious waste in the modified portion of the facility, until:
 - a. The permittee has submitted to the Executive Director by certified mail or hand delivery a letter signed by the permittee stating that the facility has been constructed or modified in compliance with the permit; and
 - b. The Executive Director has inspected the modified or newly constructed facility and finds it is in compliance with the conditions of the permit.
3. Transfers. This permit is not transferable to any person except with the approval of the Executive Director. The Executive Director may require modification or revocation and reissuance of the permit to change the name of the permittee and incorporate such other requirements as may be necessary. If the Executive Director finds that a name change is a minor modification, the requirements of § 9.17. will apply.
4. Monitoring reports. Monitoring results shall be reported at the intervals specified in the permit or these regulations.
5. Compliance schedules. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of the permit shall be submitted no later than 14 days following each schedule date.
6. Twenty-four hour reporting.
 - a. The permittee shall report to the Department any noncompliance which may endanger health or environment. Any information shall be provided orally within 24-hours from the time the permittee becomes aware of the circumstances.
 - b. The following shall be included as information which shall be reported orally within 24-hours:
 - (1) Information concerning release of any infectious waste that may cause an endangerment to public health.
 - (2) Any information of a release or discharge of infectious waste, or of a fire or explosion from an facility, which could threaten the environ-

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ment or human health outside the facility. The description of the occurrence and its cause shall include:

- (a) Name, address and telephone number of the owner or operator;
- (b) Name, address and telephone number of the facility;
- (c) Date, time and type of incident;
- (d) Name and quantity of material(s) involved;
- (e) The extent of injuries, if any;
- (f) An assessment of actual or potential hazards to the environment and human health outside the facility, where this is applicable; and
- (g) Estimated quantity and disposition of recovered material that resulted from the incident.

c. A written submission shall also be provided within 5 days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate and prevent reoccurrence of the noncompliance. The Executive Director may waive the 5-day notice requirement in favor of a written report within 15 days.

7. Other information where the permittee becomes aware that he failed to submit any relevant facts in a permit application, or submitted incorrect information in a permit application or in any report to the Executive Director, he shall promptly submit such facts or information.

§ 9.9. Establishing Permit Conditions.

A.

- 1. General. In addition to conditions required in all permits, the Executive Director shall establish conditions as required on a case-by-case basis, for the duration of permits, schedules of compliance, monitoring, and to provide for and assure compliance with all applicable requirements of these regulations.
- 2. Each permit issued under Part IX shall contain terms and conditions as the Executive Director determines necessary to protect human health and the environment.

B. An applicable requirement is a Commonwealth statutory or regulatory requirement which takes effect prior to final administrative disposition of a permit. An applicable requirement is also any requirement which takes effect prior to the

modification or revocation and reissuance of a permit, to the extent allowed in § 9.15.

- C. New or reissued permits, and to the extent allowed under § 9.15., modified or revoked and reissued permits, shall incorporate each of the applicable requirements in these regulations.
- D. Incorporation. All permit conditions shall be incorporated either expressly or by reference. If incorporated by reference, a specific citation to the applicable regulations or requirements shall be given in the permit.

§ 9.10. Duration of Permits and Renewal of Permits.

- A. Infectious waste management permit shall be effective for a fixed term not to exceed 10 years.
- B. The term of a permit shall not be extended by modification beyond the maximum duration specified in this part.
- C. The Executive Director may issue any permit for a duration that is less than the full allowable term under this part.
- D. If the holder of a valid permit for an infectious waste management facility files with the Executive Director a request to renew or extend the permit at least 180 days prior to the expiration of that permit, the Executive Director will cause an audit to be conducted of the facility's past operation, its current condition and the records held by the Department concerning the facility. Within sixty days of receipt of a proper request, the Department will report to the applicant the results of the audit and those items of correction or information required before renewal will be considered. At the time of filing, the applicant shall provide all information known to him that is changed or new since the original permit application and which he has not previously provided to the Department. If the applicant files for renewal or extension less than 180 days prior to the expiration of the original permit or files an improper application the Executive Director shall deny the application for renewal. If an application for renewal has been denied for a facility, any further applications and submittals shall be identical to those for a new facility.
- E. The Executive Director may refuse to renew a permit or issue a new permit for a facility if the facility has had a record of violations of the permit or regulations of the Department, as evidenced by notices and other enforcement actions of the Department; if the Executive Director believes current facilities may pose a threat to the health or environment or the facility will not comply with current regulations for design, siting and other physical characteristics which are applicable to new facilities.

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§ 9.11. Effect of a Permit.

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- A. Compliance with a valid permit during its term constitutes compliance for purposes of enforcement, with the Virginia Solid Waste Management Act. However, a permit may be modified, revoked and reissued, or terminated during its term for cause as set forth in these regulations.
 - B. The issuance of a permit does not convey any property rights of any sort, or any exclusive privilege.
 - C. The issuance of a permit does not authorize any injury to persons or property or invasion of other private rights, or any infringement of Commonwealth or local law or regulations.

§ 9.12. Transfer of Permits.

A permit may be transferred by the permittee to a new owner or operator only if the permit has been modified or revoked and reissued, or a minor modification made to identify the new permittee and incorporate such other requirements as may be necessary.

§ 9.13.⁵ Schedule of Compliance.

The permit may, when appropriate, specify a schedule of compliance leading to compliance with these regulations.

- A. Any schedules of compliance under this part shall require compliance as soon as possible.
- B. Except as otherwise provided, if a permit establishes a schedule of compliance which exceeds one (1) year from the date of permit issuance, the schedule shall set forth interim requirements and the dates for their achievement.
 - 1. The time between interim dates shall not exceed one (1) year;
 - 2. If the time necessary for completion of any interim requirement is more than one (1) year and is not readily divisible into stages of completion, the permit shall specify interim dates for the submission of reports of progress toward completion of the interim requirements and indicate a projected completion date.
- C. The permit shall be written to require that no later than fourteen (14) days following each interim date and the final date of compliance, a permittee shall notify the Executive Director, in writing, of his compliance or noncompliance with the interim or final requirements.

⁵ Typographical correction has been made from officially registered text, subsections renumbered.

§ 9.14. Modification, Revocation and Reissuance, or Termination of Permits.

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- A. If the Executive Director tentatively decides to modify or revoke and reissue a permit, he shall prepare a draft permit incorporating the proposed changes. The Executive Director may request additional information and, in the case of a modified permit, may require the submission of an updated permit application. In the case of revoked and reissued permits, the Executive Director shall require the submission of a new application.
1. In a permit modification under this part, only those conditions to be modified shall be reopened when a new draft permit is prepared. All other aspects of the existing permit shall remain in effect for the duration of the unmodified permit. When a permit is revoked and reissued under this part, the entire permit is reopened just as if the permit had expired and was being reissued. During any revocation and reissuance proceeding the permittee shall comply with all conditions of the existing permit until a new final permit is reissued.
 2. Minor modifications as specified in § 9.17. are not subject to the above requirements.
- B. If the Executive Director tentatively decides to terminate a permit, he shall issue a notice of intent to terminate. A notice of intent to terminate is a type of draft permit which follows the same procedures as any draft permit prepared under § 9.18.

§ 9.15. Modification or Revocation and Reissuance of Permits.

When the Executive Director receives any information, he may determine whether or not one or more of the causes listed for modification or revocation and reissuance or both exist. If cause exists, the Executive Director may modify or revoke and reissue the permit accordingly, subject to the limitations of § 9.15.C., and may request an updated application if necessary. If cause does not exist under this section or § 9.17., the Executive Director shall not modify or revoke and reissue the permit. If a permit modification satisfies the criteria in § 9.17. for minor modifications, the permit may be modified without a draft permit or public review. Otherwise, a draft permit shall be prepared and other appropriate procedures followed.

- A. **Causes for Modification.** The following are causes for modification but not revocation and reissuance of permits.
1. There are material and substantial alterations or additions to the permitted facility or activity which occurred after permit issuance which justify the application of permit conditions that are different or absent in the existing permit.
 2. If the Executive Director has received information pertaining to circumstances or conditions existing at the time the permit was issued that was not included in the administrative record and would have justified the application

of different permit conditions, the permit may be modified accordingly if in the judgment of the Executive Director such modification is necessary to prevent significant adverse effects on public health or the environment.

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3. The standards or regulations on which the permit was based have been changed by promulgation of amended standards or regulations or by judicial decision after the permit was issued. Permits may be modified during their terms for this cause only as follows:
 - a. For promulgation of amended standards or regulations, when:
 - (1) The permit condition requested to be modified was based on a promulgated infectious waste regulation;
 - (2) The Commonwealth has revised, withdrawn or modified that portion of the regulation on which the permit condition was based; and
 - (3) A permittee requests modification within ninety (90) days after notice of the action on which the request is based.
 - b. For judicial decision, a court of competent jurisdiction has remanded and stayed Commonwealth regulations, if the remanded and stay concern that portion of the regulations on which the permit condition was based and a request is filed by the permittee within ninety (90) days of judicial remand.
 4. The Executive Director determines good cause exists for modification of a compliance schedule, such as an act of God, strike, flood, or material shortage or other events over which the permittee has little or no control and for which there is no reasonably available remedy.
 5. The Executive Director may modify a permit:
 - a. After the Executive Director receives the notification of expected closure, or when he determines that extension of the 90 or 180 day periods are unwarranted⁶;
 - b. When the permittee has filed a request for a variance to the level of financial responsibility or when the Executive Director demonstrates that an upward adjustment of the level of financial responsibility is required.
 - c. To include conditions applicable to units at a facility that were not previously included in the facility's permit.

B. Cause for modification or revocation and reissuance. The following are causes to modify or, alternatively, revoke and reissue a permit:

⁶ Typographical correction has been made from officially registered text, text deleted and "or" added

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1. Cause exists for termination under § 9.16., and the Executive Director determines that a modification or revocation and reissuance is appropriate.
 2. The Executive Director has received notification of a proposed transfer of an existing permit.
- C. Facility siting. The suitability of the facility location will not be considered at the time of permit modification or revocation and reissuance unless new information or standards indicate that an endangerment to human health or the environment exists which was unknown at the time of permit issuance.

§ 9.16. Termination of Permits.

- A. The following are causes for terminating a permit during its term, or for denying a permit renewal application:
1. Noncompliance by the permittee with any condition of the permit;
 2. The permittee's failure in the application or during the permit issuance process to disclose fully all relevant facts, or the permittee's misrepresentation of any relevant facts at any time; or
 3. A determination that the permitted activity endangers human health or the environment and can only be regulated to acceptable levels by permit modification or termination.
- B. The Executive Director shall follow the applicable procedures of the Virginia Administrative Process Act in terminating any permit under this part.

§ 9.17. Minor Modification of Permits.

Upon the consent of the permittee, the Executive Director may modify a permit to make the corrections or allowances for changes in the permitted activity listed in this part, without following the required procedures for major modification, including those concerning public notice and public hearing. Any permit modification not processed as a minor modification under this part shall be made for cause and with draft permit and public notice as required. Minor modifications may only:

- A. Correct typographical error;
- B. Require more frequent monitoring or reporting by the permittee;
- C. Change an interim compliance date in a schedule of compliance, provided the new date is not more than 120 days after the date specified in the existing permit and does not interfere with attainment of the final compliance date requirement;
- D. Allow for a change in ownership or operational control of a facility where the Director determines that no other change in the permit is necessary, provided that a written agreement containing a specific date for transfer of permit responsibility between the current and new permittees has been submitted to the Director.

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Changes in the ownership or operational control of a facility may be made without further proceeding if the new owner or operator submits a revised permit application no later than 60 days prior to the scheduled change. When a transfer of ownership or operational control of a facility occurs, the old owner or operator shall comply with the requirements of any financial assurance regulations, until the new owner or operator has demonstrated to the Director that he is complying with the requirement. The new owner or operator shall demonstrate compliance with the requirements within six months of the date of the change in the ownership or operational control of the facility. Upon demonstration to the Director by the new owner or operator of compliance, the Director shall notify the old owner or operator in writing that he no longer needs to comply with § 9.7. as of the date of demonstration.

- E. Change the lists of facility personnel or equipment in the permit's contingency plan.

§ 9.18. Draft Permits.

- A. Once an application is complete, the Executive Director shall tentatively decide whether to prepare a draft permit or to deny the application.
- B. If the Executive Director tentatively decides to deny the permit application, he shall issue a notice of intent to deny. A notice of intent to deny the permit application is a type of draft permit which follows the same procedures as any draft permit prepared under this part. If the Executive Director's final decision is that the tentative decision to deny the permit was incorrect, he shall withdraw the notice of intent to deny and proceed to prepare a draft permit.
- C. If the Executive Director decides to prepare a draft permit, he shall prepare a draft permit that contains the following information:
 1. All conditions under §§ 9.8. and 9.9.;
 2. All compliance schedules under § 9.13.;

§ 9.19. Public Notice of Permit Actions and Public Comment Period.

- A. Scope. The Executive Director shall give public notice that the following actions have occurred;
 1. A draft permit has been prepared; or
 2. A hearing has been scheduled.
- B. Timing.
 1. Public notice of the preparation of a draft permit or the intent to deny a permit application shall allow at least 45 days for public comment;

2. Public notice of a public hearing shall be given at least thirty (30) days before the hearing.
- C. Methods. Public notice of activities described in this part shall be given by the following methods:
1. By mailing a copy of a notice to the following persons (any person otherwise entitled to receive notice under this paragraph may waive his or her rights to receive notice for any classes and categories of permits):
 - a. The applicant;
 - b. Any other agency which the Executive Director knows has issued or is required to issue a permit for the same facility or activity; and to each state agency having any authority under the state law with respect to the construction or operation of such facility, including the Department of Air Pollution Control for incinerator facilities;
 - c. Any unit of local government having jurisdiction over the area where the facility is proposed to be located and the appropriate regional solid waste planning agency;
 2. Publication of a notice in a daily or weekly major local newspaper of general circulation.
- D. Contents.
1. All public notices issued under this part shall contain the following minimum information:
 - a. Name and address of the office processing the permit action for which notice is being given;
 - b. Name and address of the permittee or permit applicant and, if different, of the facility or activity regulated by the permit;
 - c. A brief description of the business conducted at the facility or activity described in the permit application or the draft permit;
 - d. The name, address and telephone number of a person from whom interested persons may obtain further information, including copies of the draft permit or fact sheet, and the application; and
 - e. A brief description of the comment procedures required and the time and place of any hearing that will be held, including a statement of procedures to request a hearing unless already scheduled, and other procedures by which the public may participate in the final permit decision.
 2. In addition to the general public notice described in § 9.19.D.1., the public notice of a hearing shall contain the following information:
 - a. Reference to the date of previous public notices relating to the permit;

- b. Date, time, and place of the hearing; and
- c. A brief description of the nature and purpose of the hearing, including the applicable rules and procedures.

§ 9.20. Public Comments and Requests for Public Hearings.

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During the public comment period provided, any interested person may submit written comments on the draft permit and may request a public hearing if no hearing has already been scheduled. A request for a public hearing shall be in writing and shall state the nature of the issues proposed to be raised in the hearing. All comments shall be considered in making the final decision and shall be answered as provided in § 9.23.

§ 9.21. Public Hearings.

- A. The Executive Director shall hold a public hearing whenever he or she receives written notice of opposition to a draft permit and a request for a hearing during the public comment period specified in § 9.19.B.1.
- B. In addition to hearings required in § 9.21.A., the Executive Director may hold a public hearing at his discretion, whenever, for instance, such a hearing might clarify one or more issues involved in permit decision.
- C. Whenever a public hearing is scheduled:
 - 1. Public notice of the hearing shall be given as specified in § 9.19.B.; and
 - 2. Shall be held in the locality convenient to the nearest population center to the proposed facility.

§ 9.22. Obligation to Raise Issues and Provide Information During the Public Comment Period.

All persons, including applicants, who believe any condition of a draft permit is inappropriate or that the Executive Director's tentative decision to deny an application, terminate a permit, or prepare a draft permit is inappropriate, shall raise all reasonably ascertainable issues and submit all reasonably available arguments and factual grounds supporting their position, including all supporting material, by the close of the public comment period. All supporting materials shall be included in full and not be incorporated by reference, unless they are already part of the administrative record in the same proceeding, or consist of Commonwealth or federal statutes and regulations, documents of general applicability, or other generally available reference materials. Commenters shall make supporting material not already included in the administrative record available to the Commonwealth as directed by the Executive Director.

§ 9.23. Response to Comments.

- A. Any time that any final permit decision is issued, the Executive Director shall issue a response to comments, when a final permit is issued. This response shall:

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1. Specify which provisions, if any, of the draft permit have been changed in the final permit decision, and the reasons for the change; and
 2. Briefly describe and respond to all significant comments on the draft permit raised during the public comment period, or during any hearing.
- B. The response to comments shall be available to the public.

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7.1. If the administrator, upon inspection, investigation or through other means observes, discovers or learns of a violation of the provisions of this rule or any order issued hereunder, he or she may:

7.1.1. 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, revoking or modifying licenses, orders requiring a person to take remedial action or cease and desist orders;

7.1.2. Seek an injunction in accordance with §20-5E-16(c) of the W. Va. Code;

7.1.3. Institute a civil action in accordance with §20-5E-16(c) of the W. Va. Code; or

7.1.4. 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 §20-5E-15 of the W. Va. Code.

7.2. Any person issued a cease and desist order may file a notice of request for reconsideration with the administrator not more than seven (7) days from the issuance of such order and shall have a hearing before the administrator contesting the terms and conditions of such order within ten (10) days of the filing of such notice of a request for reconsideration. The filing of a notice of request for reconsideration shall not stay or suspend the execution or enforcement of such cease and desist order.

864-56-8. Civil penalties

8.1. Any person who violates any provision of this rule or an order issued pursuant to this rule shall be subject to a civil administrative penalty, to be levied by the administrator, of not

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more than seventy-five hundred dollars (\$7,500) for each day of such violation, not to exceed a maximum of twenty-two thousand five hundred dollars (\$22,500).

8.2. In assessing any such penalty, the administrator shall 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 degree of substantial probability that death or serious physical harm will result and, if applicable, did result from the violation; (2) the severity of serious physical harm most likely to result, and if applicable, that did result, from the violation; (3) the extent to which the provisions of this rule were violated; and (4) any previous violations committed by the alleged violator. No assessment shall be levied pursuant to this subsection until after the alleged violator has been notified by certified mail or personal service.

8.2.1. The notice shall 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.

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

8.2.3. Within thirty (30) days following the informal hearing, the administrator shall issue and furnish to the violator a written decision, and the reasons therefore, concerning the assessment of a civil administrative penalty.

8.3. The authority to levy an administrative penalty shall be in addition to all other enforcement provisions of State law or this rule and the payment of any assessment shall not be 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 shall 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 shall 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.

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8.4. No assessment revised pursuant to 8.1 of this rule shall become due and payable until the procedures for review of such assessment as set out herein and in state law have been completed.

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

8.6. The administrator 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 administrator 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.

864-56-9. 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.

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FEE SCHEDULE

Transporters - per vehicle = \$ _____

Infectious Waste Management Facilities

Non-Commercial:

No on-site treatment/disposal = \$ _____

On-site treatment/disposal = \$ _____

Commercial:

No on-site treatment/disposal = \$ _____

On-site treatment/disposal = \$ _____

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