WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION

Form #3

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1992 MAR 20 AM 11:02

OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

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

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

AMENDMENT TO AN EXISTING RULE: YES____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

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

TITLE OF RULE BEING PROPOSED: Infectious Medical Waste

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

W. Donald Weston, M.D.
Acting Secretary

FISCAL NOTE FOR PROPOSED RULES

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2002 MAR 20 AM 11:03

OFFICE OF SECRETARY OF STATE

Rule Title: Infectious Medical Waste

Type of Rule: X Legislative ____ Interpretive ____ Procedural

Agency Department of Health and Human Resources

Address Building 3, Capitol Complex Charleston, W. Va. 25305

1. Effect of Proposed Rule	ANNUAL Increase	ANNUAL Decrease	FISCAL YEAR Current	FISCAL YEAR Next	FISCAL YEAR Thereafter
Estimated Total Cost	$	$	$165,550	$165,550	$165,550
Personal Services			83,100	91,100	91,100
Current Expense			71,350	73,450	73,450
Repairs and Alterations			--	--	--
Equipment			11,100	1,000	--
Other			--		
Estimated Total Revenue			165,550	165,550	165,550

2. Explanation of above estimates.

Staff includes 1 program manager, 2 field staff and 1 secretary/audit clerk. Field staff are projected to be hired for 10 months during the first fiscal year of operation. Current expense includes employee benefits, travel, rent, general office, rental, computer software and miscellaneous other. Equipment includes 2 computers, a printer, office furniture and protective and other equipment for field personnel.

3. Objectives of these rules:

The purpose of this new rule is to regulate the generation, handling, storage, transportation, treatment and disposal of infectious medical waste. It is mandated by W. Va. Code §§20-5J-6(a) and 20-5E-7(d).

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

Administration of the rule will be supported by the fees generated. State facilities will not be charged permit fees but will be required to comply with the rule. Data is not available to estimate costs of compliance at this time.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

Counties or municipalities supporting hospitals, nursing homes or other health care facilities required to comply with this rule will be subject to permit fees and compliance costs. Hospitals, nursing homes and other health care facilities will have permit and compliance costs. The cost of compliance will vary depending on the state of a facility's current infectious medical waste program. (New incinerators which will be needed by some hospitals, depending on yet-to-be-issued U.S. Environmental Protection Agency guidelines may cost from $500,000 to $1,000,000. Strictly speaking, however, compliance with incinerator guidelines will be dependent on rules of the federal government and the State Air Pollution Control Commission.

C. Economic Impact on Citizens/Public at Large.

Costs to industry will undoubtedly be passed through to the general public utilizing the providers and facilities impacted by this new rule.

Date August 21, 1991

Signature of Agency Head or Authorized Representative

Taunja Willis Miller, Secretary
Department of Health and Human Resources

DATE: March 20, 1992

FILED

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE 1992 MAR 20 AM 11:02

FROM: DEPARTMENT OF HEALTH AND HUMAN RESOURCES OFFICE OF WEST VIRGINIA SECRETARY OF STATE

LEGISLATIVE RULE TITLE: Infectious Medical Waste

1. Authorizing statute(s) citation W. Va. Code §§20-5J-6(a) and 20-5E-7(d)

2. a. Date filed in State Register with Notice of Hearing:

September 3, 1991

b. What other notice, including advertising, did you give of the hearing?

Mailed notice and rule to hospital, nursing home associations, various health care professional associations, interested state agencies, consumer and industry groups, numerous individuals and newspapers requesting copies.

c. Date of hearing(s): October 3, 1991

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached X No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

March 20, 1992

f. Name and phone number of agency person to contact for additional information:

Kay Howard, 348-3223

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

   a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

      Not applicable

   b. Date of hearing: _____

   c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

      _____

   d. Attach findings and determinations and reasons:

      Attached _____

[PROPOSED]

TITLE 64

WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

INFECTIOUS MEDICAL WASTE

SERIES 56

[199_]

For Submission to the Legislative
Rule-Making Review Committee

RULE ABSTRACT

Agency: Department of Health and Human Resources

Rule Title: Infectious Medical Waste

CSR Title and Series: 64 CSR 56 Type: Legislative

Summary: This proposed new rule establishes standards regarding the generation, storage, treatment, transport and disposal of infectious medical waste. Permits are required for infectious medical waste management facilities, which includes some facilities which generate infectious medical waste. Permits are also required for infectious medical waste transporters. Persons (primarily physicians) who generate fifty (50) pounds or less of infectious medical waste per month as a result of the provision of health care services in their offices are not required to obtain a permit but are required to have an infectious medical waste management plan.

The disposal (as defined in W. Va. Code §20-5J-3(2)) of infectious (i.e., untreated) medical waste is prohibited. Infectious medical waste which has been rendered non-infectious by approved treatment methods is considered to be solid waste and may be placed in a sanitary landfill. The rule does not apply to individual households.

The rule includes definitions, permit application and approval procedures for both commercial and non-commercial infectious medical waste facilities, permit fees, and standards for infectious medical waste management plans, packaging, storage and containment, methods of treatment, and record keeping. The rule also includes standards relating to transportation and manifests and details a permit application and approval process for transporters of infectious medical waste.

For further information contact: Joseph A. Wyatt, Director, Infectious Medical Waste Program, Office of Environmental Health, Bureau of Public Health, Department of Health and Human Resources, Building 3, Capitol Complex, Charleston, West Virginia, 25305, telephone 348-2981 or Joseph P. Schock, Director, Office of the Office of Environmental Health, Department of Health and Human Resources, telephone (304) 348-2981, or the Regulatory Development Unit, Bureau of Administration and Finance, Department of Health and Human Resources, telephone 348-3223.

8/28/91

64 CSR 56

[PROPOSED]
WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
INFECTIOUS MEDICAL WASTE

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64 CSR 56

[PROPOSED]
TITLE 64
WEST VIRGINIA LEGISLATIVE RULES
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SERIES 56
INFECTIOUS MEDICAL WASTE

§64-56-1. General.

1.1. Preamble.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Therefore, it is the policy of the State of West Virginia to prohibit commercial infectious medical waste facilities; to regulate and control the generation, handling, storage, transportation, treatment and disposal of infectious and noninfectious medical waste; to reduce the generation of infectious and noninfectious medical waste; to encourage local responsibility for the minimization, management and disposal of infectious and noninfectious medical waste; and to authorize the department of health and human resources to promulgate rules and regulations necessary to carry out the purposes of this article."

1.2. Scope.

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

1.3. Authority.

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

1.4. Filing Date -

1.5. Effective Date -

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

2.1. Applicability.

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

2.2. Exemptions.

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

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

2.3. Enforcement.

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

§64-56-3. Definitions.

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

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

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

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

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

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

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

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

3.9. **Infectious Medical Waste.**

3.9.1. Infectious medical waste is medical waste which is

capable of producing an infectious disease. Medical waste shall be considered capable of producing an infectious disease if it has been, or is likely to have been, contaminated by an organism likely to be pathogenic to healthy humans, if such organism is not routinely and freely available in the community, and such organism has a significant probability of being present in sufficient quantities and with sufficient virulence to transmit disease.

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

3.9.2.1. Cultures and stock of microorganisms and biologicals;

3.9.2.2. Blood and blood products;

3.9.2.3. Pathological wastes;

3.9.2.4. Sharps;

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

3.9.2.6. Isolation wastes;

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

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

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

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

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

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

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

3.9.3.5. Hair, nails, and extracted teeth;

3.9.3.6. Waste generated by veterinary hospitals, except for waste meeting the criteria found in Sections 3.9.2.1, 3.9.2.4, or

3.9.2.5 of this rule; and

3.9.3.7. Medical tubing and devices with a signed and dated certification by the facility which states: "I hereby certify under penalty of law that this waste has not been contaminated with infectious medical waste, as defined in **Infectious Medical Waste**, 64 CSR 56."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.28. **Treatment** - Any method, technique or process, including neutralization, designed to change the physical, chemical or biological character or composition of any infectious medical waste so as to render such waste noninfectious.

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

4.1. On or after the first day of October, one thousand nine hundred ninety-one, no person may own, construct, modify or operate an infectious medical waste management facility, nor shall any person store, transport, treat or dispose of any infectious medical waste without first obtaining a permit from the secretary, unless exempted by Sections 2.1, 2.2 or 4.15 of this rule: Provided, however, That submission of an application for a permit under this rule within forty-five (45) days after the effective date of this rule shall be a rebuttable presumption of compliance with this rule until such time as the secretary grants or denies the permit.

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

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

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

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

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

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

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

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

4.5.1. The map scale and date;

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

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

4.5.4. The legal boundaries of the facility site;

4.5.5. Access control (fences, gates); and

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

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

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

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

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

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

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

4.12. A permit shall be issued if the facility is, or in the

case of a projected facility, is planned to be, in compliance with the applicable provisions of this rule and has submitted the application fee.

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

4.14. A permittee shall submit an application for approval of a major change in the permittee's infectious medical waste management plan before implementing the change. Minor changes in the infectious medical waste plan may be made without notifying the secretary and shall be included in the next application for permit renewal. All major changes shall be approved prior to implementation: Provided, however, That no prior approval is necessary in the case of a hospital in any instance in which, in the sole discretion and judgement of the hospital, an immediate change in any part of the infectious medical waste plan is required to protect the safety and care of patients, employees or the public. In such an event, the hospital will notify the secretary within fifteen (15) days of any changes to its plan. An application for approval of any change in the plan which is beyond the control of the permittee shall be submitted within fifteen (15) days of its occurrence.

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

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

5.1. All infectious medical waste management facilities shall develop an infectious medical waste management plan. Existing facilities which are small quantity generators shall develop a plan within ninety (90) days of the effective date of this rule.

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

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

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

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

5.2.4. Transportation method;

5.2.5. Manifest systems and labeling;

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

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

5.2.8. Training procedures, including an outline of training programs, and procedures for the certification of personnel involved in the treatment of infectious medical waste;

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

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

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

5.2.12. A description of the procedures used to:

5.2.12.1. Prevent hazards in loading and unloading operations;

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

5.2.12.3. Prevent contamination of water supplies;

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

5.2.12.5. Prevent exposure of personnel to infectious medical waste;

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

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

5.3. Infectious medical waste management facilities which are

willing to accept infectious medical waste generated off-site for treatment shall also include the following in their infectious medical waste management plan:

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

5.3.2. A statement as to whether the facility plans to receive from off-site more than thirty-five (35) percent by weight of the total amount of infectious medical waste treated at the facility;

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

5.3.4. Procedures for keeping records in accordance with Section 13 of this rule;

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

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

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

5.4. The secretary may grant a period of no more than one (1) year from the date of issuance of final applicable United States Environmental Protection Agency rules relating to medical waste incineration standards for an infectious medical waste management facility which has been granted a waiver under Section 10.2.7 of this rule to develop a proposal to modify or upgrade its treatment process to comply with this rule. The plan for modification or upgrading shall be considered to be part of the facility's infectious medical waste management plan.

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

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

5.7. Disposal of untreated infectious medical waste in this State is prohibited.

§64-56-6. Packaging and Labeling.

6.1. General.

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

6.1.2. Contractors or other agents may provide services to the generator, including packaging and labeling of infectious medical waste: Provided, however, That no contract or other relationship shall relieve the generator of the responsibility for packaging and labeling the infectious medical waste as required by this rule. Nothing in this section shall be construed to prevent or limit any cause of action by a generator against any other party for any reasons for which the law gives a remedy.

6.1.3. No person shall knowingly accept for transportation, storage, treatment or disposal any infectious medical waste that is not packaged and labeled in accordance with this rule. Contractors or other agents may package or repackage infectious medical waste to comply with this rule, if the packaging or repackaging is performed prior to transportation off-site or storage on-site. Proper repackaging of infectious medical waste that has spilled during transportation is required prior to further transportation.

6.2. Packaging.

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

6.2.2. Infectious medical waste shall be contained and sealed on-site in leak-proof plastic bags capable of passing the American Society for Testing and Materials drop weight test (ASTM-D-959-80) using one hundred twenty-five (125) pounds, or in three (3) mil plastic bags or containers with equivalent containment properties. Free liquids shall be contained in break-resistant, tightly stoppered containers. Heavier materials shall be supported in double-walled corrugated fiberboard boxes or equivalent rigid containers.

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

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

6.2.3.2. Sharps which are rendered noninfectious and encapsulated in a solid state on-site may be discarded as solid

waste. The encapsulated container shall be labeled in accordance with Section 6.3.2 of this rule.

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

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

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

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

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

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

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

6.2.8. Employers shall make reasonable efforts to direct employees packaging infectious medical waste to use personnel protection equipment and shall provide training in its use.

6.3. Labeling Requirements.

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

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

6.3.1.2. The words "infectious medical waste" or "bio-medical waste" or "bio-hazard";

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

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

6.3.2. Recognizable treated noninfectious medical waste shall be labeled prior to being transported off-site. Treated medical waste that will pass through a screen with a one-half inch (½") grid shall be considered not recognizable. The label shall be sized and attached in the manner required by Section 6.3.1 of this rule for infectious medical waste. The following information shall be included on the label:

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

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

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

6.3.2.4. A signed and dated certification by the facility at which the waste was rendered noninfectious which states: "I hereby certify under penalty of law that this waste has been rendered noninfectious in accordance with procedures required by Infectious Medical Waste, 64 CSR 56."

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

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

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

7.1.2. The kit shall contain one (1) gallon of hospital grade disinfectant in a sprayer capable of dispersing its charge in a mist or in a stream at a distance. The disinfectant shall be hospital-grade and effective against myco bacteria.

7.1.3. The kit shall contain enough red plastic bags to enclose one hundred and fifty percent (150%) of the maximum quantity stored or transported. The bags shall meet the American Society for Testing and Materials drop weight test (ASTM-D-959-80) using one hundred twenty-five (125) pounds or shall be three (3) mils thick or the equivalent and shall be accompanied by sealing tape or devices and labels or tags. These bags shall be large enough to enclose any box or other container normally used for infectious medical waste management by that facility or carried by a transport vehicle.

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

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

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

7.3. The cleanup crew shall implement the following proce-

dures for cleaning up a spill:

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

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

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

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

7.3.5. Clean and disinfect non-disposable items and clothing;

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

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

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

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

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

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

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

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

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

8.6. Carpets and floor coverings with open seams in which water may be entrapped shall not be used in storage areas. All floor drains shall discharge directly to a sanitary sewage disposal system which is in compliance with Sewage System Rules, 64 CSR 9 or other containment system which prevents any spilled materials from reaching the environment.

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

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

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

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

§64-56-9. Transportation.

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

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

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

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

9.2.3. Via the U.S. postal service, if the requirements set by that agency are met.

9.3. A generator that transfers infectious medical waste on-

site shall be exempt from Sections 9.9, 9.10, 9.11 and 9.12 of this rule: Provided, That:

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

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

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

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

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

9.6.1. The international biohazard symbol;

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

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

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

9.7. Vehicles that transport infectious medical waste:

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

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

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

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

9.7.5. Shall not be used to transport food, foodstuffs, food additives, food containers or any substances to be ingested by people or animals or applied to food or feed simultaneously with the transport of infectious medical waste.

9.7.6. Separate, removable cargo-carrying containers are acceptable and if used, Sections 9.7.1 through 9.7.5 of this rule shall apply to the containers in lieu of the entire vehicle.

9.8. All vehicles transporting infectious medical waste shall carry a spill containment and cleanup kit as required by Section 7 of this rule in the vehicle whenever infectious medical waste is conveyed. Spills of infectious medical waste during transportation shall be managed as required by Sections 7.2 and 7.3 of this rule. Any spill of fifty (50) pounds or more shall be reported as soon as possible to the employer and the secretary. Direct physical contact of the transport vehicle or equipment with infectious medical waste shall be considered and managed as a spill.

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

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

9.10.1. The applicant's name;

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

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

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

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

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

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

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

9.10.9. Designation of the treatment facilities to be used.

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

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

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

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

§64-56-10. Methods of Treatment.

10.1. General.

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

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

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

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

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

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

10.2. Incineration.

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

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

10.2.2.2. Whenever infectious medical waste is present in the incinerator combustion chamber, carbon monoxide emissions shall be less than one hundred (100) ppm on a sixty (60) minute rolling average corrected for stack oxygen concentration according to the following formula:

$$CO_C = CO_m \times \frac{14}{21-Y}, \quad \text{where:}$$

CO_C is the corrected carbon monoxide concentration; CO_m is the measured carbon monoxide concentration of the incinerator exhaust gas prior to release to the air; and Y is the measured oxygen concentration (by basis) of the incinerator exhaust gas prior to release to the air.

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

10.2.4. There shall be continuous monitoring and recording of primary and secondary chamber temperatures or carbon monoxide emissions shall be continuously monitored downstream of the final combustion chamber but prior to release to the air. Monitoring data shall be maintained for a period of three (3) years.

10.2.5. All combustible waste shall be converted by the incineration process into ash that is not recognizably in its pre-incineration form. Incinerator ash shall be tested at least quarterly, using a commingled random sample, for total organic carbon content, and annually for lead, mercury, cadmium, and other heavy

metals. A maximum of five percent (5%) fixed carbon shall be permitted (minimum ninety-five percent (95%) burnout).

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

10.2.7. Facilities with incinerators in operation at the time this rule becomes effective may apply to the secretary for a waiver to Sections 10.2.2 through 10.2.4 of this rule. The waiver, if granted, shall be in effect for a maximum of two (2) years after issuance of applicable final Environmental Protection Agency rules relating to medical waste incineration and shall be contingent upon submission of plans to upgrade the facility so as to be in full compliance with Sections 10.2.2 through 10.2.4 of this rule. The plans shall be submitted as part of the infectious medical waste facility management plan required in Section 5 of this rule and shall be subject to approval by the secretary.

10.3. Steam Treatment.

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

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

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

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

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

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

10.3.1.6. Other combinations of operational temperatures, pressure and time approved by the secretary. Other combinations may be approved if the installed equipment has been proved to achieve a reliable kill of all infectious microorganisms in infectious medical waste at design capacity. Complete and thorough

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

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

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

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

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

10.3.4.2. The type and approximate amount of waste treated;

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

10.3.4.4. The dates and results of calibration; and

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

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

10.4. Sanitary Sewer.

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

10.5. Alternative Methods.

10.5.1. The secretary may approve an alternative method of treatment not described in this rule if the secretary determines that the proposed process will render infectious medical waste

noninfectious and will provide protection to the health and safety of the public and workers at least the equivalent to the methods found at Sections 10.2, 10.3 and 10.4 of this rule.

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

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

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

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

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

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

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

10.5.3.6. A copy of an evaluation report provided by a testing laboratory independent of the applicant using a testing protocol approved by the secretary confirming the efficacy of the treatment process and that the process does not produce a hazardous waste, discharge or air emission.

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

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

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

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

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

11.5. No person may establish, construct, operate, maintain, or allow the use of property for a commercial infectious medical waste management facility within an area where the secretary has determined, after consultation with relevant State and federal agencies, that the facility will be in violation of applicable State or federal laws or regulations concerning:

11.5.1. Wetlands;

11.5.2. Any endangered or threatened species of animal or plant;

11.5.3. Surface water;

11.5.4. Groundwater quality; or

11.5.5. The emission of any air contaminant.

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

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

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

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

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

11.8. A pre-siting notice shall be filed with the secretary and the applicable county solid waste authority within five (5) days of the publication of the legal advertisement required under Section 11.7 of this rule. The pre-siting notice shall include a certification of publication of the legal advertisement required under Section 11.7 of this rule from the newspaper in which the advertisement was published with a copy of the advertisement.

11.9. A person proposing to operate a commercial infectious medical waste management facility shall conduct a public hearing in

the county where the proposed facility is to be located in accordance with the following guidelines:

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

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

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

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

11.10.2. Require an additional public hearing.

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

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

11.13. A commercial infectious medical waste management facility shall employ a treatment technology approved according to the provisions of Sections 10.3 through 10.5 of this rule.

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

11.15. Based on comments received at the public hearing or upon written recommendations received, the secretary may within thirty (30) days after receipt of the permit application, require the person who submitted the application to furnish additional information regarding the impact the siting of the proposed facility may have upon wetlands, endangered or threatened species of plants and animals, surface waters, underground waters, air quality, and other matters as determined by the secretary.

11.16. A retailer of sharps to be used by individuals in their own medical treatment may establish a small commercial infec-

tious medical waste management facility to be used solely for the treatment of sharps sold by and returned to the retailer for treatment. Such small commercial infectious medical waste management facility shall apply for and obtain a permit according to the provisions of Section 4 of this rule. In addition to the requirements of Section 4, the application shall include a letter describing the location and estimated volume of sharps to be treated and a certified letter from an approved solid waste disposal facility agreeing to accept the treated wastes. Such small commercial infectious medical waste management facility shall comply with Sections 6 and 10 of this rule, and may be exempted by the secretary from the requirements of Sections 11.4 through 11.15 of this rule.

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

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

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

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

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

12.5. An infectious medical waste management facility shall not accept more than fifty (50) pounds of infectious medical waste

from a generator per month or any quantity of infectious medical waste from a transporter unless it is accompanied by a properly completed manifest.

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

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

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

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

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

12.10.1. The name and address of the generator;

12.10.2. The weight of the waste received;

12.10.3. The date of receipt of the waste; and

12.10.4. The signature of the person receiving the waste.

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

12.12. Nothing in this rule shall prevent any hospital or other facility which receives infectious medical waste from any small quantity generator, including any ambulance company, from requiring a completed manifest as more fully described in Sections 12.1 through 12.5 of this rule.

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

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

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

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

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

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

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

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

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

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

vehicle or permitted facility at which the alleged violation is occurring.

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

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

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

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

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

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

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

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

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

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

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

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

§64-56-16. Criminal Penalties.

Criminal penalties are applied according to the provisions of W. Va. Code §20-5E-15 as described in this Section.

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

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

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

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

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

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

16.5.1. Bodily injury which involves a substantial risk of death;

16.5.2. Unconsciousness;

16.5.3. Extreme physical pain;

16.5.4. Protracted and obvious disfigurement; or

16.5.5. Protracted loss or impairment of the function of a bodily member, organ or mental faculty.

§64-56-17. Civil Penalties.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§64-56-19. Administrative Due Process

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

§64-56-20. Severability.

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

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

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

Discussion of Public Comments Received
Concerning the Proposed Rule,
Infectious Medical Waste, 64 CSR 56

The purpose of the proposed new rule is to regulate the generation, handling, storage, transportation, treatment and disposal of infectious medical waste. It is mandated by W. Va. Code §§20-5J-6(a) and 20-5E-7(d). The Department made a major effort to involve representatives of a broad scope of interests in the preliminary drafting of the rule. Several preliminary drafts were prepared and circulated for comment among representatives of health care providers, industry, transporters, and consumer interests prior to scheduling the public hearing. Development of this new rule has been and continues to be a major concern and effort of the Department.

A public hearing was held October 3, 1991. Eight persons commented at the hearing, most of whom had written comments. An attendance record and a transcript of the hearing are attached. Thirty sets of comments were received by mail or hand delivery. Copies of written comments are attached.

Comments were extensive and detailed as might be expected for a new rule which deals with an area where technology is evolving rapidly. Comments represented several broad interest groups. Hospitals as major generators and possible infectious medical waste treatment facilities were well represented on an individual basis and by the West Virginia Hospital Association. Environmental interests provided many comments as did representatives of various facets of the infectious medical waste industry. Other groups represented were physicians, dentists, veterinarians and manufacturers.

General

1. Comment: In addition to a large number of comments about specific provisions of the proposed rule and the issue of combined hospital infectious medical waste treatment facilities (discussed more fully in Item #61), a number of hospitals expressed general concerns that compliance with this proposed new rule will be unduly costly. They question the benefits of what they believe to be an unnecessarily restrictive rule. It was stated that the proposed rule is similar to the federal Medical Waste Tracking Act of 1988 which increased the cost of infectious medical waste disposal in participating states from $1.04 per patient to $5.19 due to an increase in the amount of medical waste considered to be infectious and the greater cost for disposal of infectious medical waste.

Hospitals comments on this theme were varied. Some believe it will be necessary to ship waste to either in or out of state treatment facilities thus going against the Code finding related to minimizing transport and encouraging local/on-site treatment. Others believe that every hospital will need its own treatment facility, which will be costly. It was said that increased needs

for storage and transport (apparently if incineration is not possible) will compromise staff safety and increase possible exposure to infectious medical waste. Another concern expressed was for the potential joint impact of projected landfill closures, increased costs of solid waste disposal and the proposed rule. One hospital stated that it estimates its costs for sending infectious medical waste to a commercial facility at $18,500 per month. Another noted that increasing concern for patient and employee safety may increase the volume of waste considered to be infectious and stated that the true cost of this rule will be enormous. One hospital stated that: "The economic consequences for the healthcare community can be disastrous as options for disposal and waste management are eliminated." This hospital further stated that: "It is our belief that the healthcare facilities in the state of West Virginia will be adversely affected in both time and money without the benefit of protecting the public health and the environment from a waste stream that has had no demonstrated environmental damage."

In commenting on the perceived restrictiveness of the rule, a few hospitals questioned the some of the assumptions underlying the rule. It was stated that the benefits are questionable and that the rule would be more appropriate for the disposal of hazardous chemical waste. It was also stated that the health hazards of current medical waste disposal methods have not been demonstrated and that the infection potential of medical waste other than sharps is virtually nonexistent. One commenter suggested that the term "infectious medical waste" is a misnomer and misleading. This commenter stated that: "Most health care/ infection control persons would agree that less than 1% of what is included in this definition is truly 'capable of producing infectious disease.'" The commenter recommended the use of the term "regulated medical waste" as has been used by other states and stated that: "This simple revision will more accurately and appropriately describe what is in those red bags and provide a better basis for educating those not knowledgeable with the industry."

Response: The Department agrees with the West Virginia Hospital Association that hospitals and state government have a common interest in protecting the public at large, the community, patients, and hospital employees and believes that West Virginia hospitals are genuinely concerned for public health and safety. The Department has recognized the soundness many of the individual suggestions and has made a number of clarifications and modifications to the rule which the Department believes will achieve the original purpose in an improved fashion. These changes are documented and discussed below. The Department further believes that some of these changes will reduce the cost of compliance with this rule.

Part of the cost issue for hospitals is related to the issued of combined or coordinated hospital treatment facilities. That issue is discussed more fully in Item #61. Costs cannot be realistically compared to what it cost the participating states

in the Medical Waste Tracking Act. The definition of regulated medical waste was broader than infectious medical waste as used in the proposed rule. Most of the requirements are already being implemented by hospitals following 1) Centers for Disease Control Guidelines--Hospitals, and 2) Federal Occupational Safety and Health Administration requirements. Also, there are ways to reduces costs which hospitals may not have considered. In various meetings with hospital representatives, various operational procedures are being shared and communicated. A prime example will be the need to separate infectious medical waste from other non-infectious medical waste including pizza containers.

Public policy as desired by the public and put into law in West Virginia by the Legislature is to regulate infectious medical waste. The Department concurs with this policy; the potential hazards of infectious medical waste warrant regulatory oversight.

Section 1

2. Comment: Section 1.1. One commenter stated that the statement about medical waste incinerators being an important public health hazard is too strong, citing public television. The commenter also recommended that the Department become involved in the recycling program by originating a list of outlets for the solid waste which is generated.

Response: The statement about infectious medical waste incinerators in the preamble to the rule is quoted from W. Va. Code §20-5J-2. Recycling could be one result of facilities' waste minimization procedures. This proposal will receive consideration for future revisions.

Section 2

3. Comment: Section 2.2.1. One hospital questioned the authority of the Department to regulate and penalize individual households and citizens and asked who would enforce this provision.

Response: The Department interprets W. Va. Code §20-5J-1 et seq. to grant it the authority to regulate all generators of infectious medical waste, including individual households. The only requirement for individual households is that sharps be packaged in puncture resistant containers (See Section 2.2.1 of the rule). Penalties can be assessed against individuals who blatantly refuse to package sharps properly. The investigation and enforcement of the rule for individuals will be on a complaint basis only.

4. Comment: Section 2.2.2. One hospital expressed fears that the severe restrictions and penalties of the rule will preclude hospitals with treatment and disposal capabilities from accepting waste from ambulance and rescue services. Ambulance and other rescue services will as a result need to contract with commercial

haulers and disposers.

Response: The comment probably refers to concern about the possibility of the hospital being classified as a commercial facility because of the volume of off-site infectious medical waste accepted from ambulances and rescue services. The amount of waste products accompanying patients into a hospital via ambulance or rescue squad transportation would be too small to significantly affect the hospital's overall total volume of infectious medical waste. Most of the products transported with patients are not considered waste until after arrival at the medical facility and would be considered to be generated on-site.

5. Comment: Section 2. Chemical waste incinerators which are permitted hazardous waste management units should be exempt from this rule.

Response: Incinerators used for chemical hazardous wastes are usually designed with tight operational parameters for specific groups of chemicals. The introduction of infectious medical waste into such an incinerator may result in conditions which could compromise the operation of such incinerators. Under these circumstances, adequate incineration of infectious medical waste may not be achieved without physical or operational modifications. Therefore the operational parameters relative to infectious medical waste incineration have been retained and hazardous waste incinerators will be required to obtain a permit for use for incineration of infectious medical waste. Additionally, operators of such incinerators will be required to be registered under the rule.

Section 3

6. Comment: Section 3.1. One hospital commented that the definition of animal carcasses which are to be considered infectious medical waste is so open-ended by virtue of the phrase "or for any other reason" that farm animals could be included.

Response: The provision for including the possibility of exposure to infectious agents in ways other than during research, production of biologicals or testing of pharmaceuticals is to include the possibility of animals infected with zoonotic diseases, including farm animals.

7. Comment: Section 3.9. It was suggested that the definition of infectious medical waste be reviewed and revised to include body fluids due to the potential to contact HIV (human immunodeficiency virus), HBV (hepatitis B virus) or other pathogenic organisms from this source.

Response: Body fluids are defined as infectious medical waste in Section 3.18, Pathological Wastes.

8. Comment: Section 3.9. The veterinarian's association expressed concern as to how the proposed rule would apply to cer-

tain live vaccines sold to and administered by the general public for animal vaccinations.

Response: Although individual households are exempt from most provisions of the rule, Section 2.2.1 does require that sharps be placed in a container with a high degree of puncture resistance. Empty vaccine bottles and syringes used for such vaccines are sharps and as such would have to be disposed of as required by the rule. An educational brochure has been prepared and is now being distributed through various outlets. Violations will be handled on a complaint basis.

9. Comment: Section 3.9.3. Two commenters suggested that this section should include an exemption for medical tubing and devices (hemodialyzers, IV fluid bags/bottles, etc.), since they are most frequently not used in such a manner as to be infectious. One commenter also noted that some tubing and devices might be infectious, however, and would need to be handled as infectious medical waste. As it would be difficult for a landfill operator to determine whether such items were infectious, generators could be required to provide certification that all such devices in a container were non-infectious and suitable for routine solid waste handling.

Response: The rule was amended to include the exemption and a certification statement.

10. Comment: Section 3.17. One commenter asked that the last sentence in the definition of "on-site" ("Hospitals with more than one (1) facility located in the same county shall be considered one (1) site.") be deleted. The commenter stated that it does not agree with the definition of "site."

Response: This definition is taken from W. Va. Code §20-5J-3(10) and cannot be changed by the rule.

11. Comment: Section 3.22. The proposed rule defines a small quantity generator as: "any generator of infectious medical waste who generates fifty (50) pounds or less during a one month period." Two commenters suggested modification of this definition. The State Medical Association commented that physician offices, which are generally small quantity generators, may occasionally exceed the 50-pound limit, as for example, during a period of high incidence of flu. The West Virginia Manufacturer's Association noted that one of its members incinerates approximately 100 pounds of infectious medical waste consolidated from two plants and requested an increase in the limit to 100 pounds per month.

Response: The definition is taken from W. Va. Code §20-5J-3(12), and is a criterion level used by the majority of the states regulating infectious medical waste. The Department believes that the majority of physician offices will be able to remain "small" through careful distinction of medical waste from infectious medical waste. Additionally, an occasional exception

to the 50 pound limit in a physician's office would not be likely to result in the reclassification of a small quantity generator. Each of the two plants would be considered individually if they are at separate locations.

Section 4

12. Comment: Section 4. Environmentally oriented commenters requested that language from an earlier draft of the rule requiring funds to be deposited in a special revenue account and used for the purposes of permitting, training, enforcement and program development be included.

Response: It is not necessary to have a specific provision in the rule to establish such an account. The account will be established and the funds used to support the program as is required by W. Va. Code §20-5J-6(a).

13. Comment: Section 4. One hospital suggested specifying time frames by which permit applications and approval procedures are to be completed. It was noted that application forms are not available.

Response: Section 4.1 of the rule has been modified to allow a forty-five day period following the promulgation of the rule for submission of applications. Submission of an application within this time frame will be a rebuttable presumption of compliance with the rule until the Department grants or denies a permit.

14. Comment: Section 4.1. Two commenters noted that there is a reference to a Section 4.15 which does not exist.

Response: The commenters may have been looking at an earlier draft. Section 4.15 was on page 10 of the draft offered for public hearing.

15. Comment: Section 4.4.2. One commenter suggested that this section be rewritten to require the name, address, and telephone number of all owners of the facility.

Response: The rule has been modified.

16. Comment: Section 4.11. The proposed fee schedule attracted several comments. Environmental concerns are that the fees for various types of commercial facilities are too low and will encourage activities which are "prohibited or discouraged in the Legislative Findings in the Medical Waste Act." These writers also expressed concerns that the fees are not adequate to support an effective regulatory program. One commenter suggested that the $25 incinerator operator registration fee should apply only to non-commercial incinerator operators.

Two hospitals stated that the fees for hospitals are excessive. One requested that the annual fee of $250 for a transpor-

tation vehicle for "on-site" hospitals be reduced to zero, that the annual fees for hospitals be reduced, based on bed size, to a maximum of $500 and that infectious waste medical facilities located on contiguous property be required to obtain only one permit. One commented that the annual fee of $1,750 for an 80-bed small rural hospital is excessive.

Response: The Department believes that most infectious medical waste in the State will be treated on-site or at facilities close to the generator, which will discourage commercial initiatives. The statute only prohibits commercial facilities utilizing incineration. Nationally, hospitals are responsible for 84.5% of the total infectious medical waste generated. The Department projects that hospital fees will contribute slightly over 75% of the infectious medical waste program funding. A single permit will include all functions involving infectious medical waste for each generator. Hauling infectious medical waste to an on-site incinerator is included in the facility's permit, as would be the operation of a nursing home in conjunction with a hospital.

17. Comment: Section 4.14. One commenter requested that the language exempting minor changes in infectious medical waste management plans from pre-implementation approval be deleted (second sentence and "major" in the third sentence.) Conversely, the West Virginia Hospital Association stated that a hospital may need to make a change in any number of aspects of its infectious medical waste management plan on an expedited basis in order to protect patients, employees and/or the general public.

Response: The Department agrees with the Hospital Association's position and has revised Section 4.14 accordingly, but does not believe revision of Section 5.6 is necessary. Use of the term "major" is retained in order to give hospitals flexibility to make minimal revisions without major expenditures of time and resources at both the hospital and State level.

18. Comment: Section 4.15. The West Virginia Manufacturer's Association suggested that an exemption from the permit requirements be granted for small quantity generators who incinerate infectious medical waste in permitted hazardous waste management units.

Response: Small quantity generators are not required to get a permit.

Section 5

19. Comment: Section 5. One commenter suggested that infectious medical waste management plans should include the location of the facility, source(s) of any waste handled, type(s) of infectious medical waste handled and should be made available to state or local health officials upon request.

Response: Section 4.4.1 requires the address and location

of the facility for which the application is submitted to be on the permit application. Plans on file with the Department are accessible to local health officials under the State Freedom of Information Act. The infectious medical waste plans of small generators are available to the Department under the provisions of Section 13.3 of the rule. Sources and types of infectious medical waste are required in Section 12.10 for small quantity generators and in the manifest for others.

Some misunderstanding about the definition of infectious medical waste management facility has apparently occurred. Generators of infectious medical waste are required to treat infectious medical waste on-site or ship it to an approved treatment facility. Any infectious medical waste shipped must be classified and quantified and the record of this maintained for 3 years by the generator, shipper, and treatment facility. (See Section 12.10 of the rule).

20. Comment: Section 5.1. The West Virginia Manufacturer's Association suggested that small quantity generators be given 90 days from the effective date of the rule to develop an infectious medical waste management plan.

Response: Agreed.

21. Comment: Section 5.2.8. The West Virginia Hospital Association requested clarification of which personnel in a hospital setting would be required to be certified.

Response: Section 5.2.8 was modified to clarify the requirement.

22. Comment: Sections 5.3.2 and 5.3.3. One commenter requested that the word "knowingly" be deleted from both sections.

Response: Facilities which treat infectious medical waste occasionally have red bags left anonymously at the facility. The word "knowingly" was included in recognition of this, and is therefore retained. The item has been reworded to clarify that the intent of this provision is to require the facility to state whether or not it qualifies as a commercial infectious medical waste facility. (See also Item #45.)

23. Comment: Section 5.4. The West Virginia Hospital Association and one individual hospital stated that since the United States Environmental Protection Agency (EPA) hospital incinerator standards are not projected to be finalized until some time in the fall of 1993, hospitals should be given one or two years from the final approval date of these standards to develop a proposal to modify or upgrade the treatment processes being used.

Response: The Department is aware that EPA standards which will apply to hospitals are forthcoming. The rule has been modified to implement the suggestion of the Hospital Association. (See also Item #57.)

24. Comment: Section 5.7. The West Virginia Hospital Association and one individual hospital stated that the reference in Section 5.7 to Section 10.4 is in error.

Response: Section 5.7 stated that: "The disposal of infectious medical waste in this State is prohibited, except as described in Section 10.4 (sanitary sewers) of this rule." The Department has added language to clarify that persons who generate or handle infectious medical waste may not dispose of infectious medical waste until it has been treated in a manner to render it non-infectious and has deleted the reference to Section 10.4. Placement of infectious medical waste into a drain attached to a sewer approved under **Sewage System Rules, 64 CSR 9,** constitutes treatment. (The definition of "disposal" included in the rule at Section 3.5 is quoted from W. Va. Code §20-5J-(2).)

Section 6

25. Comment: Section 6. One hospital requested a definition of "package." The commenter asked whether a package would be individual bags or the container in which individual bags are boxed.

Response: The standard dictionary definition of package is adequate. Infectious medical waste should be packaged or containerized after generation. This is easily accomplished by placing the infectious medical waste in a lined waste container or sharps container. This is all the packaging necessary if treatment is to occur on-site. If treatment is to occur off-site then additional packaging must occur.

26. Comment: Section 6.1.2. The West Virginia Hospital Association suggested that an additional sentence be added at the end of the paragraph, as follows: "Nothing in this section shall be construed to prevent or limit any cause of action by a generator against any other party for any reasons for which the law gives a remedy."

Response: The suggested addition was made.

27. Comment: Section 6.1.3. The West Virginia Hospital Association noted that the prohibition of storage prior to packaging or repackaging effectively means that infectious medical waste must be packaged immediately at time of generation. This would prevent a handling/transportation concern from handling packaging. Other sections suggest that this may be an inadvertent effect.

Response: The intent of the item is to insure that: 1) infectious medical waste which is to be transported off-site for treatment is packaged prior to transport; and 2) infectious medical waste which is to be stored prior to treatment on-site or transportation off-site is packaged prior to storage. The text has been modified to clarify this.

28. Comment: Section 6.2.2. Several commenters stated that the terms "equivalent rigid containers" and "containers with equiva-

lent containment properties," do not provide an adequate description of containers required. It was suggested that "a far better yardstick than measuring the burst strength of a bag would be measuring the resistance to puncture, ASTM D-1709-85. Two commenters stated that if the drop weight test is retained, a minimum level should be specified.

Response: A minimum level of 125 pounds has been added.

29. Comment: Section 6.2.3. One hospital stated that there is no such thing as a leak proof sharps container and that "leak-resistant" would be a more appropriate adjective."

Response: This language is used by the EPA and most states.

30. Comment: Section 6.2.3.2. One commenter requested a definition of "encapsulated in a solid state."

Response: Standard dictionary definitions adequately describe the terms.

31. Comment: Section 6.2.4. One hospital stated that since all medical employees are taught that a red bag is specific in its use, the requirement that the bags be imprinted with the biohazard symbol and the words "Infectious Medical Waste" is of little, if any, benefit.

Response: Section 6.2.4. was modified to require the use of imprinted bags only if treatment is to occur off-site.

32. Comment: Section 6.2.6. Environmentally-oriented commenters requested language requiring containers to be washed and disinfected unless they have been effectively protected from contamination as opposed to the present language which requires washing and disinfection if contaminated. The commenters also stated that the rule is unclear regarding who makes the determination.

Response: Requiring disinfection after each use when the container is not contaminated is not cost effective. The user will make the determination of when to sanitize. The adequacy will be verified by inspections.

33. Comment: Section 6.2.8. The West Virginia Hospital Association and one individual hospital noted that this section appears to incorporate an Occupational Health and Safety Administration (OSHA) standard which is at present only a draft.

Response: The reference to the OSHA standards has been removed and the section has been revised to require employers to provide training in the use of personnel protection equipment.

34. Comment: Section 6.3. Several commenters stated that it should be made more clear that the labeling requirements only pertain to off-site transportation and not to waste treated on-

site. Additionally, commenters stated that the requirement for dating, weighing and labeling each package of infectious medical waste is burdensome, and that this could be performed on a bulk basis with the information best contained on manifests accompanying the shipment. Commenters believe that the labeling requirements on individual containers will greatly increase cost for large generators and serve no advantage.

Response: Section 6.3.1 has been modified to clarify the labeling requirements. The final package to be shipped off site must be labeled and dated as required. No size limitation was placed on the final package so the labeling and dating could occur on the bulk package. Dating is necessary to determine compliance with Section 8 of the rule.

35. Comment: Section 6.3.2.4. One hospital suggested that it is unclear as to where the certification of the non-infectious state of recognizable but treated medical waste required by this section goes, to what type of waste it applies, to whom it goes, and whether it is to be retained as documentation. The commenter suggested that this requirement would be better placed under the manifest requirements.

Response: Section 6.3.2. specifies that the certification goes on the required label. The manifest system applies only to untreated waste. All of Section 6.3.2 applies to recognizable treated non-infectious medical waste. The attached label simply goes with the waste to a landfill. The landfill operator should retain a copy of the documentation and the treatment facility is required by Section 10.3.4 to retain like records for 3 years.

Section 7

36. Comment: One hospital criticized Section 7.1 as having excessive requirements which would be more appropriate for hazardous (chemical) waste than for infectious medical waste. Specific mention was made of the absorbency requirements of Section 7.1.1, the requirement for red bags sufficient to enclose 150% of the transported material, and the personal protective equipment requirement. It was also suggested that "breathing devices" in Section 7.1.4 be changed to "protective facial barriers such as goggles and a mask." One commenter suggested that one hundred yards of boundary marking tape would be more appropriate than one hundred feet.

Response: Section 7.1.1 has a requirement for absorbent material capable of absorbing one gallon of liquid for each cubic foot of storage area or 10 gallons whichever is "less." Theoretically one cubic foot could contain 7.5 gallons of liquid. This means a storage room 8' x 8' x 8' could contain over 3800 gallons. The Department believes that this requirement is not excessive. In the event of a spill, extraneous materials may come in contact with the infectious medical waste. These materials become infectious medical waste by definition. It is necessary to require adequate additional red bags to enclose the addi-

tional contaminated materials; an estimate of 150% of the original waste was used. Section 7.1.4 was changed to reflect other suggestions.

Section 8

37. Comment: Section 8.1. One hospital commented that storage needs to be more adequately defined within this section to differentiate between temporary storage on a nursing unit and temporary storage prior to transport to an off-site non-owned treatment/disposal facility.

Response: Section 8.1 was modified to clarify its application.

38. Comment: Section 8.2. Environmental interests requested that language be added to specify that: "Excluding sharps, infectious medical waste stored for more than 72 hours after generation must be refrigerated at 45 degrees Fahrenheit or below."

Response: Refrigeration of infectious medical waste reduces odor. The requirement of Section 8.4 of the rule for maintaining infectious medical waste in a non-putrescent state during storage covers those situations where odor problems could develop. (See also Item #42.)

39. Comment: Section 8.6. One hospital stated that this section "will preclude the use of tiled floors in utility rooms and floors on trucks in that it states carpet and floor coverings with seams shall not be used in storage areas. The potential hazards associated with medical waste as a result of spills and leakage can be easily mitigated by application of chlorine bleach which will permeate through seams to inactivate. There is no analogy of chemical waste storage areas with infectious waste storage areas as indicated in this section."

Response: This section was modified to prohibit open seams in which water could be trapped.

40. Comment: Section 8.8. The West Virginia Manufacturer's Association noted that some companies store wastes in sealed containers for short periods of time in diked containment areas. The Association requested the addition of language to recognize an "equivalent containment system which prevents any spilled materials from reaching the environment."

Response: Equivalent language was added to Section 8.6.

Section 9

41. Comment: Section 9. One commenter requested that a provision be included to allow sharps to be transported by mail provided they are packaged according to Section 6 and meet the requirements of the U.S. Postal Service for packaging and class of mail service.

Response: Section 9.2.3 was added to allow mailing of sharps.

42. Comment: Section 9. A suggestion was made to add a requirement to the transportation section that infectious medical waste be refrigerated if not delivered to a treatment facility within 24 hours. The commenter believes this change will help to maintain infectious medical waste in a non-putrescent state.

Response: See Comment #38.

43. Comment: Section 9.3. One commenter recommended that a new Section 9.3.3. be added allowing the off-loading of infectious medical waste from a small collection vehicle to another larger properly permitted vehicle for transport to a distant treatment facility or if the first vehicle is disabled. This would require that the manifest indicate a change in custody of the infectious medical waste to the secondary transporter.

Response: Section 9.3 deals only with transfer of infectious medical waste on-site. This rule does not prohibit transfer of loads. It does allude to such transfers in Sections 9.13, 12.1, and 12.4. Since this type of activity is permitted by the rule, no change is warranted.

44. Comment: Section 9.3.2. Section 9.3.2 provides that a generator that transfers medical waste on-site is exempt from transport permit requirements provided certain conditions are met. One of the conditions is that no off-site infectious medical waste be knowingly and routinely accepted for on-site transfer. The West Virginia Manufacturer's Association stated that at least one of their member companies receives small quantities of waste for incineration from two common parent company plants and requested that a revision be made to allow the handling of minimal amounts of off-site infectious medical waste in such situations.

Response: The two generators (plants), if classified as small quantity generators (see comment 11), could transport their own waste to the treatment facility as provided for in Section 9.2 of the rule. This does not require modification of the rule.

45. Comment: Section 9.3.2. One commenter suggested that the words "knowingly and routinely" be deleted.

Response: The word "knowingly" is needed to allow movement of infectious medical waste dumped anonymously at a facility. (See also Item #22.)

46. Comment: Section 9.7.4. One hospital suggested that if waste is properly packaged and there is no leakage or spill, a vehicle used to transport infectious medical waste should not have to be cleaned and disinfected prior to any other use.

Response: Leakage and spillage may not always be easily

visible. A routine procedure will insure non-contamination.

47. Comment: Section 9.7.5. The Hospital Association and some individual hospitals objected to prohibiting the use of vehicles that are used for transporting medical waste for transporting food, food additives, or food containers. The commenters believe that if the vehicle is properly cleaned and disinfected, there is no reason why it should not be used to transport food. One commenter suggested that separate, removable, cargo-carrying portions could be acceptable. This requirement would be particularly burdensome on small rural hospitals.

Response: The suggestion was accepted. A new Section 9.7.6 has been added.

48. Comment: Section 9.9. One commenter objected to being required to obtain a transporter permit by the time that these rules are adopted. The commenter suggested a grace period of 30 days.

Response: Section 4.1 was modified to rectify the problem.

49. Comment: Section 9.10. The application should require the name, business address and telephone number of each driver who will operate in West Virginia.

Response: This information can be obtained from the permittee when needed. Collecting and maintaining current files of this type of information would require costly and prohibitive effort for both transporters and the Department.

50. Comment: Section 9.10.8. A provision should be added requiring the employees to be trained, not just that the applicant has established a training program.

Response: Section 9.10.8 was modified to implement the suggestion.

Section 10

51. Comment: Section 10.2. A number of hospitals expressed general as well as specific concerns regarding the proposed standards for the incineration of infectious medical waste. Some hospitals singled out these new incineration standards as being particularly costly. Existing incinerators may have to be replaced. It was stated that there are no known infectious health hazards associated with properly operated incinerators. Some hospitals might be forced into expensive arrangements to transport infectious medical waste out of the state if they are not able to incinerate their infectious medical waste.

The West Virginia Manufacturer's Association stated that: "This section is not necessary for RCRA (Resource Conservation and Recovery Act) permitted incinerators which burn small quantities of infectious medical waste. Because emission standards and

waste disposal requirements adequately limit releases and disposal of incineration byproducts, RCRA permitted units which burn small quantities of infectious waste should be completely exempt from this section." In the event that this recommendation was not accepted, the Association suggested changing Section 10.2.1 to read: "All owners and operators of infectious medical waste incinerators are required to comply with applicable state laws."

Response: The EPA is currently rewriting its incinerator rules. The new rules are expected in 1993. The operating parameters in this rule were chosen to best approximate what these new EPA standards will be. EPA standards will supersede West Virginia's infectious medical waste rule unless the State's rule is more stringent. The Department does believes this will not happen. Section 10.2.7 of the rule provides for a means to obtain a waiver to the infectious medical waste incinerator operation parameters until after the EPA standards are promulgated. As stated earlier in Item #5, an exemption for incinerators meeting RCRA standards is not suitable.

52. Comment: Section 10.2.2. The West Virginia Manufacturer's Association commented that incineration requirements should be performance-based rather than design-based and suggested an alternative to the combustion standard of 10.2.2.

Response: The Association's suggestion was adopted as Section 10.2.2.2.

53. Comment: Section 10.2.3. Some commenters noted that the allowance for interlock or other process control device override at start-up essentially negates the utility of the requirement for these devices, because significantly more pollutants are emitted during a cold start-up.

Response: Agreed. The override for start up was eliminated.

54. Comment: Section 10.2.4. One hospital suggested that monitoring and recording equipment for the secondary chamber is all that is needed to ensure safety. Additionally, the West Virginia Manufacturer's Association suggested adding the following as an acceptable alternative to the monitoring and recording requirements of Section 10.2.4: "Carbon monoxide emissions shall be continuously monitored downstream of the final combustion chamber but prior to release to the air. Continuous monitoring records shall be maintained for a period of three (3) years."

Response: Proper volatilization of wastes is necessary to obtain a good burnout and proper conversion to ash. The monitoring of the primary chamber temperature will insure volatilization temperatures are reached and maintained. The Association's suggestion was incorporated into the rule.

55. Comment: Section 10.2.5 was the target of a number of comments. Hospital and manufacturing interests stated that the

monthly ash testing is unnecessary and costly, and suggested that quarterly or yearly testing would be more appropriate. One hospital stated that the requirement of a 5% fix carbon and 95% burnout is not practical.

Environmental interests believe that bio-medical incinerator ash should be looked at more closely with regard to its toxicity and disposition. Data was provided indicating that heavy metals are present in incinerator ash, particularly in bio-medical waste incinerator ash. These commenters suggested adding a provision requiring that ash from medical waste incinerators be disposed of in the same manner as ash from the incineration of solid waste. Hospital interests stated that no health risks have been demonstrated for chemicals generated by incineration.

Response: The frequency of the ash testing has been modified. The 5% carbon or less rule is a good indication of an incinerator's function. Ash from medical waste incinerators has been found to contain levels of heavy metals exceeding that considered safe for landfill use.

56. Comment: Section 10.2.6. The West Virginia Manufacturer's Association suggested that in situations where infectious medical waste is incinerated in permitted hazardous waste management units, operators of such incinerators merely be required to provide evidence of registration as hazardous waste incinerator operators.

Response: See Item #5.

57. Comment: Section 10.2.7. One commenter requested reducing the time limit for a waiver of incinerator standards from three to two years to be consistent with other requirements of this rule. The Hospital Association suggested that the proposed waiver period for hospital incinerators be linked to the issuance of final EPA rules relevant for hospital incinerators in order to give hospitals a reasonable amount of time to modify or upgrade their treatment operation in order to be in compliance with both State and the new federal standards. (See also Item #23.)

Response: Agreed. Section 10.2.7 as rewritten will give facilities with incinerators in operation at the time this rule becomes effective a period of two years following the issuance of the EPA final rule to comply with this rule if they receive a waiver under Section 10.2.7.

58. Comment: Section 10.3. One hospital commented that the requirements for autoclaving are too stringent. The commenter stated that the temperatures required by the rule are not attainable and that the mandated time frames would preclude the use of steam sterilization as a treatment option.

Another commenter noted that there is not a standard for physical destruction of the treated waste which is not consistent with the 1988 Medical Waste Tracking Act and the standard for in-

cineration in the proposed rule. The commenter recommended that steam treatment should be required to achieve a physically unrecognizable end product.

Response: Most autoclave operations in medical facilities are designed to sterilize instruments for medical procedures. When medical waste is treated, there are no clean surfaces, no pre-washing occurs, and there are larger quantities of both solid and liquid material to be treated than in instrument sterilization. The increased time, pressure, and temperature requirements are necessary because of these differences. It is true that some older autoclaves may not be designed to reach some of the temperature and pressure requirements. Newer equipment capable of meeting these requirements is available. Older equipment which is not designed to reach the increased pressure and temperature parameters can extend the exposure time to obtain proper treatment.

59. Comment: Section 10.3.1.6. One commenter requested that the term "large quantity of liquid", as related to steam treatment duration, be defined.

Response: Large quantities of liquids are not disinfected well by steam treatment. Different machines can adequately treat different volumes of liquids based on their operational parameters. The machine operator, knowing the limitations of his specific machine, must make this judgement accordingly. It is, therefore, not practical to define "large quantity".

60. Comment: Section 10.5, which deals with the approval of (new) methods of treatment alternative to those specified in the rule received several comments. An industry representative recommended that the rule include the possibility for independent testing to be completed by qualified entities other than testing firms, such as government agencies (both foreign and domestic) or universities.

West Virginia University Hospitals commented as follows: "Alternative treatment methods must be encouraged, however must be carefully reviewed. The proposed rules appear to have sufficient safeguards, however it must be recognized that EPA guidelines for testing protocols are non-existent at this time. The reliance upon the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for registering disinfectants is also not appropriate because of the microbiological nature of infectious organisms. Alternate testing mechanisms must be allowed. To allow alternate treatment methods to be developed, and regulated, the discretion of the Secretary of Health must be stressed."

Environmental interests suggested that there should be a public comment period and a public hearing as part of the approval process, that the testing of an alternative method should be conducted in a controlled atmosphere where it will affect the least number of people, and that testing should be under the close supervision of the secretary.

Response: Section 10.5.3.6 was not intended to specify who should do the testing, only what protocols should be used. The Department was informed subsequent to the public comment period that EPA now plans to leave protocol approval to the individual states. Section 10.5.6.3 has been clarified and modified to reflect EPA's most recent determination. The Department believes that control of the testing protocols provides an adequate means of protecting the public interest in the highly technical area of determining treatment efficacy and assuring non-hazardous byproducts of the process. All testing would have to be in a controlled environment to prevent exposure should the process fail. FIFRA requires that a disinfectant be approved for a particular application.

Section 11

61. Comment: Section 11. Environmentally oriented commenters made a number of comments directed at expanding and strengthening this section. One asked why this section, Commercial Infectious Medical Waste Management Facilities, is included in the rule since the law prohibits such facilities. Other commenters made several general suggestions for additions to the rule in addition to recommendations for modifying existing items. They recommended that the size of the facility be limited to the needs of the region and suggested adopting the use of the waste sheds for solid waste. The use of these regions would be consistent with legislative findings calling for minimizing the necessity to transport infectious medical waste. It was also suggested that the siting of any commercial infectious medical waste management facility should be consistent with the county or regional solid waste authority's siting plan. Additionally, these commenters suggested the adoption of a number of sections from the State's solid waste regulations dealing with the following topics: geological and hydrological factors, existing land use, environmental assessment, bonding and financial assurance, disclosure, and water pollution control.

Hospitals were, however, extremely concerned about the strictness of the commercial standards. The HA and a number of hospitals expressed interest in hospitals combining resources with other hospitals and perhaps even other types of health care facilities to develop shared facilities for the treatment of infectious medical waste. The Association and these hospitals are concerned that the standards and public hearing process for commercial facilities will discourage and perhaps even be prohibitive for this type of "local" venture in that the proposed standards are designed for large-scale commercial facilities which treat large quantities of infectious medical waste. These hospitals appear to have in mind a small-scale facility which would likely be located at one hospital and would treat infectious medical waste for only a few hospitals and other health care facilities within a small region such as a county or possibly a few contiguous counties. They indicate that such infectious medical waste treatment facilities, which could be operated on a cost-sharing, non-profit basis would be a viable cost-saving

alternative and would not need to conform to stringent standards directed at large-scale, profit-oriented commercial facilities. They believe that the proposed commercial standards are costly and unreasonable for this type of facility.

Response: Only commercial infectious medical waste incinerators are prohibited by the state code. Commercial facilities using other approved methods of treatment may be granted a permit if they are in compliance with the proposed rule and the statutory requirements set forth in W. Va. Code §§20-5J-1 et seq. Review of a proposed facility is provided through the required public hearing and comments made a part of the application for permit.

The Department must conduct an investigation of the infectious medical waste stream for any proposed facility and determine that infectious medical waste minimization programs have been implemented before approval of a commercial site can be granted. Although this review process does not specifically limit the size of a facility, the economics of the minimization program requirements increases the likelihood of small infectious medical waste treatment facilities serving only limited areas.

The adoption of the county and regional waste sheds was considered but not implemented because the Department believes that the use of specific boundaries could result in increased transportation of infectious medical waste in instances of facilities at waste shed boundaries.

The final product of a commercial infectious medical waste facility is solid waste, therefore new commercial infectious medical waste facilities are not exempt from compliance with standards established by county and regional solid waste authorities.

The addition of a number of sections from the solid waste regulations would require substantial addition to the rule. The Department plans to give this comment further consideration. The Department is also sympathetic to the concerns raised by the hospitals regarding allowing some form of combined local facility and believes that it may be possible within the strictures of the Infectious Medical Waste Act to devise an approach to accommodate some form of relatively small local non-profit treatment facility. The Department intends to further consider these issues and intends to put forth a proposal for public hearing and comment for a revision of this proposed rule some time in 1992. The Department believes, however, that it is necessary to proceed with promulgating the rule in its present form (as filed with the Legislative Rule-Making Review Committee) and plans to proceed with an emergency filing early in 1992. The Department notes that Legislative deadlines for these standards have already passed.

62. Comment: Section 11.5. The West Virginia Hospital Association stated that the "criteria are so nebulous and vague as to be

unenforceable" and are not required by H.B. 2141. The Association recommended that these standards be removed.

Response: The language of Section 11.5 has been clarified. Legislative findings of the West Virginia Medical Waste Act found at W. Va. Code §20-5J-2, first and second paragraphs, clearly identify the Legislature's concern with environmental issues; there are additional references to the environment in the act.

63. Comment: Section 11.7.1.1. It was requested that the words "or locations" should be dropped to make the language consistent with the Medical Waste Act.

Response: Agreed.

64. Comment: Section 11.8. Environmentally oriented commenters suggested that a copy of the pre-siting notice filed with the Department also be provided to the appropriate county or regional solid waste authority or county commission within five (5) days of the publication of the required legal advertisement.

Response: Agreed.

65. Comment: Section 11.13. It was suggested that since commercial infectious medical waste management facilities are not permitted to utilize incineration technology in any form, the language in 11.13 should be changed to refer to Sections 10.3 through 10.5.

Response: This technical suggestion was implemented to clarify the item.

66. Comment: Section 11.15. Environmental interests requested the specific listing of a number of items about which the secretary may request additional information from a proposed commercial infectious medical waste facility. These included: impact on transportation facilities; public water supplies; land use patterns; agriculture, commercial, and residential real estate values; wildlife; endangered or threatened species of animals or plants; aesthetics; socioeconomic conditions; wetlands, surface waters and underground waters; and other impacts as determined by the secretary.

Response: Text has been added to clarify that the Secretary has the authority to ask for additional information related to the siting of a commercial infectious medical waste facility. The Department believes that an attempt to construct an exhaustive list would be fruitless and has chosen to rely on a broad general approach.

67. Comment: Section 11.16. Environmental interests noted that the exemption from the prohibition of the use of incineration in a commercial infectious medical waste facility granted to the type of small facility described in Section 11.16 is in direct contradiction to the Code. They also noted that Sections 11.4,

11.9 and 11.10 are required by statute and the exemption from the requirements of these sections granted in Section 11.16 is in direct contradiction to the Code. They further stated that the Code refers to commercial infectious medical waste facilities without separate mention of "small" commercial facilities or commercial facilities dealing with sharps and that even a "small" facility that would deal with sharps is still a commercial facility. As such it should be made to comply with all provisions applicable to any other commercial facility.

Response: This section was written only to permit local drug stores to use special small-scale processes to treat only sharps and syringes sold to their customers and returned to the store in appropriate containers. The processes contemplated for approval produce a non-infectious, non-hazardous form of the sharps (sterilized and enclosed in a form of plastic) safe for disposal in a sanitary landfill without hazardous by-products. This activity is limited to sharps used in individual households and is beneficial in that it will reduce the probability of injury to refuse workers, limit the amount of transportation of medical waste in an infectious state, and provide a cost-efficient method of treatment of these household infectious medical wastes. This type of facility would be restricted to an approved treatment method not utilizing incineration in any form.

This type of facility and process actually serve to reduce the infectious medical waste stream going in to landfills or larger treatment facilities, thereby obviating the need for investigation of the infectious medical waste stream as required by Section 11.4. Similarly the Department believes that the nature of the facility (local drug store) and process make a full-scale public hearing process unnecessary. Finally, the lack of mention by the Code of any distinction among commercial facilities by size does not prohibit the Department from establishing such distinctions as part of the licensure process.

Section 12

68. Comment: Section 12. Two suggestions for additions were received. One was to require that the number of containers in any one shipment be stated, and the second was to allow the use of computer-generated manifests provided they include all required information.

One hospital suggested that the manifest requirements seem to be designed for commercial haulers and suggested that small generators within a given area be allowed to transport quantities greater than 50 lbs. per month to a non-commercial facility without manifests. This would allow small generators such as nursing homes and clinics to operate under the same procedures as the large facilities with several sites in one county (for example, Charleston Area Memorial Center and the West Virginia University Hospitals).

Response: The number of containers shipped will be required

on the Department's manifest. The rule has been modified to allow the use of other manifests if approved by the Secretary prior to use. A facility generating more than 50 pounds of infectious medical waste per month does not meet the statutory definition of a small generator.

69. Comment: Section 12.1. One transporter suggested that all manifests should be numbered in the upper right hand corner. To assist in tracking, this number should be on every carton in a visible area. The numbers should also be a part of the logging and reporting process.

The commenter also suggested that the transporter retain photocopies of the generator-completed manifest and attach it to copy #2. This would provide protection for the generator in the event of loss or destruction of the original. This record should be maintained by the transporter for a period of three years.

Response: It would not be useful to utilize a manifest number repeated on each package of infectious medical waste since each package is required to be labeled with the pertinent information. The completed copy of the manifest would be located at the treatment facility and the generator, therefore an additional copy to protect the generator should the completed manifest be lost would not be necessary.

70. Comment: Section 12.9. The West Virginia Hospital Association noted that the rule relieves small quantity generators who elect to transport their own infectious medical waste from manifest requirements. The Association stated that hospitals should have the ability, if desired, to require manifests from any generator including small quantity generators and ambulance companies, local health departments or small physician groups, nursing homes, etc. The Association believes that such practices may result in better control of infectious medical waste.

Response: The Department notes that hospitals do not need regulatory authority to require a manifest from small generators whose infectious medical waste it treats, but has added language to clarify that the rule does not prohibit this.

Section 13

71. Comment: Section 13.4. Commenters made several suggestions about reporting by generators and transporters of infectious medical waste. It was noted that routine reporting is required only for 1991. The information for such a report would is available from manifests. Commenters believe it would not be difficult in this day of computer technology to prepare a report. Commenters suggested both annual and monthly reporting for generators and transporters. It was suggested that monthly reporting include volumes, disposal sites and methods of disposal. Commenters stated that the information is crucial in determining the need for commercial infectious medical waste facilities and also that it would be useful for purposes of verification of that

infectious medical waste is being handled in an environmentally acceptable manner. It was also suggested that all generators and transporters report any spill of 50 pounds of waste or more to the employer and the Department, with the report postmarked within two working days from the date of the spill.

Response: The rule has been modified to clarify that annual reports are required from all but small quantity generators and those exempt under Section 2 of the rule. Quarterly reports are required of transporters. A requirement for spills of 50 pounds or more by transporters to be reported as soon as possible has been added to Section 9.8 of the rule.

Section 14

72. Comment: Section 14.2. One commenter requested that the rule require inspections of infectious medical waste management facilities at least every 3 years.

Response: Infectious medical waste management facility is an all inclusive definition. Within its framework is any facility that generates infectious medical waste, including households, physician and dental offices, veterinarians, nursing homes, hospitals, and numerous others. To inspect each of the every three years would take an enormous effort, which the Department does not believe would be productive or cost effective. The Department plans to inspect infectious medical waste facilities required to have a permit to operate twice yearly. Small quantity generators will be inspected on a complaint basis. Infectious medical waste management plans for small quantity generators will be reviewed on a random selection basis until reviews are current. This review will be a lengthy process; it is estimated that there are approximately 7,000 small quantity infectious medical waste generators within the State.

Sections 16 and 17

73. Comment: Sections 16 and 17. One hospital criticized the civil and criminal penalties prescribed as entirely excessive. It was stated that: "No environmental damage has ever been associated with medical waste." ... "By virtue of these penalties one wonders if the Department of Health is attempting to protect the public's health or if the political pressure and influence exerted by extreme environmental groups are dictating public policy."

Response: These maximum penalties are set by statute to discourage violation of the rule. The language of the statute permits setting lower penalties for lesser violations. Additionally, the Department will initially take an attitude of working with facilities to correct violations and would not choose to pursue civil monetary penalties except for flagrant or chronic violations of the rule or statutes.

PUBLIC HEARING

Proposed Infectious Medical Waste Rule

October 3, 1991

NAME	ADDRESS	GROUP REPRESENTED (IF ANY)	DO YOU WISH TO COMMENT (YES/NO)
[illegible] Cunningham	125 Circle Drive Princeton, WV 24740		No
[illegible] Bailey	1301 Kenneth Blvd Chas	Eye & Ear Clinic Inc	No
[illegible] Jean	1100 Van Voorhis Rd. Morgantown	Mountain View Rehab	No
[illegible] Kadakuth	XX Garfield Ave Parkersburg WV 26101		
[illegible] Hill	1 Playland, 2000 DeBoos Lane, Powell		No
[illegible] Roach	2100 Plaza Tower ~~Dept~~ Knoxville TN 37929	Dept	Yes ✓
[illegible] Fleming	Daily Mail		No

PUBLIC HEARING

Proposed Infectious Medical Waste Rule

October 3, 1991

NAME	ADDRESS	GROUP REPRESENTED (IF ANY)	DO YOU WISH TO COMMENT (YES/NO)
Dr Harry Newell	712 McCorkle Ave SW Charleston 25303	WV Veterinary Medical Assn	Yes ✓
[illegible]	P.O. Box 296 Mt Airy MD 21771	[illegible]	[illegible]
Sandra Landfried	117½ North St.	Office of Health Facility Lic & Certif	No.
[illegible]	[illegible]	[illegible]	[illegible]
Pamela Tripp	RHMS 113 Hosp Plaza Clarksburg WVa	United Hospital Center	
Bill Cole	Kyle Industrial Park Huntington, WV 25702	Browning Ferris Industries	(written) No
Frank Crabtree		PSC	yes ✓
Mary Pendleton	Bay Virginia SJF Physician	WV CAG	
HAROLD HARPER	HEALTH SCIENCE CTR	WVU	No
Ned Cannon	Hsc Hlth Science Center	WVU	No

PUBLIC HEARING

Proposed Infectious Medical Waste Rule

October 3, 1991

NAME	ADDRESS	GROUP REPRESENTED (IF ANY)	DO YOU WISH TO COMMENT (YES/NO)
Charles Steensburg	Princeton WV	Medical Waste Disposal System Inc.	
Terrie Lee	Charleston	Charleston Area Medical Center	
[illegible]	Charleston	Charleston Area Medical Center	Yes ✓
Sandy Saunders	Charleston	Office of Health Facilities Licensure + certification	Yes
Chris McCuffin	Huntington	Marshall University School of Medicine	No
Tom Wilkinson	"	" " "	no.
[illegible]	Parkersburg	CCMH	Yes
[illegible]	Huntington	St Mary's Hosp Inc.	
Bob Foster	Chas	WV Hosp Assoc	Yes ✓
Charles L. Saber	Chas	Kan-Awha Health Dept	Yes
[illegible]	Glasgow	Hope Gas	

PUBLIC HEARING

Proposed Infectious Medical Waste Rule

October 3, 1991

NAME	ADDRESS	GROUP REPRESENTED (IF ANY)	DO YOU WISH TO COMMENT (YES/NO)
[illegible]	Charleston	WBPH	
[illegible]	PLFLD P.O. Box 5706	BRMC 800-445-4710	
[illegible]	Princeton WV	MEDICAL WASTE DISPOSAL	
[illegible]	[illegible] Mass.	Dev. Hlth OHFLC's	No
[illegible]	Chas WV	GAI Consultants	
[illegible]	Spencer, WV	Roane General Hospital	
[illegible]	Spencer WV	Roane General Hospital	
[illegible]	Thomas Hospital	Thomas Hospital	No
[illegible]	[illegible] Charleston	AMTEC Inc	No
[illegible]	Charleston	WVSWCB	No
[illegible]	Charleston WV	CAMC/Stratagene	
[illegible]	[illegible]	Env. Hlth Rep	No

PUBLIC HEARING

Proposed Infectious Medical Waste Rule

October 3, 1991

NAME	ADDRESS	GROUP REPRESENTED (IF ANY)	DO YOU WISH TO COMMENT (YES/NO)
Richard Stevens	300 Capitol St. #1002 Chas, WV 25301	WV Dental Assn.	Yes ✓
Dean Smith	79 ~~Oak~~ Milton W.Va 1511 W Main St	WV Dental Assn	Yes
[illegible]	Hamlin	Ed McMahan Sys	
Tim Tabaney	Williamstown	BMH	?

PUBLIC HEARING

Proposed Infectious Medical Waste Rule

October 3, 1991

NAME	ADDRESS	GROUP REPRESENTED (IF ANY)	DO YOU WISH TO COMMENT (YES/NO)
[illegible]	[illegible]	Logan Co Health Dept	No
Bill Campbell	Charleston WV #7 Spring St.	Dom's Disposal Service	No
Judy Robertson	RR1 Box 288 Bloverfield WV	Bio-Environmental Services	No
Phil Elliott	1506 Kanawha Blvd	Eye & Ear Clinic of Charl.	No
Lynn Adkins	DHHR		No
Charlotte Billingsley	OLS DHHR		No
Herbert U. Tieche	1009 S. Oakwood Ave, Beckley	Beckley Hospital	Yes ✓
Gil Delaura	600 D St S. Charleston	WV Hosp Assoc	Yes ✓

Beckley Hospital, Inc.

1007 S. OAKWOOD AVENUE
BECKLEY, WEST VIRGINIA 25801
(304) 256-1200

September 17, 1991
Revised 10/1/91

To: Ms Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Blvd
Charleston, WV 25305

From: Albert U Tieche II
Beckley Hospital Engineering
1007 South Oakwood Ave
Beckley, WV 25801

SUBJECT: **Comments on Proposed Infectious Medical Waste 64 CSR 56**

Dear Ms Howard,

I have reviewed the proposed Infectious Medical Waste Rule dated September 3, 1991 and I would like to voice concern regarding the provisions

Sections 9.7.1 through 9.7.5 deal with vehicles used to transport infectious medical waste. Back-hauling of foodstuffs should not be permitted and is prohibited by 9.7.5 However the present wording will require this hospital (and other small rural hospitals) to acquire an additional vehicle, as foodstuffs and infectious waste can never be transported by the same vehicle The two tasks are made mutually exclusive for the life of a vehicle by section 9.7.5. and disinfection is not made available as an alternative. In a small facility, one truck is often used for many tasks and may, on occasion, transport small amounts of infectious waste and on another occasion, transport a small amount of foodstuffs. I would like to offer an addition (possibly numbered Section 9.7.1.1) which will satisfy the intent of the rule, protect the public health and cause much less hardship and/or expense for smaller institutions

9.7.1.1 ***Separate, removable, cargo-carrying portions are acceptable and if used, shall comply with 9.7.1 through 9.7.5 in lieu of the entire vehicle.***

Received 10/3/91

This addition would allow institutions that have multi-use vehicles, *i.e.* small trucks, to obtain a separate container section for the vehicle that would be dedicated to the transport of infectious medical waste and secured in/on the vehicle only when this occurs. All other requirements would still apply to the entire vehicle. This provision would also eliminate the possibility of back-hauling of foodstuffs in any container, including trailer sections of tractor trailer trucks, that had been used for infectious waste.

Preventing the simultaneous transport of infectious waste and foodstuffs (even in seperate container sections) can be accomplished by adding the following clause to Section 9.7.5.

9.7.5. food or feed ***simultaneous to the transport of infectious medical waste.***

Making these changes would protect public health but preclude the need for the purchase of an additional vehicle. This would help minimizing the costs related to compliance with 64 CSR 56. A vehicle could then be used for occasional transportation of foodstuffs without risking exposure to infectious waste which had been transported in an entirely seperate container. It should be noted that all food is normally delivered to hospitals by suppliers but there will always be extraordinary circumstances that arise from time to time, requiring hospital vehicles to make small pick-ups.

I hope you will consider these comments in assembling the final draft of the rule. The proposed additions do not weaken the rule and would be very helpful to small institutions. I will attend the public hearing on October 3 and I would be glad to discuss this with you or your staff before or after the hearing. I can be reached at The Beckley Hospital 304-256-1408.

Sincerely,

A. U. Tieche II

Albert U. Tieche II
Beckley Hospital Engineering

cc: A. M. Tieche Jr.
Joseph A. Wyatt
Gil DeLaura

BFI Waste Systems
BROWNING-FERRIS INDUSTRIES

October 1, 1991

Ms. Kay Howard
Regulatory Development
Room 204, Building 3
Capitol Complex
Charleston, West Virginia 25305

Dear Ms. Howard:

Browning-Ferris Industries Medical Waste Systems (BFI) is engaged in the transportation of infectious medical waste in the State of West Virginia. I am pleased to have the opportunity to comment on the proposed:

Title 64
West Virginia Legislative Rules
Department of Health and Human Resources
Series 56

My initial comment concerns Rule 6.3 Labeling Requirements. The labeling requirement as proposed is burdensome. I suggest that the labeling requirement be revised to include the name and address of the generator and the original transporter. All other information such as packaging date, weight, number of containers, and any transporters other than the primary transporter will be listed on the accompanying manifest as proposed in Rule 12.

My second comment concerns the need to obtain a transporter permit by the time that these rules are adopted. I suggest that transporters be allowed a grace period of 30 days to have an application returned to the Infectious Medical Waste Program from the time that these applications are available.

My third comment is a recommendation add the following language to 64-56-9 Transportation.

> "A small quantity generator of medical waste may transport infectious waste (as defined by 64-56-3.3.9.2.4 - Sharps) via the U.S. Postal Service provided they are packaged according to 64-56-6.6.2 and meet the requirements set by the U.S. Postal Service for packaging and class of mail service."

Mail: P.O. Box 329, Lesage, West Virginia 25537-0329 (304) 525-1631
Ship: Industrial Lane, Kyle Industrial Park, Huntington, West Virginia 25702
(304) 525-1631 Wats (800) 331-0988 FAX (304) 525-0399

This will allow small quantity generators in a rural area to comply with the rules in a cost efficient manner and protect solid waste workers. By conforming with postal requirements the health and safety of postal workers will be maintained as well.

My next comment regards the off-loading of a small collection vehicle to a larger truck or trailer for transport to a distant disposal facility or the off-loading to another vehicle if the original vehicle is disabled. I recommend that a rule 9.3.3 be added that states:

> "Infectious Medical waste may be off-loaded to another properly permitted vehicle. This will require that the manifest be signed indicating a change in custody of the infectious waste to the secondary transporter."

My next comment is a recommendation be added in the Transportation Rule 64-56-9 that requires refrigeration of infectious medical waste if it is not delivered to a treatment facility within 24 hours. This change will help to maintain infectious waste in a non-putrescent state.

My final comment addresses Rule 64-56-12 requirements related to manifests. It is common to the industry to use a computer generated manifest. I recommend that language be added to allow this, but recognize that it has to duplicate the four part manifest available from the secretary.

Thank you for your time and consideration of these comments to the proposed rules. Please contact me if I or Browning-Ferris can be of any additional service to the Infectious Medical Waste Program.

Sincerely,

Tom Miller
Regional Medical Waste Manager

TM:cah

cc: Jackie Flora
Charles McLaurin
Judd Doerfler

Received 10/3/91

CALHOUN GENERAL HOSPITAL

October 1, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Dear Ms. Howard:

Calhoun General Hospital wishes to comment on the proposed rules for Infectious Medical Waste Rule. The legislature stated that the public interest is best served by on-site separation and treatment of infectious medical waste. Our hospital is very concerned and has taken all necessary steps to ensure the safety of all concerned parties.

The proposed rules gives some needed direction, but taken as a whole they increase the cost to a prohibitive amount for a small rural hospital. These rules would further comprise the safety and welfare of the citizens of West Virginia. If the infectious medical waste is stored and then transported, there will be additional opportunities that will compromise individual staff safety and possible exposure to infectious medical waste.

The better view would be to develop rules that would be practical and effective to protect all citizens of West Virginia. The hospital would support and does support such effects by the legislation. Mr. Donald Eurich, of Eurich Incinerator, will be testifying at the public hearing on October 3, 1991 in this regard. The committee should evaluate his comments and re-evaluate the proposed rules and regulations.

The hospital does not feel that the public interest and safety will be improved by the proposed regulations. The hospital does not support the interlocks on loading doors, this is simply not feasible. It is not necessary to have monitoring and recording equipment for primary and secondary chambers of the incinerator. Monitoring is needed, but monitoring of the secondary chamber is all that is needed to ensure safety.

The requirement that requires a 5% fix carbon and 95% burnout is not practical. A more realistic approach is needed. A cost benefit analysis of the other purposed rules, such as monthly organic carbon content

P.O. BOX 490 / GRANTSVILLE, WEST VIRGINIA 26147 / TELEPHONE (304) 354-6121

testing, permits, operator fees, spill management kits, and storage area, among other items, needs to be evaluated.

The total increased cost to the hospital depends upon several unknown factors, but an increase of $5,000 - $10,000 per year is likely. This increased cost would not result in making the citizens of West Virginia safer. We would request that additional research and evaluation, along with more public hearings be held before any rules be adopted. We appreciate your consideration.

Sincerely,

A Lawson J.D.

Al Lawson, J.D.
Administrator

AL/lke

Charleston Area
Medical Center

September 30, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

RE: Proposed Infectious Medical Waste Rule

Dear Ms. Howard:

The process for promulgating the proposed infectious medical waste rule has been a long and arduous one. The Department of Health and Human Services, specifically Joe Schock and his staff, are to be commended for the collaborative method used in development of the proposed rule.

However, it is our considered opinion that the proposed rule places unnecessary restriction and requirements on the healthcare industry in several areas:

1. Many activities required by this rule are appropriate for the management of hazardous materials (chemicals) but are unnecessary and extremely costly for the appropriate management of infectious medical waste. It must be emphasized that there is no factual information to indicate infectious waste causes environmental consequences (see New England Journal of Medicine, August, 1991) but the rule is written as if infectious waste poses the same threat to the public as chemical waste regulated under subtitle C.

2. This rule may discourage efficient treatment and disposal by placing burdensome restrictions on the healthcare industry. The rule does not solve a problem but instead creates larger concern for good management practices due to the complicated system required. Individuals who find the required activities confusing or non-essential will find alternatives resulting in poor practice. The economic consequences for the healthcare community can be disastrous as options for disposal and waste management are eliminated.

VHA

3. Restrictions placed on generators of infectious waste having on-site treatment facilities will, from a liability and regulatory perspective, preclude that generator from accepting infectious waste from off-site generators. In as, it is the "policy of the state of West Virginia to prohibit commercial infectious medical waste facilities", small generators (physicians, dentists, public health clinics) will be forced to contract with out-of-state medical waste disposers. The intent of this regulation to inhibit or prohibit the construction of commercial medical waste facilities intended for treatment and disposal of out of state medical waste has resulted in West Virginia exporting medical waste to other states at an economic cost and burden to the citizens of West Virginia.

4. The proposed rule does not provide an effective mechanism for hospitals to coordinate efforts in waste management, i.e. to develop joint ventures to manage medical waste within a local area. Section 11.5 outlines stringent requirements that would effectively preclude establishing new facilities.

We would like to make the following comments as listed below in reference to section numbers identified:

SECTION 2.2 - Exemptions

2.2.1 states that "householders shall place sharps in a container...". Does the legislative authority vested in WV Code Section 20-5J-2 give the Department of Public Health the power to regulate and penalize individual households and citizens? If so, who will enforce this provision?

2.2.2 requires ambulance and rescue services to package and deliver their own generated medical waste to a permitted Infectious Medical Waste Management Facility. The rule with its severe restrictions and penalties will preclude hospitals with treatment and disposal capabilities from accepting this waste. Ambulance and other rescue services will as a result need to contract with state registered commercial haulers and disposers.

SECTION 3 - Definitions

3.1 animal carcasses: this definition is so open ended by virtue of the phrase "or for any other reason" that farm animals could be included.

SECTION 4 - General Permit Application and Approval Procedures

In the existing language provided, no time frames are set forth by which permit applications and approval procedures are to be completed. Language states that upon date of promulgation, health facilities will be required to submit permit applications within a 60 day period. While this time frame will allow the health care facility to complete the application process, no form has yet been provided for this process.

SECTION 6 - Packaging and Labeling

There is no definition provided of what constitutes a package. Is it an individual bag or infectious waste bags contained in a corrugated container?

6.2.2 The provision for heavier materials to be "supported in double-walled corrugated fiberboard boxes or equivalent rigid containers", does not provide adequate description of containers required. Containers should meet performance standards in that they are to remain crush proof during storage and transport operations. This has been the policy of the US EPA in their "standards for tracking and management of medical waste 40 CFR Part 259."

6.2.3 there is no such thing as a leak proof sharps container. Leak resistant is a more appropriate adjective.

6.2.8 Personal Protective Equipment for workers is essential. However, the OSHA Bloodborne Pathogen Standard has not been enacted and should either be identified here as a proposed standard or deleted.

6.3 it is unclear under 6.3.1 as to what time a label is to be affixed on the infectious waste "package". If this labeling requirement initiates at the time infectious wastes are temporarily stored or intrafacility transported, this will create an undue and unnecessary burden to the healthcare facility.

The requirement that the label should include weight would mandate that each hospital unit have a scale for measurement at every area.

It should be made clear that these labeling requirements only pertain to off-site transportation of medical waste for treatment and disposal to non-owned treatment/disposal facilities. This information is best contained on manifests accompanying the above shipments.

6.3.2.4 where does this statement go? On manifest? On treated but still recognizable waste? To whom does it go? Is it to be retained in documentation? This provision is better place under manifesting requirements as provided in Section 12.

SECTION 7 - Management of Spills of Infectious Waste

7.1.1 under this section it is obvious that the writers of this regulation know little about what constitutes an infectious waste. and the hazards that are associate with it. The absorbent requirements are totally excessive. Based on the liquid contents typically found in a medical waste load, liquid in medical waste is less than 5%. For a hauler to be required to have enough absorbent (to absorb 10 gallons of liquid for every cubic foot of waste) would cause an economic and logistic burden in medical waste transport.

7.1.3 the kit contents requiring 150% of capacity is also unnecessary. If a transportation incident were to occur, outside response would or could be called to provide the materials required for decontamination and cleanup. A requirement such as this for medical wastes is inconsistent with standard required of hazardous waste transporters.

7.1.4 the personal protective equipment required in this section is excessive, reflective of hazardous material (chemical) protection where the potential for chemical permeation is present. This requirement for infectious waste is unnecessary and costly.

SECTION 8 - Storage

8.1 storage needs to be more adequately defined within this section to differentiate between temporary storage on a nursing unit and for temporary storage prior to transport to an off-site and non-owned treatment/disposal facility.

8.6 will preclude the use of tiled floors in utility rooms and floors on trucks in that it states carpet and floor coverings with seams shall not be used in storage areas. The potential hazards associated with medical waste as a result of spills and leakage can be easily mitigated by application of chlorine bleach which will permeate through seams to inactivate. There is no analogy of chemical waste storage areas with infectious waste storage areas as indicated in this section.

SECTION 10 - Methods of Treatment

10.2.5 monthly testing of ash is unnecessary and generates additional cost. Alternative testing schedules such as quarterly then with decreasing frequency if ash is within established limits should be considered.

10.3 Steam Treatment

10.3.1.3, 10.3.1.4, 10.3.1.5, are physically non-attainable. The application of principles of steam sterilization need to be applied to this section. As principles of physics, temperature and pressure are interrelated and are not independent functions; as the pressure increases so does the temperature. Time requirements for microbial kill are dependent on temperature and are predicated on criteria provided by biological indicators. (See "Draft Manual for Infectious Waste Management, September, 1982 - US EPA) The time requirements for 10.3.1.1 and 10.3.1.2 should be eliminated and times for treatment should be based upon documentation that biological indicators have been rendered non-viable. In some cases this would require infectious waste to be treated for 30 minutes or less dependent on temperature or for greater periods dependent on temperature, volume density and size. Mandated time frames provided in the proposed regulation would preclude the use of steam sterilization as a treatment option for medical waste generated by hospitals.

SECTION 16, SECTION 17

Civil and Criminal penalties prescribed are entirely excessive. These penalties would indicate that infectious waste is more hazardous than hazardous chemical waste as defined under 40 CFR Part 261. No environmental damage has ever been associated with medical waste. (ATSDR - Center for Disease Control - Report November, 1990.) By virtue of these penalties one wonders if the Department of Health is attempting to protect the public's health or if the political pressure and influence exerted by extreme environmental groups are dictating public policy.

SUMMARY

We would ask that the Department of Health seriously reevaluate the language and restrictions contained in the proposed draft of September 3rd prior to filing of these regulations. It is our belief that the healthcare facilities in the state of West Virginia will be adversely affected in both time and money without the benefit of protecting the public health and the environment from a waste stream that has had no demonstrated environmental damage.

Lillian D. Morris
Safety Director

Robert L. Deitz
Vice President for
Support Services

Charleston Area
Medical Center

Clinical Epidemiology

October 1, 1991

Attention: Kay Howard
Director, Regulatory Development
Department of Health and Human Resources
Room 204, Building 3
Capitol Complex
Charleston, WV 25305

Dear Ms. Howard:

We are writing to express our comments on the Proposed Infectious Medical Waste Rule for the State of West Virginia's Bureau of Public Health. We will be limiting our specific comments to our areas of our expertise:infectious diseases, infection control, and epidemiology.

S 64-56-3 - Definitions. We commend you for maintaining definitions of infectious waste that are consistent with what has long been defined by the Centers for Disease Control. Our only concern is in the section 3.9.3. where exemptions are defined. All of the exemptions listed are accurately classified as non-infectious waste. However, there may be many other items that are not infectious waste which are not listed. For example, an I.V. tubing set that was used to deliver I.V. fluids to a patient is not considered infectious waste. We are concerned that items such as this will be left up to individual interpretation, if not addressed formally. One way to do this might be in the Question and Answer Document that the Environmental Health Division has been planning to develop.

The requirements for labeling, packaging, transporting, weighing, and storing infectious waste need to be more clearly applied to the intra-hospital setting. For example, if infectious waste is held for two hours on a nursing unit, and then picked up by housekeeping staff, is that considered "storage" and is detailed labeling required, or can the red biohazard bag serve as sufficient in-house "labeling?" It would seem that the additional labeling, weighing, and storage requirements would be unnecessary for a hospital doing on-site treatment, for example, but these details are not sufficiently clear in the proposed rule.

S64-56-7. Management of Spills of Infectious Medical Waste. 7.1.4. lists the contents of the cleanup kit, and includes "Protective eye and breathing devices." What is a protective "breathing device?" A mask is not a breathing device. You may consider changing this to say protective facial barriers such as goggles and a mask. There are some facial shields which cover the entire face, and remove the need for any additional facial gear. To call it a

breathing device, though, is inaccurate.

S64-56-9. Transportation. 9.7.5. States that vehicles that are used to transport medical infectious waste cannot be used to transport any type of food, food additives, or food containers. If a vehicle were adequately disinfected and if food were properly packaged, there is no scientific reason to prohibit this singular type of transportation.

Thank you for your consideration of these points.

Sincerely,

Terrie Lee

Elizabeth A. Funk, MD/gr

Terrie Lee, RN, MS, CIC
Director, Clinical Epidemiology

Elizabeth A. Funk, MD
Hospital Epidemiologist and
Chair, Infection Control
Committee

Received
10/3/91

October 3, 1991

Regulatory Development
Room 2C4, Building 3
Capitol Complex
Charleston, WV 25305

Attn: Ms. Kay Howard

Subject: Comments on Proposed Infectious Medical Waste Rule

Ms. Howard:

This letter is written in response to the emergency rules filed September 3, 1991 entitled "Title 64, West Virginia Legislative Rules, Department of Health and Human Resources; Infectious Medical Waste, Series 56, 1991." After reading this set of emergency rules, I feel that three items are in need of clarification.

1) Section 6.2.3.2 - Please define "encapsulated in a solid state."

2) Section 10.3.1.6 - "... Longer steam treament times are required when

a load contains a large quantity of liquid." Please clarify as to what amount of liquid per load constitutes "large" and how much longer the load needs to be treated.

3) Section II - "Commercial Infectious Medical Waste Management Facilities." If the State of West Virginia prohibits such facilities (H.B. 2141, Section 20-5J-2, Lines 75-77), why is this section included with the rules? It seems that the preamble should be changed to read "Therefore, it is the policy of the State of West Virginia to prohibit commercial infectious medical waste facilities [that utilize incineration technology in any form]...." Section II as a whole implies that this is the case.

Very Truly Yours,

Michele Daniell
4715-C MacCorkle Ave. SE
Charleston, WV 25304

Enclosed please find our comments and suggestions concerning the proposed Infectious Medical Waste Rules, Title 64, series 56 dated September 3, 1991.

The language in Section 6.2.6 under Packaging has been weakened. The basic statement here is that containers don t have to be washed and disinfected unless they are contaminated or come in contact with improperly contained items. It is not clear who makes the determination that they are contaminated. The language in 7.2.5 in the previous draft dated April 22, 1991 is much more clear. The basic statement in that draft is that containers do have to be washed and disinfected unless they have been effectively protected from contamination. We would like to see the language from the last draft reinserted here in that it provides for better protection of the worker s and the public's safety.

Concerning Section 8 **Storage of Infectious Medical Waste**, we would like to see 8.2 written as follows: "Excluding sharps, infectious medical waste stored for more than 72 hours after generation must be refrigerated at 45 degrees Fahrenheit or below." Then 8.2.1 would read "No infectious medical waste shall be stored for more than thirty (30) days, even if refrigerated." This is the language that is in the previous draft, dated April 22, 1991.

Concerning Section 9 **Transportation**, under 9.10 we suggest that the application state the name, business address and telephone number of each driver who will operate in West Virginia. We also suggest that Section 9.10.8 be written so as to actually require the employees to be trained, not just that the applicant has established a training program.

Concerning Section 10 **Methods of Treatment**.

Section 10.2.3 has language that requires the use of interlocks or other process control devices to prevent feeding of the incinerator until the temperatures specified in Section 10.2.2 are achieved. This is a good provision, but then there is an override for start-up allowed. It is well documented that significantly more pollutants are emitted during a cold start-up and it is for this reason that the interlocks, etc. are needed. To allow an override for those conditions is to negate the language almost completely. We suggest that the allowance for an override at start-up be dropped.

In light of the fact that heavy metals that are present in incinerator ash, and Bio-Medical Waste Incinerator Ash in particular(see chart), we feel that

Received 10/3/91

ash should be looked at more closely in regards to it's toxicity and disposition.

Metals in Fly Ash

Average Cadmium and Lead Concentrations from Bio-Medical Waste Incinerators, Municipal Waste Incinerators and Hazardous Waste Incinerators

Facility	Concentration ug/g on fly ash: Cadmium	Lead
BMWI (1)		
St Agnes	566	5990
Cedars Sinai	1790	15100
Sutter General	504	6480
Stanford	735	24200
St Bernadines	211	2640
LA County	279	21800
Kaiser-Permanente	550	12600
MWI (2)		
A	42	4000
B	185	-
HWI (3)		
A	590	55500
B	140	3100
C	1120	25600
D	4000	98000

(1) CARB tests 2,3,4,5,6,7,8
(2) Greenburg, R R et al.
(3) Oppelt, T E.

"Cadmium and Lead in Bio-Medical Waste Incinerators," D.C. Hickman and D.P.Y. Chang, Department of Civil Engineering and Mechanical Engineering University of California, Davis. Presented at the 82nd Annual Mtg. of the Air and Waste Management Association, 1989, June 25-30th Anaheim CA 16 Pages. Copies available from CCHW for $3.20 copy and postage costs

From "Medical Waste: Public Health vs Private Profit" pg 8
Published by the Citizen's Clearinghouse for Hazardous Waste, PO Box 926 Arlington, Va. 22216

Ash from infectious medical waste incinerators should be regulated at least as strictly as ash from solid waste incinerators. We suggest that the following language in 10.1.2 read as follows: "The residue or ash remaining after the treatment of infectious medical waste in accordance with this rule becomes noninfectious medical waste and may be disposed of in the same manner as ash from the incineration of solid waste."

Concerning Section 10.5 **Alternative Methods** we feel that there should be a public comment period and a public hearing as part of the approval process for alternative methods.

Concerning Section 11. **Commercial Infectious Medical Waste Management Facilities**:

Language should be introduced stating that the size of the facility must be limited to the needs of the region. The waste sheds that are used in the solid waste legislation are the regions that come to mind. This would make section 11 more consistent with the language in the following legislative findings presented in WV Code §20-5J-2: "The Legislature further finds that ... its transportation in the infectious state, pose a potentially serious threat to the health, safety and welfare of West Virginians." and "The Legislature further finds that the necessity for transporting infectious medical waste be minimized....".

Also, the siting of the facility should be consistent with the county or regional solid waste authority's siting plan.

Section 11.7.1.1 has apparently been taken from the solid waste regulations and we applaud the addition. However, the words "or locations" should be dropped to make the language consistent with the Medical Waste Act.

We would add to Section 11.8 on page 26 the following, labeled as 11.8.1:
"A copy of the pre-siting notice shall be provided to the appropriate county or regional solid waste authority or county commission within five (5) days of the publication of the legal advertisement required under Section 11.7 of this rule."

Section 11.2 states that "A commercial infectious medical waste management facility may not utilize incineration technology in any form." Therefore the language in 11.13 should be changed to read: "A commercial infectious medical waste management facility shall employ a treatment

technology approved according to the provisions of Sections 10.3 through 10.5."

We think the language under 11.15 should read as follows:

"Based on comments received at the public hearing or upon recommendations received from the county or regional solid waste authorities within thirty (30) days after their receipt of the pre-siting notice, the secretary may require the person who submitted that notice to furnish additional information on the siting of the proposed facility. Such additional information may include, but not be limited to, the following:

11.15.1 Impacts upon transportation facilities;

11.15.2 Impacts upon public water supplies;

11.15.3 Impact upon land use patterns;

11.15.4 Impacts upon agricultural, commercial, and residential real estate values;

11.15.5 Impacts upon wildlife;

11.15.6 Impacts upon endangered or threatened species of animals or plants;

11.15.7 Impacts upon aesthetics;

11.15.8 Impacts upon socioeconomic conditions;

11.15.9 Impacts upon wetlands, surface waters,. and underground waters.

11.15.10 Other impacts as determined by the secretary."

If there is going to be a commercial infectious medical waste facility, it ought to be regulated to at least the same extent as solid waste transfer stations and processing facilities. Therefore we feel the following from the Title 47 Series 38 solid waste regulations should be applied to commercial Infectious Medical Waste Management Facilities:

* 47-38-3.2 Location Standards

* 1 through 11 under 47-38-3.7 Permit Application Requirements

* 16 under 47-38-3.7 Permit Application Requirements

* 1 and 9 under 47-38-3.8 General Geological and Hydrological Submission Requirements

* 47-38-3.9 Existing Land Use and Environmental Assessment

* 47-38-3.13 Bonding and Financial Assurance

* 47-38-3.14 Disclosure Statement

* 47-38-3.15 Water Pollution Control Requirements

* 47-38-3.16.3 Requirements for Transfer Stations. 3.16.3.a.A is covered by the above, and 3.16.3.b (Operations Plan) is covered fairly well by 64-56-5 (Infectious Medical Waste Management Plan), although there may be some portions of 3.16.3.b that could be applied such as posting the hours of operation.

The references to **solid waste** would have to be changed to **infectious medical waste** and the references to the **Chief** and the **Department** would have to be changed to the **Secretary** or whatever is appropriate. Also there may be some provisions that obviously won't apply, such as those pertaining strictly to landfills.

§20-5J-4 states that: "It shall be unlawful to construct or operate a commercial infectious medical waste facility in the state of West Virginia *Provided,* That the secretary may authorize an exception to this prohibition solely for facilities not utilizing incineration technology in any form, including the manufacture or burning of refuse derived fuel: *Provided, however,* That such an exception may be granted only following: (1) the promulgation of legislative rules, in accordance with the provisions of chapter tweny-nine-a of this code containing guidelines for such an exception that are being fully consistent with the findings and purposes contained in section two of this article; (2) a public hearing on the record in the region affected by the proposed facility; (3) an investigation of the infectious medical waste stream in the region affected by the proposed facility; and (4) a determination that programs to minimize and reduce the infectious medical waste stream have been implemented."

It is quite clear that no commercial infectious medical waste facility shall utilize incineration in any form. Therefore the exemption from the

requirements of Section 11.2 granted in Section 11.16 should not be granted and is in fact in direct contradiction to the Code.

It should also be noted that (2), (3) and (4) in §20-5J-4 are all addressed in Section 11.4, 11.9 and 11.10. Therefore the exemption from the requirements of these sections granted in Section 11.16 should not be granted and is in fact in direct contradiction to the Code. The logic in granting the exemption from other requirements of Section 11 escapes us. The Code refers to commercial infectious medical waste facilities without separate mention of "small" commercial facilities or commercial facilities dealing with sharps. This "small" facility that would deal with sharps is still a **commercial** facility and as such should be made to comply with all the provisions that any other commercial facility would.

Concerning Section 12, **Requirements Related to Manifests.** We suggest that there be clear language requiring that the number of containers in any one shipment be stated.

Section 13.4 puzzles us in that a report is required only for the year of 1991. The information that such a report would present is continuously being supplied by the manifest system and it would not be difficult in this day of computer technology to prepare a report annually. This information is crucial in determining the need for commercial infectious medical waste facilities.

The previous draft of these regulations, dated April 22, 1991, had the following language: "**SPECIAL REVENUE ACCOUNT** - The funds collected from the fees applicable in this article shall be deposited in a special revenue account in the state treasury to be used by the director of the Department of Health and dedicated to the purposes of this article which include, but are not limited to, permitting, technical assistance, training, enforcement and program development for infectious medical waste." We would like to see this language retained in these regulations.

Concerning Table 64-56A **ANNUAL INFECTIOUS MEDICAL WASTE MANAGEMENT FACILITY PERMIT FEES**:

The fee for a Commercial Infectious Medical Waste Management Facility has been cut from $10,000 in the previous draft to $5,000 in the current draft. The fee for a Commercial Storage and Transfer Facility has been cut from $2,500 in the previous draft to $250 in the current draft. The fee for an Incinerator Operator Registration has been cut from $250 in the previous draft to $25 in the current draft. The previous fees did not seem

unreasonable to us. It seems that by reducing these fees by such drastic amounts these activities are being encouraged when they are in fact prohibited or discouraged in the Legislative Findings in the Medical Waste Act. It also seems to us that these substantial cuts in fees are paving the way for another of the underfunded and therefore ineffective regulatory programs that are so common in West Virginia. We recommend that the higher fees in the previous draft dated April 22, 1991 be reinstated.

As we mentioned before, we feel that the "Small Commercial Infectious Medical Waste Management Facility for Sharps Only" should be treated the same as any other Commercial Infectious Medical Waste Management Facility.

Sincerely,

Missy Woolverton

Tom Degen

ED'S ALL CLEAN DISPOSAL, INC.

P.O. Box 6488
Charleston, WV 25362

(304) 342-4827

1-800-345-4660
(In W.Va. outside Charleston)

Department of Health and Human Resources
Regulatory Development
Room 204 Building 3
Capitol Complex
Charleston, WV 25305
Attn: Kay Howard

Comments to draft rule Title, Infectious Medical Waste
CSR Title and Series 64 CSR 56.

Pg 13- 6.2.3.2 - this should read, All sharps rendered Non-Infectious should be placed in a sharps proof container before transporting off site for landfill disposal to protect the health of sanitation and landfill employees. Should one of these employees be injured by an accidental stick after exposure to bacteria in the trash truck or landfill the potential risk to the victim could be great with possible damages by litigation to the generator.

Designate a separate portion of the landfill for the disposal of treated medical waste in the event the following should occur.

1) Accidental disposal of non-treated waste
2) Accidental disposal of radio active waste
3) Making landfill employees more aware of possible dangers
4) Reduced clean up cost in the event of accidental disposal of non-treated waste

Monthly reporting to the West Virginia Department of Health by all transporters and all generators. This portion would verify that all generators and transporters are treating infectious waste in an environmental acceptable manner. Provide monthly volumes and disposal site and methods of disposal also providing a system of checks and balances. (see attached exhibit #1)

Any spill of 50 pounds of waste or more must be reported to the employer and the West Virginia Department of Health on a form provided by the Department of Health postmarked within two working days from the date of the spill. This should include all generator and all transporters. (see Attached exhibit #2)

64-56-12 Manifest

All manifest should be numbered in the upper right hand corner.

1) Tracking purposed - this number should be on every carton in a visible area in the event of co-mingled waste, an accident, discrepancies by generator or transporter. This is another means of check and balance, thus providing some protection for the generator.

ED'S ALL CLEAN DISPOSAL, INC.
P.O. Box 6488
Charleston, WV 25362

(304) 342-4827

1-800-345-4660
(In W.Va. outside Charleston)

2) Needed to be a part of the logging and reporting process
3) The transporter must retain photo copies of generator completed manifest and attached to copy #2. This would again provide another method of protection for the generator in the event of:
    1) generator losing the original
    2) destroyed by fire, flood, theft ect.

This should be maintained by the transporter for a period of three years.

Respectively submitted by
Ed's All Clean
PO Box 6324
Charleston, WV 25362

B.M.W. Med Tec
PO Box 275
Williamstown, WV 26187

By James Parks

Encl:ls/jp

Exhibit #1

Transporter

Transporter's Name _____ Phone # _____

Address _____

P.S.C. # _____ WV Dept. of Health # _____

Manifest #	Generator Name	PU date	Total weight	# Containers	Treatment method	Gen. permit	State Dispo
000260	Hosp. U.S.A.	7-3-91	1,920	99	Inc.	00023	N.C
000261	WV Hosp.	7-3-91	265	12	A/C	00091	W.V
000262	Dr. Joe	7-4-91	26	1	Inc.	N.A.	N.C

Signature of Employee Filing Report _____

Date Completed _____ for the month of _____

Note: A/C = Auto Clav
Inc = Incineration
O/M = Other method, explain on back.

Exhibit #1
Generator:

Generator's Name _____ Phone # _____

Address _____

Permit # _____

Transportation Method:

Transporter Name _____ Phone # _____

Address _____ P.S.C.# _____

_____ Dept of Health _____

Manifest #	Disposal Site	PU Date	Total weight	# Containers	Treatment Method	Competed manifes return
	30 LINES ARE NEEDED					

Month of _____ Total weight for month _____

Signature _____ Date _____

A/C = Auto-Clave
Inc = Incinerate
O/M = Other method Explain _____

_____

Exhibit #2
Spill Report (Generator and Transporter)
Enity Making Report

Reporting Date _____

Name _____ Phone # _____

Address _____ Permit # _____

_____

Location of spill _____

Date _____ Time _____

Employees Involved _____

Est. weight involved in clean up _____

If accident or spill on roadway complete:

Street or Rt # _____ Closest town _____

Est. mileage from city _____ County _____

Injuries or Exposure? Yes _____ No _____ Explain on reverse side

Name of investigating officer _____

Citations issued? Explain _____

_____

Name of driver _____

Number of contains involved _____

Manifest numbers _____

Explain containment procedures _____

_____

_____

Was this situation avoidable? _____

Corrective action taken _____

Signature _____ Date _____

HIMOLENE
A SUBSIDIARY OF FIRST BRANDS CORPORATION

RECEIVED
Sept. 30, 1991
OCT 0 1991
REGULATORY DEVELOPMENT SECTION

September 30, 1991

Ms. Kay Howard
Regulatory Development
Room 204, Building 3
Capitol Complex
Charleston, WV 25305

Dear Ms. Howard,

This letter is submitted as input on the proposed rule, Infectious Medical Waste, CSR Title and Series: 64 CSR 56. Himolene's comments pertain to paragraph 6.2.2 of the September 3, 1991 draft of the proposed rule.

In paragraph 6.2.2 it states "Infectious medical waste shall be contained and sealed on-site in leak-proof, plastic bags capable of passing the American Society for Testing and Materials drop weight test (ASTM-D-959-80) or, in three (3) mil plastic bag or containers with equivalent containment properties."

We have two suggested improvements to the above sentence, which will make the rule less ambiguous.

1. The proposed sentence does not state the "weight" which the ASTM drop weight test must pass in order to be acceptable. Other states which have used the ASTM drop weight test as a standard, such as Virginia, state the weight as 125 pounds. In the ASTM's wording a weight is not stated. The test procedures are the same for different applications, although the test procedures allow for different weights depending upon your needs. For a meaningful specification, we suggest you include a weight amount, i.e. "125 pounds" in the sentence between the words "Materials" and "drop".

2. The proposed sentence allows a three (3) mil plastic bag to be used as an alternative to a plastic bag which passes the ASTM test. We suggest that "any and all" plastic bags, regardless of thickness, be required to pass the same "performance test". Just because a plastic bag is 3 mil thick does not necessarily mean that it will pass the ASTM 125 pound drop weight test. Various manufacturers of 3 mil plastic bags may use different types of seals, resins, or blends of resins, which exhibit different strength properties for the same thickness. To ensure the containment of infectious waste, why not require all plastic bags to pass the same performance test?

Sincerely,

Robert L. Heustis

J. Edward Hamrick III
Joyce Marnik
John H. Martin
Laura Willis-Miller
[illegible]
Harold A. Taylor
BOARD MEMBERS

WEST VIRGINIA SOLID WASTE MANAGEMENT BOARD

[illegible]
Phone 304 [illegible] FAX 304 [illegible]-3936

[illegible]
GOVERNOR

George A. Chace, Sr.
EXECUTIVE DIRECTOR

September [illegible], 1991

Regulatory Development
Room 204, Building 3
Capitol Complex
Charleston, WV 25305
Attn: Kay Howard

Dear Sir or Madam:

I have recently read your proposed Title 64 Series 56 rules and have a few personal comments on them.

For section 64-56-3.9.1, I suggest the wording be changed to "For the purposes of this rule, infectious medical waste includes, but is not limited to, the following material:".

For section 64-56-5, I suggest the Infectious Medical Waste Management Plans include the location of the facility, source(s) of any waste handled, type(s) of infectious medical waste handled and that the plan be made available to state or local health officials upon request.

For section 64-56-7.1.5, I feel one hundred feet of boundary marking tape is insufficient for a vehicle. This would only rope off a twenty-five by twenty-five foot square. I suggest one hundred yards to be a more appropriate amount.

Other than these minor issues I feel these rules are very well done. I will be glad to see them become final so all parties involved will know the rules by which they must play.

Sincerely,

James E. "Jim" Hudson
Senior Planner

RECEIVED
SEP 1 . 1991
REGULATORY DEVELOPMENT SECTION

NEPHROLOGY ASSOCIATES, INC.
NEPHROLOGY, HYPERTENSION, INTERNAL MEDICINE

DERRICK L. LATOS, M.D., F.A.C.P.
MARION H. DREWS, JR., M.D.
T. GARY KENAMOND, M.D.

MEDICAL PARK PROFESSIONAL CENTER
WHEELING, WEST VIRGINIA 26003
TELEPHONE (304) 242-7751

September 18, 1991

Joseph P. Schuck, M.P.H., P.E., Director
Office of Environmental Health Services
State of West Virginia
Department of Health and Human Resources
1900 Kanawha Boulevard, East
Charleston, WV 25305

Dear Joe:

This letter contains my comments and concerns regarding the proposed Rule for Infectious Medical Waste. Specifically, section 3.9.3 includes several items which are excluded from considerations in the Rule. Previous drafts of the Rule contained language excluding medical tubing and devices. These items were initially included at my request during debate at the interim study meetings.

Most frequently, medical tubing and devices (hemo dialyzers, IV fluid bags/bottles, etc.) are used solely for administration of noninfectious fluids and for administration of medications. With increasing frequency, such therapy is being provided in physician's offices and other non-hospital settings. In addition, such medical tubing is frequently used in the home setting by patients themselves or by home health care workers. With rare exception, these devices are not contaminated by body fluids and should not be considered as infectious waste, but rather solid waste. While some of the tubing and bags may still contain liquid, this liquid is simply a solution of electrolytes and occasionally residual medication, and is by in large neither toxic nor infectious.

Requiring that these devices be considered infectious will pose an unreasonable and unnecessary burden for small quantity generators, especially physicians' offices. In a physician's office, for example, these empty bags and tubing may accumulate quickly and result in that physician exceeding the 50 pound limit that would qualify him/her to be considered as a small quantity waste generator.

I understand that the landfill operator would not be able to determine whether or not such devices were infectious. I think that any such device that does not appear to have gross contamination with blood can be reasonably considered noninfectious, and therefore could be handled simply as solid

waste. However, only the generator can establish this with proper certainty, since said generator would be aware of how the device was used and whether contamination had, in fact, occurred. It might, therefore, be suitable to require that the generator provide an attestation statement that all medical tubing and devices contained in a given solid waste container is deemed to be solid waste and not infectious. This attestation statement can be affixed to the label on the outside of the container.

Some tubing and devices may be infectious, however, and need to be handled as infectious waste. Examples would include bags that have contained blood or plasma for transfusion, drainage from body cavities such as chest or peritoneal fluid (including peritoneal dialysis bags), and used hemo dialyzers and blood tubing. Such devices may be rendered noninfectious by either the addition of hypochlorite solution or formalin, and could then be handled as solid waste. Alternatively, such contaminated devices could be handled as are other infectious wastes.

I respectfully request that the topic of medical devices and tubing be included in the Rule as an exclusion, with discussion as appropriate, to include the above specific circumstances.

My primary concern is to allow for proper handling of noninfectious, potentially high weight/volume materials as solid waste in order to avoid unnecessary financial burdens and penalties on small generators. On the other hand, it is important to recognize those specific circumstances in which these devices may be properly considered infectious.

Sincerely,

Derrick L. Latos M.D.

Derrick L. Latos, M.D.
Member
Legislative Interim Committee
on Medical Waste

DLL/lh

M.D. Industries, Inc.

3100 DUNDEE ROAD ■ SUITE 308 ■ PO BOX 1355 ■ NORTHBROOK ILLINOIS 60065-1355
708 498 1234
800 421 8372
FAX 708 498 2987
TELEX 9102407830

September 11
1 9 9 1

State of West Virginia
Dept. of Health & Human Resources
Regulatory Development Office
Room 204, Building 3, Capitol Complex
Charleston, West Virginia 25305

Attn: Ms. Kay Howard

Re: Proposed Infectious Medical Waste Rule

Dear Ms. Howard:

Thank you for sending me a copy of your above proposed new Rule, one we believe to be vastly improved compared to the legislation that has been in place until this time.

The covering memo (dated September 5) invited comments or suggestions. We would like to make a suggestion re: the detail in your Para 6.2.2. that addresses the strength requirement for bags used for Infectious Waste.

The wording in the proposed rule uses the yardstick of the Drop Weight Test, ASTM testing protocol D-959-80.

#1. We believe a far better yardstick than measuring the "burst strength" of a bag would be measuring the resistance to puncture, ASTM D-1709-85 - a requirement in many states already. Those states have uniformly elected to specify 165-grams as the resistance level minimum on this test.

#2. If the determination is to retain the Drop Weight Test above, we believe it necessary to specify a minimum level, rather than just list the testing protocol without that addition. In the one state (Virginia) where we're aware of this test being required, the 125-lb. level is specified.

We appreciate your solicitation of comments from folks such as us (we make the bags used in thousands of U.S. hospitals now), and hope the above is of some help. Don't hesitate contacting the writer on any questions.

Sincerely,

M. D. INDUSTRIES, Inc.

MARK H. BASKIN
Vice President

MHB/s

Medical SafeTec

September 16, 1991

Regulatory Development
Room 204, Building 3
Capitol Complex
Charleston, WV 25305

Attention: Kay Howard

Medical SafeTec is a manufacturer of infectious medical waste processing equipment located in Indianapolis IN. In addition to the manufacturing business of the company, Medical SafeTec operates a permitted medical waste processing facility in Indiana.

Medical SafeTec has two comments on the proposed Infectious Medical Waste Rule. The first comment relates to the lack of a physical destruction standard for steam treatment. The second comment concerns the requirement for an independent testing agency evaluation as part of the package for alternative technology applications.

The rules for the operation of steam treatment equipment do not include a standard for physical destruction of the treated waste. This is not consistent with standard of treatment detailed in the 1988 Medical Waste Tracking Act (MWTA) and the standard for incineration in the proposed rule. Steam treatment should be required to achieve a physically unrecognizable end product.

The MWTA lists a number of exclusions and exemptions from the requirements of tracking regulated medical waste. One of these exemptions is for incineration ash and treatment/destruction residue {Section 259.30(b)}. The destruction standard is described as "when the waste is ruined, torn apart, or mutilated so that it is no longer generally recognizable as medical waste" in the preamble.

The requirement to achieve an acceptable standard for physical destruction is also recognized in 10.2.5 of the proposed rule. The requirement that combustible waste no longer be recognizable in its preincineration form is appropriate for the end product of steam treatment also.

5610 West 82nd Street · Indianapolis, Indiana 46278 U.S.A.
Telephone (317) 879-8080 · Fax (317) 876-2669

The requirement for an evaluation report by an independent testing firm sets an appropriate standard, but is to narrow in the specification testing entities. This section should include the possibility for the independent tests to be completed by other qualified institutions. Examples would be government agencies (both foreign and domestic) or universities.

Medical SafeTec appreciates the opportunity to comment on the proposed regulations. I am at your disposal to provide clarification or further information on any of the points in this letter.

Sincerely:

William D. Farrington
Vice President

TEC

Monongalia
General
Hospital

September 25, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Blvd., East
Charleston, W. Va. 25305

Dear Ms. Howard,

After reviewing the draft of the Medical Waste Rule dated September 3, 1991, I offer the following comments:

My primary concern is that the Rule will severely over regulate medical infectious waste to the point that options for disposal will continue to diminish due to lack of space and environmental concerns. The Rule contains no provisions to encourage hospitals to band together to establish non-commercial regional infectious waste management facilities or for hospitals to share expensive alternative means of disposal (equipment) without meeting the requirements of commercial medical waste management facilities.

Tough emission restrictions and ash testing requirements discourage the use of on-site incinerators for waste disposal, even though there are no known infectious health hazards associated with properly operated incinerators. Incineration produces a sterile ash, there is no difference between bacteria in stock emissions and those in ambient air.

Although hospital on-site incinerators do generate a variety of chemicals, such as carbon monoxide, metals, dioxins, and furans, no health risks from their generation in this way have been demonstrated. As a result of the stringent rules for incinerator operation, regulated medical infectious waste will conceivably have to be transported out of the state for incineration, increasing the costs of disposal tremendously.

The proposed Medical Infectious Waste Rule has many similarities to The Medical Waste Tracking Act of 1988. The Medical Waste Tracking Act increased costs for disposing of medical infectious waste radically in participating states. The daily cost for regulated medical waste per patient increased from $1.04 to $5.19. This increase was largely the result of considering a larger portion of medical infectious waste and of the difference in cost between the disposal of non-regulated waste (i.e., $0.02 to $0.05 per pound) and regulated (i.e., $0.20 to $0.60 per pound) infectious waste.

In conclusion, I think that the proposed Infectious Medical Waste Rule further encourages the mismatch between science and policy.

The language in the Rule clearly implies that medical infectious waste poses a threat to human health and must therefore be strictly regulated. However, the alleged health hazards of our current medical-waste disposal have not been demonstrated. The potential for infection from medical-waste other than sharps is virtually nonexistent. All reports describing transmission of infectious agents by contaminated sharps have occurred in settings of occupational health care, and none, have been associated with environmental injuries occurring after the disposal of the waste outside the hospital. There is no epidemiologic evidence that hospital waste-disposal practices have caused disease in the community.

Thank you for giving me the opportunity to submit my comments. If I can be of any assistance in the future, please feel free to call me at (304) 598-1525.

Sincerely,

Sandy Friedman
Director of Environmental Services

cc: Gil DeLaura, VP/General Counsel WVHA

SF:dal

In most hospitals, angioplasty can be used successfully in only a small and select group of patients. This includes patients with iliac-artery stenoses, superficial femoral-artery stenoses, or short occlusions with vessels open distally to allow a good blood flow. Dilation of distal vessels may not be equally successful. Arterial occlusion is a complication of angioplasty that may require vascular surgery. During the past two decades, simpler vascular procedures that do not involve major surgery have become more common. A subcutaneous femoral–femoral graft to supply a limb with an obstructed iliac artery or an axillofemoral–femoral graft to bypass an aortic obstruction avoids major abdominal surgery. In patients with total occlusion of one iliac artery and a stenosis of the contralateral iliac artery, angioplasty may be used to dilate the stenosed artery. Then a femoral–femoral bypass can be performed to supply the limb distal to the obstructed iliac artery. Some patients may therefore undergo both angioplasty and vascular surgery. More surgery is being performed with grafts to distal calf vessels and even pedal arteries in an attempt to save ischemic limbs. Such procedures can be performed with success in patients considered to be at high risk from major surgery and are one reason for the increase in vascular operations.

The surprising finding in the study by Tunis et al.[1] is that the rate of amputation has not decreased despite the increase in bypass surgery and the advent of angioplasty. Although other studies have shown a decrease in the rate of amputation, they have been criticized for their small size. Each study, of course, represents the experience of one institution with an obvious interest and expertise in vascular surgery. However, the impressive earlier study by Veith and coworkers[11] included 2829 procedures performed over a 15-year period. Angioplasty, bypass surgery, or a combination of the two were performed in an attempt to save limbs with critical ischemia. The rate of major amputations decreased from 41 to 5 percent, and that of total amputations from 49 to 14 percent — a remarkable result. There were many reoperations after failed procedures, but this fact could be one key to the overall success rate. Unfortunately, the indications for angioplasty and bypass surgery were not given in the Maryland study.[1] If the patients included those with mild-to-moderate disease, limbs would not have been saved. In fact, complications resulting from intervention in these patients could lead to amputations. Tunis et al. do not report the sites of the angioplasty procedures. If more procedures were being performed distal to the inguinal ligament, as suggested by the increased age of the patients in 1989, the rates of failure and amputation may have been higher than before. Perhaps, in many of the hospitals, interventions were not being performed after failed procedures, as they were in the study of Veith et al.[11] The Maryland study included many institutions, although half the angioplasty procedures were performed in hospitals with large numbers of such procedures. High volume does not always translate into skill, however.

The absence of any decrease in the rate of amputation despite a large increase in the rate of vascular procedures is an important revelation of the Maryland study. The most likely explanation is that angioplasty and vascular surgery were being performed in patients for whom these procedures *were* not appropriate and in too many hospitals, rather than only in centers where expertise was greater. When problems occur in most hospitals, staff with the technical proficiency to perform complicated corrective surgical procedures may not be available. The availability of an expert vascular team at the center being studied is probably the primary reason, in addition to the careful selection of patients, that the smaller studies found a decrease in the rate of amputation. Unless the rate of amputation can be shown to decrease in a hospital, it is possible that neither angioplasty nor vascular surgery should be performed.

The treatment of patients with intermittent claudication alone should be conservative, because the prognosis for the limb is favorable, because surgical mortality from cardiovascular events is high among such patients, and because the use of interventions has not decreased the rate of amputation in many hospitals. Invasive procedures are indicated only for the severely ischemic limb and should be performed in an institution and by a team with a good track record.

Boston University Medical Center
Boston, MA 02118 JAY D. COFFMAN, M.D.

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SOUNDING BOARD

INFECTIOUS WASTE — Mismatch between Science and Policy

DISPOSAL of medical waste has emerged as a major problem in the United States. The problem was brought to public attention by recent episodes of

lated medical waste in sanitary landfills.[9] The evidence suggests that untreated medical waste can be disposed of safely in such landfills provided that procedures are used to prevent it from coming in contact with workers during disposal.[11] Studies demonstrate that pathogenic bacteria and viruses are significantly reduced in number in properly operated sanitary landfills because of such processes as thermal inactivation, antimicrobial characteristics of the leachate, and adsorption to organic material in solid waste.[15-17] Although on average municipal solid waste contains more microorganisms with pathogenic potential for humans than does medical waste,[18-22] there are no restrictions on the placement of municipal wastes into landfills. In any event, the use of sanitary landfills for medical-waste disposal is not a satisfactory long-term alternative, since one third of the remaining landfills will reach their capacity within the next five years.[23] Clearly, proper hospital-waste management must include methods to reduce the total output of waste and to recycle or reuse medical materials when feasible.

Paradoxically, although strict waste-tracking laws encourage on-site incineration,[2] tough emission restrictions are discouraging the use of this form of waste disposal,[8] even though there are no known infectious health hazards associated with properly operated incinerators. Incineration produces a sterile ash,[24,25] there is no difference between bacteria in stack emissions and those in ambient air,[26] and when *Bacillus subtilis*, for example, is mixed with waste, it is inactivated.[27]

Although hospital and municipal waste incinerators generate a variety of chemicals, such as carbon monoxide, metals, dioxins, and furans,[28-30] no health risks from their generation in this way have been demonstrated. Nonetheless, public health anxieties about the chemical emissions from incinerators mandate further investigation and the subsequent development of scientifically based emission standards. Currently, statewide moratoriums, stringent rules, and requirements for permits restrict hospitals from using incinerators even if they have already been installed. As a consequence, regulated medical wastes are sometimes transported long distances to regional incinerators, increasing the costs of disposal.

The Medical Waste Tracking Act of 1988

The beach wash-ups and resultant beach closings brought pressure on state and federal legislators to prevent future closings, and several states issued strict emergency regulations. The Medical Waste Tracking Act was pushed rapidly through Congress in October 1988 and signed into law on November 1. It directed the EPA to begin a two-year pilot program on the disposal of infectious waste. Although the act expired on June 22, 1991, and affected only four states (New York, New Jersey, Connecticut, and Rhode Island) and the commonwealth of Puerto Rico, it is likely that it or similar legislation will be included in the reauthorization of the Resource Conservation and Recovery Act in 1992 and will be extended to all the states. Under the tracking plan, health care providers (physicians, dentists, veterinarians, small clinics, laboratories, and hospitals) that generate more than 50 lb of regulated medical waste per month are required to maintain detailed records that track such wastes from point of origin to final disposal. At present, the EPA has exempted providers that generate less than 50 lb per month from the full tracking requirements of the act, but not from other requirements for disposal and treatment. Those that do not comply are subject to civil penalties of up to $25,000 per day and criminal penalties of up to $50,000 per day for each violation and a maximal penalty of five years in prison.[2]

The passage of this law was opposed by the CDC, the Association for Practitioners of Infection Control, and the National Institutes of Health, all of which testified that medical waste generated in traditional health care settings posed no hazard to the general public, although it was an occupational health concern.[31] The same conclusion was reached by the Agency for Toxic Substances and Disease Registry of the Department of Health and Human Services, which presented a report to Congress in September 1990.[11]

If regulatory control were based on epidemiologic and microbiologic data, only two types of medical waste would require special handling and treatment — sharps and microbiologic waste.[32] Such an approach should be the basis for a uniform definition of regulated medical waste, which could be monitored by appropriate accrediting agencies, such as the Joint Commission for the Accreditation of Health Care Organizations or the State Division of Facility Services, during their periodic reviews.

The Discrepancy between Science and Policy

Governmental regulations are intended to protect the public health and limit the degradation of the environment by medical waste. It is extremely unlikely, however, that the Medical Waste Tracking Act will have any effect on the public health or prevent medical debris from washing up on public beaches, for several reasons.

First, three detailed reports of beach wash-ups found that about 99 percent of the waste on beaches was debris such as wood, plastics, and paper, not medical waste.[33-35] Despite extensive investigations, the washed-up materials could not be traced to illegal dumping or to a specific source, such as a hospital, but were related more directly to malfunctioning sewage-treatment systems and prevailing winds and currents.[2,33] EPA officials acknowledged that some 65 percent of the medical waste that washed ashore in the summer of 1988 was related to syringes and was from use in home health care or intravenous drug abuse. Chemical analysis identified insulin or cocaine in three of five syringes collected during the EPA Harbor Studies Program.[2,34,36] Even though a single syringe on a beach is one too many, the Medical Waste Tracking Act will not prevent an occasional appearance, because waste from home health care and intravenous drug users is not regulated. Thus, the amount

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CORRESPONDENCE

UNTOWARD EFFECTS OF GAS MASKS DURING PERSIAN GULF WAR

To the Editor: During the recent Persian Gulf war, there were 18 missile attacks from western Iraq on scattered areas in Israel. The fear of chemical warheads resulted in the preventive use of gas masks by the Israeli population for variable periods after each alarm. We would like to report some of the medical complications that were associated with the wearing of gas masks.

Seven people were reported to have died of asphyxia because of their failure to remove the protective plastic seal on the gas-mask filter. Lesser degrees of transient hypoxia were noted, especially in persons with cardiopulmonary disorders. In some cases, the initial symptoms of hypoxia were erroneously interpreted by the victims as manifestations of gas poisoning and resulted in self-injections of atropine.

An 84-year-old man was admitted because of syncope that occurred repeatedly several minutes after he put on the gas mask. An extensive workup disclosed a severe stenosis (more than 85 percent) of both internal carotid arteries. Recurrent transient cerebral hypoxia in this patient resulted from compression of the stenotic carotid arteries by the lower pair of rubber straps of the gas mask.

A purpuric rash developed over the chin of a healthy 50-year-old physician 10 minutes after the removal of the gas mask, gradually disappearing within 48 hours. This "suction purpura" probably resulted from the vacuum induced by the well-sealed mask, causing extravasation of erythrocytes into the skin. Additional dermatologic complications noted in other people included recurrent facial contact urticaria and dermatographism.

The medical community should be aware of the possible side effects of the use of gas masks, ranging from minor and transient to severe and sometimes even fatal.

DAVID HUMMER, M.D., SILVIO D. PITLIK, M.D.,
ABRAHAM KATZ, M.D., ARYEH METZKER, M.D.,
AND MICHAEL DAVID, M.D.
Petah Tikvah 49 100, Israel — Beilinson Medical Center

To the Editor: An eight-year-old girl with adult-type Gaucher's disease presented at our clinic with facial purpura of acute onset. There was no history of viral illness, exposure to drugs, or similar

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Putnam General Hospital

HCA The Healthcare Company

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FAX (304) 757-0710

October 2, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Dear Ms. Howard:

SUBJECT: Proposed Infectious Medical Waste Rule

Providing for healthcare needs of area residents is a primary concern of Putnam General Hospital. Our goal is to provide a reasonably secure environment in which to facilitate the care of area residents. Meeting the needs and expectations of our customers in today's market place is very challenging.

A detailed review of the proposed legislative rule relative to infectious medical waste illustrates the complexity of providing a reasonably secure environment in which to provide healthcare. A quick plunge into the pool of infectious wastes' ever changing technologies could cause irreversible fiscal damage to small and rural hospitals. Therefore, I would like to express the importance of granting waivers on incinerator permits as addressed in Section 10.2.7. Obtaining such a waiver would be vital to our facility in being able to implement the proposed rulings within fiscal constraints and to assure prompt disposal of infectious wastes. Small hospitals would need time to assess all options available to meet their needs for disposal of infectious wastes and to explore new technologies available for incineration. Compliance to the ruling could then be viewed as a benefit to the hospital and to the general public, and not as an unavoidable burden.

I hope that my comments will be considered before making a final decision concerning the proposed infectious medical waste rule.

Sincerely,

Lyndon Jones
Chief Engineer

LJ:pbs

Kenneth M. Holt
President/Chief Executive Officer

HCA Raleigh General Hospital

October 1, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Dear Ms. Howard:

After an indepth review of the proposed Infectious Medical Waste Rules, I would like to submit the following comments for the record.

Hospitals which are located in geographically close proximity will, most likely, be unable to work cooperatively in the disposal of infectious wastes under the new Rules without establishing a commercial infectious waste management facility. The Rules define this facility as "Any infectious waste management facility at which thirty-five (35%) or more by weight ..... is generated off-site."

The Rules as written will require very costly proof to demonstrate that there is "no reasonable probability" of damage to wetlands, etc. In addition, in attempting to establish a commercial facility, numerous public hearings would be required affecting multiple groups, not only the Department of Health, in the commercial permitting process.

While the public health and safety is of great and ultimate concern to all parties, the Rules should allow more flexibility in the development of alternative forms of waste disposal by hospital groups including incineration and other cooperative initiatives.

A second concern involves the cost of compliance with the Rules relating to incineration. Recent cost projections have indicated that in order to comply with the incineration regulations, facilities may require an investment of over $300,000 to upgrade existing incinerators. This may involve additional equipment

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A Subsidiary of HCA The Healthcare Company

for the one second retention time burn, scrubbers to remove carbon, dioxins, etc., and automatic loaders to achieve the specifications of Section 10.2.2. Achieving the permissible levels of carbons and dioxins may in fact be impossible.

Additional monies may also be required to upgrade existing incinerators in order to reduce the wastes to ash form which is non-recognizable from its original form. Many hospitals may find it difficult if not impossible to upgrade their existing incinerators to meet these requirements. Their alternative is to install new incinerators which will meet regulations, but only at a high or prohibitive cost. The added cost of registration, required training and licensure will undoubtedly force many hospital to seek other alternatives.

This leads to my final statements regarding the new regulations. Cooperative arrangements among hospitals are not encouraged and the development of commercial facilities and compliance with incinerator regulations are both costly or prohibitive under the new Rules. Other than steam treatment, the only other alternative for disposal of infectious wastes is apparently through the use of established commercial facilities approved for infectious wastes.

With the closure of all but thirteen approved landfills in the State of West Virginia, our organization would or will be faced with monthly solid waste removal fees being tripled to over $10,000. In addition, we have estimated that to send our infectious waste to a commercial facility would cost an added $18,500 per month or over $222,000 per year in new costs. These costs undoubtedly would need to be passed on to our patients in increased charges if so allowed by HCCRA. With the ever increasing rules and regulations regarding employee and patient safety and universal precautions, just to cite two examples, infectious waste products will most likely continue to increase in hospitals and other healthcare settings. Thus, the true cost of these new Rules will be enormous.

In summation, while the new Rules are intended to and will enhance the public health and safety, their impact on the increase of overall costs to the healthcare industry must be reevaluated. More flexibility should be written into the Rules for cooperative arrangements to be developed among groups of hospitals and/or other

healthcare providers. Compliance factors for incinerators should also be reconsidered in view of the lack of less costly alternatives as cited in the use of established commercial facilities. And finally, additional disposal sites should be approved and/or regulation of disposal fees instituted.

Thank you for the opportunity to comment on the proposed Infectious Waste Rules.

Sincerely,

Phillip M. Zsoldos

Phillip M. Zsoldos
Assistant Administrator

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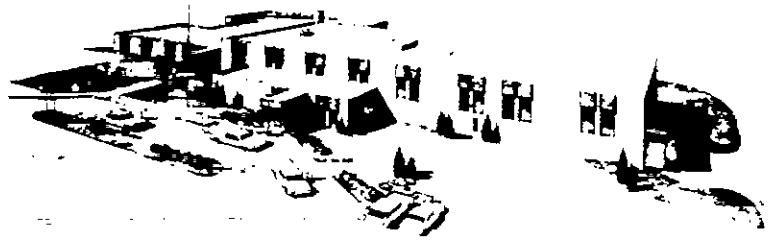

September 25, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard East
Charleston, WV 25305

Dear Ms. Howard:

I am writing to comment on the proposed infectious medical waste rule (series 56).

West Virginia has needed a law dealing with infectious waste in order to provide for appropriate and consistent handling of infectious medical waste. The Division of Health has recently taken on a big job in developing the legislative rule. I applaud them for soliciting information and opinions from the various parties that will be affected by the rule. I am glad that the definitions for infectious medical waste have remained consistent with the Centers for Disease Control categories. I also appreciate the specific definition of "isolation waste" to be those generated from the care of a patient with a "Class IV" disease as classified by the Centers for Disease Control. This will reduce confusion in light of "universal precautions" in place in most hospitals now.

It is too bad, however, that incineration becomes practically impossible for individual hospitals. The Centers for Disease Control still recommends incineration for treatment of infectious waste. Complying with the standards, testing, etc. will make incineration unaffordable. Provision should be made for hospitals that choose to go together to dispose of waste. Going together can make a process more affordable, but it should not be considered commercial since the commercial requirements are much too diffcult to fulfill. Considering such an endeavor commercial seems especially inconsistent when House Bill 2141 encourages "treatment and disposal of infectious medical waste in local infectious medical waste management facilities;" and "Treatment and disposal in approved regional infectious waste management facilities when administrative proceedings result in a finding that on-site or local treatment of infectious medical waste is not feasible".

My facility will probably be forced to deal with a hauler which will take our infectious waste out of state. This does not seem compatible with the intent of the legislature.

I would also comment that the annual $1750.00 fee for an 80 bed hospital is excessive. Small hospitals are already hard pressed to meet their financial demands, especially since they are unable to pass on any of that burden.

Thank you for your consideration and for the opportunity to make comments.

Sincerely,
Martha Hardman
Martha Hardman, BSMT (ASCP), CIC
Infection Control Coordinator

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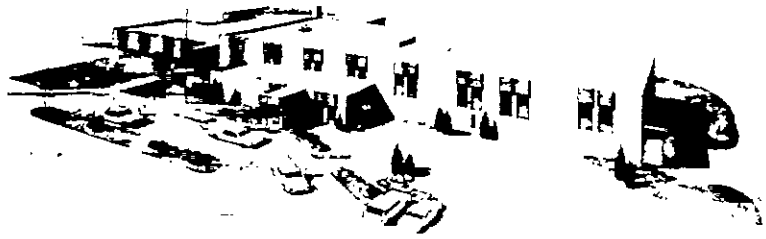

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September 26, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Dear Ms. Howard:

Regarding the Proposed Infectious Medical Waste Rule, I would like to comment that we feel West Virginia is in need of a law governing the matter of infectious waste and we appreciate the opportunity to voice our opinions which will have a direct affect on our facility.

As stated in the CEO Bulletin dated September 6, 1991, I would like to state some issues which we feel would provide a hardship to our hospital and/or other items we feel should be considered:

1) OPERATION OF AN INCINERATOR -- Roane General Hospital is operating an incinerator that is only five (5) years old and is air pollution control approved. Under the proposed Medical Waste Rule, our incinerator will be shut down. I have been told that it cannot be updated to meet the standards.

2) COMMENT ON INFECTIOUS MEDICAL WASTE -- It was my understanding that there was going to be a provision made for hospitals who wanted to go together and install a central incinerator, they could. The way it is now, they fall under the Commercial Plan, which the Proposed Commercial Plan is <u>extremely</u> hard to meet in the State of West Virginia.

3) COMMENT ON TESTING ASH -- Ash test will not change from one month to another; therefore, is there any need for this test monthly? This would make an unnecessary burden on facilities such as ours.

I would like to take this opportunity to thank you for your consideration and appreciate the opportunity to express my comments.

Sincerely,

Ronald Bartlett

Ronald Bartlett
Maintenance Engineer

RB/bk

Rt. 3, Box 25
Ivydale, WV 2511
286-2204

September 12, 1991

REGULATORY DEVELOPMENT
Room 204, Building 3
Capitol Complex
Charleston, WV 25305
Attn: Kay Howard

Please see that the following comments are included in the Infectious Medical Waste Rule #56, prior to being issued into law by the Secretary of State.

Page 7, Para. 3.17:
Delete the last sentence.
This does not agree with the definition of a "site"

Page 8, Para. 4.4.2:
Rewrite as follows:
"The name, address, and telephone number of all owners of the facility;"

Page 10,Para. 4.14:
Second sentence: Delete entirely
Third sentence: Delete the second word "major"

Page 11, Para. 5.3.2:
Delete word: "knowingly".

Page 11, Para. 5.3.3:
Delete word: "knowingly".

Page 18, Para. 9.3.2:
Delete words: "knowingly and routinely".
Page 22, Para. 10.2.7:
Second sentence: Change "three" to, "two", to be consistent with other requirements of this rule.

Page 24, Para.10.5.2: Rewrite Paragraph to read as follows:
"The secretary will issue provisional approval for ANY alternate method for an appropriate test trial period to validate performance. This test shall be conducted in a controlled atmosphere where it will affect the least number of people, and be under close supervision of the secretary. Alternate methods employing disinfection must have the disinfectant registered for that purpose in accordance with federal Insecticide, Fungicide, and Rodenticide Act as amended. If the test of the process fails to provide adequate treatment when operated according to manufacturer's instructions, the provisional approval shall be revoked."

Page 29, Para. 14.2:
Rewrite sentence 1 to add between, "necessary" and, "to" the following: ", but at least every three(3) years,".

Page 36, Item F:
Rewrite as follows:
"F. Non-commercial incinerator operator registration 25.00".
Thanks for the opportunity to comment.

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WRITER'S DIRECT DIAL NO.

340-1355

October 2, 1991

Joseph P. Schock, M.P.H., P.E.,
Director
Office of Environmental Health Services
1900 Kanawha Boulevard, East
Building 3, Room 550
Charleston, WV 25305

Re: Proposed West Virginia Infectious Medical Waste Regulations - 64 CSR §56 - et seq.

Dear Mr. Schock:

The following comments are filed on behalf of Strategic Environmental Services, Inc. ("SES"), a West Virginia corporation involved in the promotion, sale and operation of infectious medical waste technologies as an alternative to incineration. SES offers the following proposed revised regulatory language which is intended to lessen the impact of the "commercial infectious medical waste facility" restrictions inherent in the present version of the draft rule, on the amount of infectious medical waste that a hospital may receive and process from other health care facilities in its locality. The current proposed regulatory language is very restrictive and will prevent hospitals from agreeing with one another, as well as the doctors and other health care facilities served in their area, to jointly manage their infectious waste. The cost of requiring each individual hospital and health care facility in an area to have full facilities for treating infectious medical waste, whether such treatment is by incineration or an alternative technology, will pose a tremendous financial burden on the hospitals and other health care facilities in the State.

While it is the policy of the West Virginia Medical Waste Act [W. Va. Code §20-5J-2] to "prohibit commercial infectious waste management facilities," it is also the stated policy of the Act to encourage "treatment and disposal of infectious medical waste in local infectious waste management facilities," "local responsibility for the minimization management and disposal of infectious and non-infectious waste," and to provide for both the "safe and economical management" of infectious waste. Regardless of whether the infectious medical waste technology is traditional incineration or an alternative treatment method, any method of properly managing infectious medical waste is extremely expensive, and

Rec'd. 10/3/91

> infectious medical waste stored, treated, or disposed of by said facility in any calendar year is generated off-site. [W. Va. Code §20-5J-3(1)]

The WV MWA further provides that:

> 'Off-site' means a facility or area for the collection, storage, transfer, processing, treatment or disposal of infectious medical waste that is not on the generators site, or a facility or area that received infectious medical waste for storage or treatment that has not been generated on-site.
>
> 'On-site' means the same or geographically contiguous property which may be divided by a public or private right-of-way, provided the entrance and exit between the properties is at a cross-roads intersection, and access is by crossing, as opposed to going along, the right-of-way. Noncontagious properties owned by the same person, but connected by a right-of-way controlled by said person and to which the public does not have access, is also considered on-site property. Hospitals with more than one facility located in the same county shall be considered one site. [W. Va. Code §20-5J-3(9) & (10)]

There are three possible infectious medical waste regulatory provisions that will aid in providing flexibility for local and/or regional medical infectious waste facilities as mandated by the legislative policy of W. Va. Code §20-5J-2 for treatment and disposal of infectious medical waste in local infectious waste management facilities in a safe and cost-effective manner:

1. In calculating the "thirty-five percent" cut-off for a commercial infectious waste facility, any medical waste generated by small quantity generators (generation of medical waste of less than fifty pounds during one month; i.e., most doctors' and dentists' offices would not be included in the 35% volume when such waste is managed by an infectious waste facility associated with a hospital. Any waste generated by a hospital with related facilities, i.e., facilities which are

if each individual hospital must, pursuant to the regulations, manage and treat only its waste plus 35% additional volume, virtually every hospital in the State will be required to have their own individual medical waste management facility which will be cost prohibitive.

As background and support for the revisions discussed herein, it is relevant to consider the definition of "commercial facility" as that term is utilized in both the West Virginia Solid Waste Management Act ("WV SWMA") and the Hazardous Waste Management Act ("WV HWMA"). Similar to the West Virginia Medical Waste Act ("WV MWA"), both the WV SWMA and the WV HWMA prohibit the establishment of the "commercial facilities" unless stringent local approval is obtained. Similarly, the Acts, like the WV WMA, promote local and regional handling of waste. Both the WV SWMA and the WV HWMA allow generators of waste to agree to utilize a single facility for the environmentally sound and economically reasonable management of their waste so long as the waste generators are sharing costs in the utilization of the facility and are not individually obtaining a profit from waste management activities. The term "commercial facility" in both the WV SWMA and the WV HWMA is defined as follows:

> 'Commercial solid waste facility' means any solid waste facility which accepts solid waste generated by sources other than the owner or operator of the facility and shall not include an approved solid waste facility owned and operated by a person for the sole purpose of disposing of solid wastes created by that person or such person and other persons on a cost-sharing or nonprofit basis . . . . W. Va. Code §20-5F-2(c) (WV SWMA); W. Va. Code §20-9-2 (West Virginia County and Regional Solid Waste Authority Act); W. Va. Code §20-10-2 (West Virginia Commercial Hazardous Management Facilities Siding Board).

In contrast to the definition of "commercial facility" set forth in the WV SWMA and WV HWMA, the WV MWA provides:

> 'Commercial infectious medical waste facility' means any infectious medical waste management facility at which thirty-five percent or more by weight of the total

is at a cross-roads intersection, and access is by crossing, as opposed to going along, the right-of-way. Noncontagious properties owned by the same person, but connected by a right-of-way controlled by said person and to which the public does not have access, is also considered on-site property. Hospitals with more than one facility located in the same county shall be considered one site, and facilities owned by a person generating infectious waste or such person and other persons generating infectious waste who agree to utilize a facility on a cost-sharing or nonprofit basis is also considered one site. (Underlined language is added to existing definition.)

The foregoing alternatives are certainly not preclusive of one another. A combination of all three would provided needed flexibility for hospitals and effect the statutory mandate for local facilities.

Very truly yours,

Barbara D. Little

BARBARA D. LITTLE
JACKSON & KELLY
as counsel to
Strategic Environmental
Services, Inc.

BDL/efb

subsidiaries, divisions or affiliates of a hospital, including medical office buildings, emergency-care, outpatient facilities, etc., would also be excluded in calculating the 35% volume. The current proposed definition of "on-site" allows hospitals with more than one facility located in the same county to be considered as one site. This provision is problematic when two small hospitals which may be under common ownership or affiliated are in separate counties. For instance, Jackson County Hospital and Roane County Hospital are approximately 32 miles apart, but under the current proposal, these hospitals could not share an infectious waste management facility.

2. The definition of "hospital" could be revised to take advantage of the "on-site" definition by allowing hospitals which are affiliated with one another by ownership, operational control or agreement to be considered as one site. As revised, a "hospital" could be defined as:

> An institution or group of institutions which have entered into a cooperative agreement or affiliation for waste management, which is (are) primarily engaged in providing in-patient care, by or under the supervision of physicians, diagnostic and therapeutic services . . . (no change in the balance of the definition).

Additionally, to allow small hospitals in adjacent counties to agree to jointly share cost-effective medical waste management facilities, the last sentence of §3.17 should be revised to read:

> "Hospitals with more than one (1) affiliated facility shall be considered one(1) site."

3. Another option for possible regulatory change is to revise the regulatory definition of "on-site," [to include language similar to the exemptions provided in the WV SWMA and WV HWMA which allow for "cost sharing of a waste disposal facility among waste generating companies] as follows:

> 'On-site' - the same or geographically contiguous property which may be divided by a public or private right-of-way, provided the entrance and exit between the properties

suggest that arrangements be included to allow small generators to group resources together so as to be able to afford the latest technology and equipment to be used without having to file as a commercial facility. This would seem reasonable from a cost stand point.

S64-56-122 Manifest Requirements

This section seems to be directed toward commercial haulers moving through various areas. I would suggest that small generators with a "given area" be allowed to transport quantities greater than 50 lbs. per month to a non commercial facility without this requirement. This would allow small generators like nursing homes and clinics to operate under the same procedures that the larger facilities (i.e., CAMC and WV Medical Facilities) are allowed to do.

S64-56-6.2.4 Packaging

I question the requirement that all red and orange bags be imprinted with the biohazard symbol and the words "Infectious Medical Waste". AS a small generator, our costs are determined by the quantity of an item purchased. I see very little, if any, benefit arrived from this requirement as long as the bags are not allowed to leave the facility. All medical employees are taught that a red bag is specific in its use.

I thank you for this opportunity to comment on this draft and hope my thoughts, along with other small generators, will be considered.

Sincerely,

James E. Rucker
Manager Plant Operations

SMH SUMMERSVILLE MEMORIAL HOSPITAL
400 Fairview Heights Road • Summersville, West Virginia 26651 • 872-2891

September 30, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, WV 25301

Re: Infectious Medical Waste Proposed New Rule #56, Title #64

Dear Ms. Howard:

In reviewing the latest draft of the proposed infectious medical waste rule, I would like to make the following observations:

S64-56-1 Section 1.1 Preamble

With the continuous advances in incineration technology, I believe the statement about medical waste incinerators being an important public health hazard to be too strong. Public broadcasting stations ran a program on the latest technology and used a plant in Japan as an advanced model of incineration. The comment was made in this program that the stack discharge air was cleaner than the combustion air entering the firebox.

I have no quarrel with the remainder of the preamble. However, I strongly recommend that the Health Department become involved in the recycling program by originating a list of outlets for the solid waste which is generated.

S64-56-3 Section 3.14 Definitions

This section defines a non-commercial infectious medical waste facility as being limited to accepting no more than 35% by weight medical waste generated off site. Under 3.17 there is an explanation of on site which allows hospitals with more than one facility in the same county to combine their waste without this restriction. I view this rule as a hindrance for small hospitals and strongly

client's TraceCart, also be considered as a container with equivalent containment properties. In addition, 6.2.2 indicates that heavier materials must be supported in double wall, corrugated, fiberboard boxes or equivalent rigid containers. Does the terminology, "equivalent rigid containers" address itself only to fiberboard type containers or may rigid plastic containers (polyethylene - polystyrene), such as the "TraceCart," meet the standard.

Again, we would suggest that the TraceCart represents something, if not state of the art, very close to state of the art containment facilities for both sharps and non-sharps, and that our client's product should be considered in that manner.

Enclosed you will find brochures describing the TraceCart as well as material data safety sheets and test results which relate to the Tracecart's structural soundness as well as the results from testing the residue and emissions from incineration.

It is our intention to make an oral presentation at the hearing on October 3, 1991, and to demonstrate and leave for your Department's consideration, the actual product.

If you have any questions or desire any further information concerning our product, please do not hesitate to contact us.

Very truly yours,

Jon G. Roach

JGR:mvl

Enclosures

Received 9/13/91

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October 3, 1991

Mr. Joseph A. Wyatt
Chief
Infectious Medical Wastes Program
Public Health Sanitation Division
Bureau of Public Health
Department of Health and Human Resources
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Re: TraceCart, Product of Qualtex Division of DeRoyal Industries, Inc.

Dear Mr. Wyatt:

We are in receipt of your memorandum dated September 5, 1991, regarding the proposed Infectious Medical Waste Rule currently being proposed and scheduled for a hearing on October 3, 1991, at 10:00 A.M. in Charleston, West Virginia.

We have previously corresponded with you setting forth our concern relative to the regulations which at that time you were in the process of developing. We understand that the proposed regulations being considered for public hearing on October 3, 1991, are the product of your efforts to date.

Our comments will be directed to the provisions of Section 64-56-6, specifically 6.2, as it relates to packaging.

Our product, the TraceCart, will meet the requirements of 6.2.3 which relates to sharps. Our container is rigid, leak-proof and puncture resistant and is designed to be clearly marked a container of infectious medical waste. We believe that a product which will meet the requirements of 6.2.3 should also be considered to meet the provisions of 6.2.2, which addresses itself to infectious medical waste. The issue which we raise as to 6.2.2 may simply be one of clarification. It is not clear to us what the term "containers with equivalent containment properties" means. Is it intended to state that containers must be ones that are plastic bags or completely flexible like a plastic bag and meeting the ASTM-D-959-80 test or might a rigid container, such as our

In the interest of all members of our community, we advise that the definition of infectious waste be reviewed and revised to include body fluids due to the potential to contact HIV, HBV or other pathogenic organisms from this source.

This will not pose any hardship to hospitals because blood and body fluids are already classified as potentially infectious.

Sincerely,

Susan Colpo RN, BSN

Susan Colpo, RN, BSN
Infection Control Nurse

Kevin Davis
Safety Coordinator

References:
CDC, Recommendations for prevention of HIV transmission in health care settings. MMWR 1987; 36 (Suppl. No 2S): 1-18S.

OSHA Instruction CPL 2-2.44B, US Department of Labor, Feb. 27, 1990.

SC/jas

CENTER

September 30, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Dear Ms. Howard,

Upon review of the Department of Health Proposed Infectious Medical Waste Rule (CSR Title 64, Series 56) the following concerns were discussed:

> The definition of infectious medical waste (64-56-3) leaves the interpreter with many ambivalent descriptions to decipher.
>
> "Definition of infectious medical waste - considered capable of producing an infectious disease if it has been, or is likely to have been, contaminated by an organism likely to be pathogenic to healthy humans, if such organism is not routinely and freely available in the community, and such organism has a significant probability of being present in sufficient quantities and with sufficient evidence to transmit disease."

This proposal has eliminated body fluids in all definitions and descriptions of infectious waste. The Centers of Disease Control (CDC) advises adherence to the principles of universal precautions. Universal precautions classifies body fluids as potentially infectious. In addition, the Occupational Safety and Health Administration (OSHA) considers possible exposure to Human Immunodeficiency Virus (HIV) Hepatitis B Virus (HBV) to occur through contact with blood or body fluids.

The hospital's Infection Control Programs and Safety Programs are required to comply with OSHA and JCAHO and CDC standards. The policies, procedures and practices are actively in place identifying all blood and body fluids as potentially infectious. If this definition is eliminated from the rule, we have ignored the impact that this might have on our public and environmental community, especially when area landfills begin to accept waste from out of state or less strict health care facilities.

Essentially, regulatory requirements which are not mandated by the statute but are left to the discretion of the Department should meet two fundamental tests:

- o The requirements should respond to actual health risks
- o The action prescribed by the Department should be reasonably effective in reducing risk.

Proposed rules which increase the amount of regulatory compliance without a corresponding clear benefit to the public health should be avoided.

Such an example is found in the transportation section of the proposed rule at 9.7 et seq. This section requires that vehicles which transport infectious medical waste shall be cleaned and disinfected following leakage or spills in the manner prescribed in section 6.8.3: swabbing or rinsing with a chemical sanitizer double the strength of hypochlorite solution of one hundred parts per million available chlorine; iodoform solution of 25 parts per million available iodine or quaternary ammonium solution of two hundred parts per million active agent. The rule continues that the vehicle shall also be cleaned and disinfected prior to using the conveyance for any other purpose via the above standards. What is not reasonable is the proscription immediately following at 9.7.5, that the vehicle:

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

Thus, even if a vehicle is properly disinfected after transporting of infectious medical waste in accord with standards set by the Department, it cannot be used to transport foodstuffs. It is suggested that this requirement from a public health perspective is illogical and unnecessarily burdensome.

This conclusion is especially true in light of requirements that infectious waste transported by a hospital must be packaged in accordance with standards listed in section 6.2 of the rule which requires, among other things, "double wall corrugated fiberboard boxes or equivalent wooden containers" (6.2.5).

The risk of infection, taking all of these factors into consideration, is minimal. The public health benefit is illusionary at best.

Thus, the blanket restriction serves no appropriate purpose. Inclusion by the Department will simply increase hospital costs for a questionable rationale.

The impact of this requirement in some instances is that hospitals, particularly in rural areas which of necessity must use vehicles for multiple purposes, are faced with a needless and unnecessary restriction. The rule assumes a problem of a significant risk of infection where one does not exist. For all of the above reasons, the requirement at section 9.7.5 should be eliminated and left to the discretion of the individual hospital.

WVHA
West Virginia Hospital Association

October 3, 1991

Ms. Kay Howard
Director
Regulatory Development Section
Department of Health
Room 204, Building 3
The Capitol
Charleston, West Virginia 25305

Re: Proposed 64 CSR 56
Infectious Medical Waste

Dear Ms. Howard:

The West Virginia Hospital Association (hereinafter, "WVHA" or "the Association"), wishes to commend the Department of Health and Human Resources (hereinafter, "DOH" or "the Department") for affording opportunity for written comment relating to the proposed Infectious Medical Waste Rule following enactment of HB 2141.

The Association would be remiss if it did not comment on the constructive and positive efforts of the Department in the major challenge it faces in implementing the Medical Waste Act. We wish to express our appreciation for the patience and dedication consistently exhibited by the Department since the passage of infectious waste legislation.

Prior to articulation of our specific recommendations and supporting rationale, a threshold explanation of the general position of the Association may be helpful to provide a reference point from which our reactions to these proposed rules are framed. West Virginia hospitals have a commonality of interest with the Department in protecting the health and safety of health care workers, hospital staff and the patients we serve. Proper management of infectious wastes in order to prevent transmission of communicable disease is part of our joint concern. Thus, the Association supports the Department in its effort to devise and formulate sound public health measures, within the requirements of the Medical Waste Act.

The Association recognizes that hospitals, as well as other infectious waste generators, have a responsibility to our communities to dispose of infectious waste in a manner which decreases risk of injury and attempts to prevent infection in those instances of known risk. State government, however, also has a corresponding obligation.

Received
10/3/91

> Department within fifteen days of any changes to its plan. An application for approval of any change in the plan which is beyond the control of the permittee shall be submitted within fifteen days of its occurrence.

Additionally, section 5.6 of the rule should be changed to reflect the flexibility in redrafted section 4.4.

An infectious waste management plan should provide the Department with a reasonably accurate but flexible guide to the management of infectious wastes in an acute patient care facility. It should not be a rigid lock step plan from which major deviations are not permitted without prior approval of the secretary or her designee.

A second aspect of the plan which should be clarified occurs at section 5.2.8 which sets out a certification requirement. It is assumed that certification of personnel in a hospital setting refers to those personnel involved in the final treatment of infectious waste and employees involved in transportation, 9.10.8 e.g. the American Hospital Association has developed an extensive training program for medical waste and small volume waste incinerators. It is further assumed that section 5.2.8 does not involve required certification of each and every RN, LPN, MD, houseman, etc. that may be in the presence of infectious waste.

The last portion of the management plan which merits comment is at section 5.4, which allows facilities time to determine treatment choices.

> "The Secretary may grant a period of no more than two years for a facility . . . to develop a proposal to modify or upgrade the treatment process being used."

The latest estimate of a release date for draft EPA hospital incinerator standards is June or July of 1992, with final standards releasable approximately in fall, 1993.

It is respectfully submitted that the earliest time in which a hospital will have the ability to comprehensively assess whether or not it wishes to upgrade incineration capabilities will be at or reasonably after the time of issuance of final EPA regulations. The danger of using draft federal regulations as a decision making guide for hospitals is well known. Draft regulations are notorious in their ability to change in the process of becoming a final product due to many factors: reaction of the public, hardship imposed upon the regulated community, costs of compliance, ability of the agency to maturely reflect upon the subject matter over time, and additional considerations evolving from a public comment process.

A good example of the lack of prudence which occurs in relying upon standards set in a draft rule has recently occurred in the proposed OSHA Requirements on Occupational Exposure to Bloodborne Pathogens. The draft was released for

Infectious Waste Management Plan

All hospitals will be required to develop and submit to the Department an infectious waste management plan ("the plan") for review and approval. Section 4.14 states:

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

The problem with 4.14 for hospitals is obvious. What constitutes a major or minor change is subjective. Second, a hospital may have to make a change in any number of aspects of its plan on an expedited basis. If a hospital discovers that a change should be made based upon quality of care, employee, patient or community safety considerations, it may be ethically and legally bound to initiate appropriate changes, be they major or minor, without obtaining prior permission of the Department.

The Joint Commission on Accreditation of Healthcare Organizations requires every accredited hospital to have the ability to take immediate action to eliminate or minimize hazardous conditions that pose a potential risk of harm to life, health and/or property (Plant, Technology and Safety Management Standard No. 1). Compliance with this requirement has been identified as a key factor in the accreditation decision process. Adherence to the JCAH standard has been widely interpreted to require that any (potential) safety problem of sufficient urgency to require immediate action does not, contrary to section 4.14, require prior approval.

Accordingly, it is recommended that section 4.14 of the rule be changed to include the following language:

> A permittee shall submit an application for approval of a major change in the permittee's infectious medical waste management plan before implementing the change. Minor changes in the infectious waste plan may be made without notifying the secretary and shall be included in the next application for permit renewal. All major changes shall be approved prior to implementation. Provided, however, that no prior approval is necessary in the case of a hospital in any instance in which in the sole discretion and judgment of competent hospital authority, an immediate change in any part of the infectious medical waste plan is required to protect the safety and care of patients, employees and/or the public. In such an event, the hospital will notify the

Packaging

Section 6.2.8 requires adherence to the personal protection equipment as specified in OSHA Bloodborne Pathogen Standards, the citation given is "29 CFR Part 1910.1030", which does not presently exist. The Association believes that the bloodborne pathogen rule will be released on or before December 1, 1991.

The portion of the draft federal rule pertaining to protective gear appears to have little scientific basis. If the Department intended at this section to promulgate the draft standard contained at 54 FR 23041, May 30, 1991, we adopt the following comments of the American Hospital Association (letter dated August 14, 1989 from Mr. Paul Rettig, Executive Vice President, AHA to Mr. Alan C. McMillan, Acting Assistant Secretary of Labor) as our own relating to personal protective equipment:

"Sec. 1910.1030 (d) (3) of the rule would require that employers make personal protective equipment accessible to employees, and assure that they use it. Also, the employer would have to provide appropriate sizes of equipment, and clean, launder and repair it as needed. Mandated equipment would include, but not be limited to: gloves, masks, goggles, face shields, gowns, aprons, surgical caps, hoods, and shoe covers. Some general specifications for fluid resistance capabilities would be set by the rule."

"This section of the rule is problematic in several ways: due to vagueness in some areas, it fails to set limits on the employer's responsibilities and, in other areas, it exceeds prevailing standards of infection control by addressing situations in which transmission has not been known to occur. In yet other parts, equipment is required that will not be useful in protecting employees."

"The rule is vague regarding the employer's obligation to "assure" the use of equipment and make it "accessible". This is especially confusing in view of section 1910.1030 (d) (1), which permits employee discretion over when to forego precautions."

> "Recommendation: Clarify the provision in sec. 1910.1030 (d) (3) (i-iii) to require only that the employer take "reasonable efforts" to direct employees to use personal protective equipment, and to provide the training necessary for them to use it."

"In several areas, the rule needlessly would require the use of specific equipment which goes beyond what is necessary to prevent occupational exposure. The provision about glove usage is an especially troubling example of this problem: the language is so broad -- "gloves shall be worn whenever the employee has the potential for exposure" -- that the rule could be construed to require glove use for all contact with patients, including such activities as simple examinations and phlebotomy. If so, the rule would go significantly beyond CDC guidance, which focuses on situations where exposure can reasonably be anticipated. In simple exams, there is no reason to anticipate contact with the fluids covered by this rule. Also, phlebotomy rarely involves worker contact with such fluids (except when the employee is inexperienced, or has

public comment May 30, 1989. The final rule is not expected to issue until December 1, 1991. Due to extensive public comment, it is not expected that the draft and final rule requirements will be compatible.

The same scenario may apply for hospital incineration standards. Final EPA standards are not scheduled to appear until September/October 1993. Thus, hospitals should have some reasonable amount of time in which to determine the impact of the final EPA rule. Once the standards are known, the hospital should have one year in which to develop a proposal to modify or upgrade treatment processes. It is therefore recommended that section 5.4 be revised to read as follows:

> "The Secretary may grant a period of no more than one year from the date of issuance of final EPA rules relating to hospital incineration standards for an infectious medical waste management facility in existence as of the effective date of this rule to develop a proposal to modify or upgrade the treatment process being use. Such plans shall be considered to be part of the facility's infectious waste management plan."

In similar fashion, section 10.2.7 should be revised accordingly. Calculation of the maximum three year waiver period should be changed to allow a maximum waiver period of two years after issuance of final EPA standards.

Packaging and Labeling

Section 6.13 of the rule states in part: "Contractors or other agents may package or repackage infectious medical waste . . . if the packaging or repackaging is performed on site where the infectious medical waste was generated and if no storage or treatment occurs prior to the packaging or repackaging." The prohibition of no storage occurring prior to packaging or repackaging effectively means that infectious medical waste must be packaged immediately at time of storage. This will prevent a handling/transportation concern from packaging prior to transport, even if this would be normal business practice. Containment of infectious medical waste on a temporary basis may, for a short period of time, be in bags (6.2.4) until the transporter arrives, at which time the bags may be placed in appropriate transport devices (6.2.6). Section 6.1.3 would appear to prevent this practice from occurring. Section 6.1.2 makes it clear that it is the ultimate responsibility of the generator to insure proper packaging and labeling. The Department should consider removing the underlined portion of 6.13.

In an unrelated matter, it is recommended that section 6.12 should contain an additional sentence to be added at the end of the paragraph, as follows:

> "Nothing in this section shall be construed to prevent or limit any cause of action by a generator against any other party for any reasons for which the law gives a remedy."

exposure situations and match the precautions to the potential, rather than adhering to rigid checklists of certain procedures and equipment which may or may not be effective in specific instances."

"Recommendations: Revise sec. 1910.1030 (d)(3)(v-vi) to:

- Require the use of gloves, masks, eye protection, and face shields for those situations posing "reasonably anticipated exposures", as defined by prevailing CDC guidelines on universal precautions.
- Eliminate the distinction among types of clothing. Delete the reference to aerosolization.
- Delete entirely the sections on surgical caps or hoods and shoe covers."

As is evident from the above recitation, there are numerous problems involved in the present state of development with section 6.2.8. We recommend that any reference to 29 CFR Part 1910.1030 be eliminated, as final standards do not yet exist. Should the Department intend to adopt the draft standards, the Association strongly believes that the DOH should refrain from such action for the reasons cited above.

Commercial Medical Waste Management Facilities

So much of section 11.5 states that no person may construct a commercial facility within an area where there is a reasonable probability that the facility will cause:

- a significant adverse impact upon wetlands (11.5.1)
- a significant adverse impact upon any endangered or threatened species of animal or plant (11.5.2)
- a statistically significant adverse impact upon any surface water (11.5.2)
- a statistically significant adverse impact upon ground water quality (11.5.4)

The above "criteria" are so nebulous and vague as to be unenforceable. Inclusion of these vague requirements is certainly not required by HB 2141.

To the contrary, the legislature found, among other things:

> "That safe and cost effective alternatives to the incineration of infectious and noninfectious medical waste should be encouraged."

sores or dermatological conditions of the hands, and in those cases, CDC recommends glove use). However, the real risk in blood drawing procedures is due to needlesticks, which glove use cannot prevent. Only better training in alternative work practices can prevent such injuries. In addition, mandated glove use by phlebotomists could result in injury to the worker's hands and perhaps a portal of entry for infectious diseases due to the chaffing that would be caused by changing gloves after each patient (which is proper to prevent the spread of nosocomial infections between patients)."

"Similarly, by enumerating requirements to wear other protective equipment like masks, face shields, goggles, and aprons, but not limiting application to situations when exposure can reasonably be anticipated, the rule is vague enough to be construed to require such equipment for all patient encounters, regardless of the potential for exposure. Such excessive use of equipment could seriously interfere with the health care worker's ability to provide care. This could have a chilling psychological effect on the health care setting, where patients or workers could begin to fear others because of the perception that they are at increased risk."

"OSHA's attempt to differentiate between splashing, spraying, and soaking is specious, and will only burden workers and the health care facility, who must then attempt to use this basis to determine when to use "fluid proof" or "fluid resistant" protective clothing. Because there is no method to assess the ability of a material to resist penetration of fluids and thus no scientific measures of barrier effectiveness against bloodborne pathogens, nothing can be gained by attempting to differentiate between fluid proof and fluid resistant garb. However, this provision could be relied upon by compliance officers to demand heavier protective equipment that is appropriate for health care."

"In response to Question 17, the rule should not include any criteria for the effectiveness of barriers. The choice of barrier should be left to a facility's medical professionals based on the probability of exposure, type and amount of fluid likely to be encountered, and the probable route of transmission if no barrier were used. For similar reasons, our response to OSHA's Question 19 is that puncture resistant gloves should not be mandated for housekeeping, since in most cases they would exceed the necessary level of protection."

"Finally, the requirements for "fluid proof shoe covers" and "surgical caps or hoods" are not justified by any known risk. Bloodborne disease transmission has never been shown to occur through spills onto the foot or splashes onto the scalp."

"If implemented, these requirements will cause serious confusion for the employer who is already using CDC's universal precautions. Here again it is our suggestion that OSHA incorporate CDC's universal precautions, instead of listing specific equipment and setting standards for its use. In fact, by establishing such new standards, OSHA may undermine reliance on universal precautions -- which attempts to make workers constantly aware of all potential

including small quantity generators and ambulance companies, local health departments or small physician groups, nursing homes, etc.

On an individual as needed basis, hospitals may find that requiring manifests from small quantity generators may result in better control of infectious waste received by individual hospitals which is generated off site.

Accordingly, a separate section should read as follows:

12.12. "Nothing in this rule shall prevent any hospital or other facility which receives infectious waste from any small quantity generator, including any ambulance company, from requiring a completed manifest as more fully described in sections 12.1 through 12.5. The decision regarding implementation of this requirement is one which is in the discretion of each individual hospital. Any hospital which so elects to require manifests from any or all small quantity generators may refuse to accept any infectious waste from any such generator without proper manifesting."

Miscellaneous

Section 5.7 of the proposed rule states that:

> "Disposal of infectious medical waste in this state is prohibited, except as described in section 10.4 of this rule."

Section 10.4 of the proposed rule is entitled "Sanitary Sewer". It is assumed that the intent of the Department is to allow disposal as found throughout section 10, and that the language of 5.7 is merely inadvertent.

****

The Association again wishes to thank the Department for an opportunity to comment on this proposed rule. I am available at your convenience for discussion of any of the above.

Respectfully yours,

Gil DeLaura
Vice President/General Counsel

GD/pdp

The legislature further found that the public interest is best served by:

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

Application of the above nonstandards at 11.5 will have precisely the opposite effect. These questionable criteria will discourage establishment of alternatives to incineration and widely penalize hospitals and other generators that wish to form regional facilities. The only choice that hospitals have due to the language of the statute at 20-5J-3(1) (the 35% rule) is to opt for formation of a commercial facility. Inclusion of the arbitrary criteria contained above and at section 11.5 will simply frustrate the intent of the legislature, as no entity, including any given group of West Virginia hospitals, can comply. It is respectfully recommended that these highly questionable, vague and capricious standards as listed above be removed.

Non-Commercial Medical Waste Management Facilities

The proposed rule does not encourage the formation of non-commercial medical waste facilities on a local level. For example, hospitals located within the same city or town who may be able to realize economies of scale by combining together in an efficient manner for waste disposal will be unable to do so.

Hospitals in rural areas of our state, already under financial duress, will find themselves in a precarious position if they are forced to dispose of infectious medical waste exclusively by commercial haulers.

An untenable financial dilemma may develop for both urban and rural hospitals.

The Department should develop standards which encourage (as opposed to discourage) local joint efforts among health care providers in responsible disposal of infectious waste.

This goal can be met by using the definitional concept of solid waste commercial facilities, which is an entity which ". . . shall not include an approved solid waste facility owned and operated by a person for the sole purpose of disposing of solid wastes created by that person or . . . other persons on a cost sharing or non-profit basis." West Virginia Case 20-5F-2(c).

Similar flexibility should be given to West Virginia hospitals and other health care providers, based upon the findings and preamble of the Medical Waste Act 20-5J-2.

Requirement Relating to Manifests

Section 12.9 of the rule relieves small quantity generators who elect to transport their own infectious waste from manifest requirements. Hospitals should have the ability, if desired, to require manifests from any generator

medical waste washing ashore in some coastal states and the perceived threat of contracting the acquired immunodeficiency syndrome from it. This has led to restrictive rules governing the disposal of medical waste in most states and to more waste being defined as infectious. Coincidentally with the broadening of the definition of infectious waste, the options for the treatment and disposal of medical waste are diminishing because of lack of space and environmental concerns. In this article we define and characterize medical waste, assess its public health implications, evaluate current waste-management practices, and examine federal legislation in this area that could have an impact on health care providers.

Medical Waste

Despite the attention given the subject by the public and the media and at all levels of government, the terms "hospital waste," "medical waste," "regulated medical waste," and "infectious waste" are often taken to be synonymous. Hospital waste refers to all waste, biologic or nonbiologic, that is discarded and not intended for further use. Medical waste refers to material generated as a result of the diagnosis or treatment of a patient, such as soiled dressings or intravenous tubing. Infectious waste refers to the portion of medical waste that might potentially transmit an infectious disease.[1,2] Congress and the Environmental Protection Agency (EPA) used the term "regulated medical waste" rather than "infectious waste" in the Medical Waste Tracking Act of 1988, because the possibility of transmission of disease by such waste was remote.[2] Thus, medical waste is a subcategory of hospital waste, and infectious waste, which is synonymous with regulated medical waste, is a subcategory of medical waste.

Guidelines produced by the Centers for Disease Control (CDC) have designated five types of hospital waste as infectious — microbiologic material, pathological material, contaminated animal carcasses, blood, and "sharps" (i.e., instruments such as needles or scalpels).[3,4] The EPA guidelines also include all waste from patients who have communicable diseases and are isolated.[5] In a survey of U.S. hospitals in July 1987 and January 1988, the overall rates of compliance with the CDC and EPA recommendations were 82 and 75 percent, respectively. Not only were the majority of hospitals in compliance, but they also frequently designated additional hospital waste as infectious, including contaminated laboratory waste (87 percent of hospitals), surgical waste (78 percent), waste from dialysis (69 percent), items contacting secretions (63 percent), waste from intensive care (37 percent), and emergency room waste (31 percent).[1]

A key component in evaluating the effect of a medical-waste management program is the quantity of waste produced per patient. Hospitalized patients generate about 15 lb of hospital waste per day. Approximately 6700 tons are generated by U.S. hospitals daily, about 1 percent of the 158 million tons of municipal solid waste produced annually. U.S. hospitals designate at least 1000 tons of waste per day as infectious (approximately 15 percent of total hospital waste according to weight).[1] Of course, the fraction of medical waste treated as if it were infectious increases with the number and types of medical waste classified as infectious.[1,6] For example, about 6 percent of hospital waste will be treated as infectious if the CDC guidelines are followed,[1] but 45 percent of hospital waste could be considered infectious under the Medical Waste Tracking Act.[7]

Although hospitals are considered to be the primary generators of medical waste and the focus of most regulations,[2,8,9] they are only a part of the health care facilities that generate medical waste, including 180,000 physicians' offices, 98,400 dentists' offices, 38,000 veterinarians' offices, 15,500 medical clinics, 12,700 long-term health care facilities, 4300 laboratories, and 900 free-standing blood banks.[6] Reliable data are not available on the amount of medical waste produced from these nonhospital health care sites. In addition, there are 2 million diabetics and 1.2 million intravenous drug abusers nationwide who use more than 1 billion insulin-type syringes annually, which are not regulated.[11]

Public Health Effects

Most proponents of state and federal medical-waste legislation have claimed that medical waste poses a threat to human health and must therefore be strictly regulated. However, the alleged health hazards of our current medical-waste disposal practices have not been demonstrated. The potential for infection from contact with medical waste other than sharps is virtually nonexistent.[11] Contaminated sharps are the only form of medical waste that has been associated with the transmission of infectious disease. This is not surprising, given the intrinsic capability of sharps to disrupt the integrity of the skin and introduce infectious agents into the wound. All the reports describing the transmission of infectious agents by contaminated sharps have occurred in settings of occupational health care, however, and none have been associated with environmental injuries occurring after the disposal of the waste outside the hospital.[11] There is no epidemiologic evidence that hospital waste disposal practices have caused disease in the community.[11,12]

Medical Waste Management in the United States

The vast majority of U.S. hospitals designate and treat waste, including microbiologic agents, pathological specimens, material from patients in isolation, blood, and sharps, as infectious.[1] At U.S. hospitals, infectious waste is most commonly incinerated — 84 to 93 percent of it, depending on the type of waste. About one third of U.S. hospitals sterilize their microbiologic waste with steam, and about one fourth pour blood down a drain connected to a sanitary sewer (unpublished data). Most states have rules for medical waste that are overly restrictive, and thereby increase the volume of infectious waste that must be treated.[2,9] At the same time, they have restricted the use of certain treatment methods, such as the disposal of regu-

The West Virginia Hospital Association and Monongalia General Hospital submitted this article as part of their comments.

SOUNDING BOARD

INFECTIOUS WASTE —

Mismatch between Science and Policy

Disposal of medical waste [illegible] emerged as a major problem in the United States. The problem was brought to public attention [illegible] recent episodes

of medical waste deposited on beaches may not be reduced by the requirements of the act — its principal purpose.

Second, studies have shown that U.S. hospitals are generally in compliance with the CDC infectious-waste guidelines. In fact, most hospitals consider more types of medical waste infectious than the CDC recommends.[3] Possible explanations for this overly broad definition of infectious waste include a misinterpretation of universal precautions (i.e., the incorrect belief that all patient-contacted waste must be treated as infectious),[27] overly restrictive state regulations, and fear that the hospital may be identified as a mismanager of medical waste by state or federal surveyors who might choose to include items among the regulated waste for aesthetic reasons or perceived health risks. In addition, in certain locations used for patient care (e.g., operating rooms and emergency rooms) it might be difficult to maintain separate waste containers for regulated and nonregulated medical waste in a manner that ensures no confusion. In such situations, some facilities have decided to designate all waste as regulated medical waste.

Third, household waste contains on average 100 times more microorganisms with pathogenic potential for humans than medical waste.[18-20] From our daily experience with household waste and decades of waste removal and burial in landfills, we can deduce that the incremental health risks from the less microbially contaminated medical waste are nominal.

Finally, with the exception of sharps, which have caused disease only in occupational settings, there is no scientific evidence that medical waste has led to disease in the hospital or the community.[11,12] Although the public is concerned that blood-borne pathogens, such as hepatitis B virus and human immunodeficiency virus (HIV), could be contracted through accidental exposure to infectious waste in the environment, the probability, on theoretical grounds, that the events necessary for infection to occur and that a person will acquire HIV infection from a needle on a beach is vanishingly small (1 in 15 billion to 1 in 390 trillion).[11,28-32] Although sharps are the only medical waste known to be involved in disease transmission, there are several medical wastes that are regulated because of aesthetic considerations and the perceived rather than proved risk of disease transmission. Except in the case of pathological specimens, the use of aesthetic criteria for the regulation of waste is subjective and establishes a controversial precedent.

The Medical Waste Tracking Act also requires all regulated medical waste to be not only treated (i.e., processed to reduce or eliminate its potential for causing disease) but also destroyed, so that it is no longer recognizable. This environmental standard could halt the development of new forms of technology that would provide "treatment" without "destruction" and would render previously available methods of treatment (e.g., steam sterilization without subsequent destruction) illegal. In addition, the terminology associated with some categories is nebulous, such as "items saturated and/or dripping with human blood."[2] Such an approach would result in an enormous increase in the volume of regulated medical waste and in the costs of hospital-waste disposal, well beyond the EPA estimate of $3,757 per hospital per year.[2] To illustrate, a New York academic center reported that to comply with the act, it increased the amount of regulated medical waste by 315 percent from 1984 (443,000 lb) to 1989 (1,837,000 lb). The total cost increased nearly 700 percent, from $106,000 to $835,000 per year, resulting in a rise in the daily cost for regulated medical waste per patient from $1.04 to $5.19.[7] This effect was largely the result of considering a larger portion of medical waste as regulated medical waste and of the difference in cost between the disposal of nonregulated (i.e., $0.02 to $0.05 per pound) and regulated (i.e., $0.20 to $0.60 per pound) medical waste. On the basis of these data and patient-census data from the American Hospital Association, it would cost U.S. hospitals about $1.3 billion a year to comply with the Medical Waste Tracking Act — approximately seven times the amount ($182 million) allotted by the federal government in 1991 for all childhood immunizations. Ultimately, this additional cost will be passed on to the public in the form of higher medical fees, insurance rates, or taxes.

Nonetheless, because of intense and often misleading media coverage of this issue and a lack of understanding of disease transmission, the states and the federal government created strict regulations, which aggravated the problem by defining more waste as infectious. To complicate matters further, some waste-treatment options such as landfilling have been eliminated, and others such as incineration may be eliminated. The result is an extraordinary increase in cost with no environmental or public health benefit. The medical-waste policies that have evolved from perceived risks over the past few years should be supplanted by rules based on scientific considerations.

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DAVID J. WEBER, M.D., M.P.H.

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lated medical waste in sanitary landfills.[9] The evidence suggests that untreated medical waste can be disposed of safely in such landfills provided that procedures are used to prevent it from coming in contact with workers during disposal.[11] Studies demonstrate that pathogenic bacteria and viruses are significantly reduced in number in properly operated sanitary landfills because of such processes as thermal inactivation, antimicrobial characteristics of the leachate, and adsorption to organic material in solid waste.[13-17] Although on average municipal solid waste contains more microorganisms with pathogenic potential for humans than does medical waste,[3,12] there are no restrictions on the placement of municipal wastes into landfills. In any event, the use of sanitary landfills for medical-waste disposal is not a satisfactory long-term alternative, since one third of the remaining landfills will reach their capacity within the next five years.[18] Clearly, proper hospital-waste management must include methods to reduce the total output of waste and to recycle or reuse medical materials when feasible.

Paradoxically, although strict waste-tracking laws encourage on-site incineration,[3] tough emission restrictions are discouraging the use of this form of waste disposal,[8] even though there are no known infectious health hazards associated with properly operated incinerators. Incineration produces a sterile ash,[24,25] there is no difference between bacteria in stack emissions and those in ambient air,[26] and when *Bacillus subtilis*, for example, is mixed with waste, it is inactivated.[27]

Although hospital and municipal waste incinerators generate a variety of chemicals, such as carbon monoxide, metals, dioxins, and furans,[28-30] no health risks from their generation in this way have been demonstrated. Nonetheless, public health anxieties about the chemical emissions from incinerators mandate further investigation and the subsequent development of scientifically based emission standards. Currently, statewide moratoriums, stringent rules, and requirements for permits restrict hospitals from using incinerators even if they have already been installed. As a consequence, regulated medical wastes are sometimes transported long distances to regional incinerators, increasing the costs of disposal.

The Medical Waste Tracking Act of 1988

The beach wash-ups and resultant beach closings brought pressure on state and federal legislators to prevent future closings, and several states issued strict emergency regulations. The Medical Waste Tracking Act was pushed rapidly through Congress in October 1988 and signed into law on November 1. It directed the EPA to begin a two-year pilot program on the disposal of infectious waste. Although the act expired on June 22, 1991, and affected only four states (New York, New Jersey, Connecticut, and Rhode Island) and the commonwealth of Puerto Rico, it is likely that it or similar legislation will be included in the reauthorization of the Resource Conservation and Recovery Act in 1992 and will be extended to all the states. Under the tracking plan, health care providers (physicians, dentists, veterinarians, small clinics, laboratories, and hospitals) that generate more than 50 lb of regulated medical waste per month are required to maintain detailed records that track such wastes from point of origin to final disposal. At present, the EPA has exempted providers that generate less than 50 lb per month from the full tracking requirements of the act, but not from other requirements for disposal and treatment. Those that do not comply are subject to civil penalties of up to $25,000 per day and criminal penalties of up to $50,000 per day for each violation and a maximal penalty of five years in prison.[2]

The passage of this law was opposed by the CDC, the Association for Practitioners of Infection Control, and the National Institutes of Health, all of which testified that medical waste generated in traditional health care settings posed no hazard to the general public, although it was an occupational health concern.[31] The same conclusion was reached by the Agency for Toxic Substances and Disease Registry of the Department of Health and Human Services, which presented a report to Congress in September 1990.[11]

If regulatory control were based on epidemiologic and microbiologic data, only two types of medical waste would require special handling and treatment — sharps and microbiologic waste.[32] Such an approach should be the basis for a uniform definition of regulated medical waste, which could be monitored by appropriate accrediting agencies, such as the Joint Commission for the Accreditation of Health Care Organizations or the State Division of Facility Services, during their periodic reviews.

The Discrepancy between Science and Policy

Governmental regulations are intended to protect the public health and limit the degradation of the environment by medical waste. It is extremely unlikely, however, that the Medical Waste Tracking Act will have any effect on the public health or prevent medical debris from washing up on public beaches, for several reasons.

First, three detailed reports of beach wash-ups found that about 99 percent of the waste on beaches was debris such as wood, plastics, and paper, not medical waste.[33-35] Despite extensive investigations, the washed-up materials could not be traced to illegal dumping or to a specific source, such as a hospital, but were related more directly to malfunctioning sewage-treatment systems and prevailing winds and currents.[34,35] EPA officials acknowledged that some 81 percent of the medical waste that washed ashore in the summer of 1988 was related to syringes and was from use in home health care or intravenous drug abuse. Chemical analysis identified insulin or cocaine in three of five syringes collected during the EPA Harbour Studies Program.[34,35] Even though a single syringe on a beach is one too many, the Medical Waste Tracking Act will not prevent an occasional appearance, because waste from home health care and intravenous drug users is not regulated. Thus, the amount

COMMENTS OF THE
WEST VIRGINIA MANUFACTURERS ASSOCIATION
TO THE WEST VIRGINIA DEPARTMENT
OF HEALTH AND HUMAN RESOURCES
64 C.S.R. SERIES 56
INFECTIOUS MEDICAL WASTE REGULATIONS

On September 3, 1991, the West Virginia Department of Health and Human Resources filed with the Secretary of State an emergency rule, 64 C.S.R. Series 56, covering infectious medical wastes. Accompanying the emergency rule was a notice of a public hearing to receive comments from the public regarding these rules.

The WVMA represents a broad cross-section of large and small industrial concerns throughout West Virginia. The emergency rule will affect several of the member companies. In keeping with WVMA's supportive position regarding the development of sound and reasonable regulations affecting its members, the following comments and suggestions are offered for your consideration:

1. Section 2: Exemptions

Chemical waste incinerators, which are permitted hazardous waste management units, should be exempt from the requirements of this regulation. To ensure that the medical wastes are managed in an environmentally sound manner at RCRA permitted units, the following language is suggested for inclusion in Section 2. Exemptions.

"**2.2.3. Small quantity generators which burn infectious medical waste and which have received a hazardous waste management permit is issued by the State Air Pollution Control Commission must comply with the applicable parts of Sections 5 through 9.**"

2. Section 64-56-3. Definitions

Section 3.22 defines a small quantity generator as any generator of infectious medical waste who generates fifty (50) pounds or less during a one (1) month period. One of our member companies incinerates about 100 pounds per month of medical wastes that have been consolidated from two plants. We request that this definition be revised as follows:

"**3.22. Small Quantity Generator - Any generator of infectious medical wastes who generates an average of one hundred (100) pounds or less during a calendar month.**"

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"A small quantity generator which receives less than twenty-five (25) pounds per month of infectious medical waste from off-site facilities which are under the ownership of a common parent company is exempt from the requirements of Sections 9.9, 9.10, 9.11 and 9.12 of this regulation."

7. Section 10.2 Incineration

This section is not necessary for RCRA permitted incinerators which burn small quantities of infectious medical waste. Because emission standards and waste disposal requirements adequately limit releases and disposal of incineration byproducts, RCRA permitted units which burn small quantities of infectious waste should be completely exempt from this section.

If this recommendation is not accepted, the following comments are provided for consideration.

Section 10.2.1. provides: "All incinerators of infectious medical waste are required to comply with applicable State laws and with laws of the West Virginia Air Pollution Control Commission. This language should read:

"All owners and operators of infectious medical waste incinerators are required to comply with applicable state laws."

Incineration requirements should be performance based rather than design based. Monitoring of carbon monoxide emissions is a valid indicator of incinerator performance. It is recommended that Sections 10.2.2 and 10.2.4 be revised as follows:

Renumber 10.2.2. as 10.2.2.1.
Add a semicolon ";" and the word "or" at the end of 10.2.2.1.
Insert the following after the word "or":

"10.2.2.2. Whenever infectious medical waste is present in the incinerator combustion chamber, carbon monoxide emissions shall be less than 100 ppm on a sixty (60) minute rolling average corrected for stack oxygen concentration according to the following formula:

$$CO_c = CO_m X \frac{14}{21-Y}$$ **where**

CO_c is the corrected carbon monoxide concentration.
CO_m is the measured carbon monoxide concentration of the incinerator exhaust gas prior to release to the air.
Y is the measured oxygen concentration (by basis) of the incinerator exhaust gas prior to release to the air.

The following comments cover Sections 5 through 10.

3. Section 64-56-5. Infectious Medical Waste Management Plan

Section 5.1. provides: "All infectious medical waste management facilities shall develop an infectious medical waste management plan." Sufficient time should be provided to allow completion of the plan for facilities which are not required to obtain a permit. The following sentence should be added:

"Existing facilities which are small quantity generators, shall develop an infectious waste management plan within ninety (90) days of the effective date of this regulation."

4. Section 64-56-6. Packaging and Labeling

Section 6.3.1.1 provides that waste shall be labeled with "The name, address and business telephone number of the generator." This requirement is unnecessary for wastes generated and treated on-site. The following sentence should be added:

"This requirement does not apply to medical waste generated and incinerated on-site."

5. Section 64-56-8. Storage of Infectious Medical Waste

Section 8.8. provides: "All floor drains shall discharge directly to a sanitary sewage disposal system which is in compliance with Sewage Rules, 64 CSR 9." Some member companies store wastes in sealed containers for short periods of time in diked containment areas. Insert the following after the word "system":

", or other equivalent containment system which prevents any spilled materials from reaching the environment,"

6. Section 64-56-9. Transportation

Section 9.3.2. provides that a generator that transfers infectious medical waste on-site is exempt from permit requires provided: "No off-site infectious medical waste is knowingly and routinely accepted for on-site transfer." At least one of our member companies receives small quantities of waste for incineration from two common parent company plants. This section should be deleted or revised to exclude infectious medical waste received in deminimus amounts. The following language is suggested for inclusion at the end of 9.3.2.

WEST VIRGINIA STATE MEDICAL ASSOCIATION
Written Comments on
Proposed Rules Addressing Infectious Medical Waste

The West Virginia State Medical Association wants to thank the Department of Health and Human Resources for this opportunity to comment on the proposed rules addressing "Infectious Medical Waste".

The proposed rules provide complex procedures for generators of large amounts of infectious waste. There are considerably fewer requirements for those who generate smaller amounts of infectious waste. The guidelines for Small Quantity Generators (SQG) provide that fifty (50) pounds or less of infectious medical waste may be produced in a single month.

It appears that an exemption is needed for exceptional situations where this limit may be exceeded on an occasional basis. Otherwise, these typically small generators would be subject to all of the responsibilities and requirements of a large generator even if they only exceeded the monthly limit one time.

It is possible that a SQG could exceed the weight limit in any given month due to circumstances beyond his or her control; i.e., a flu epidemic, an unanticipated increase in a particular type of illness which is transient in nature, etc.

To force a physician's office to adhere to the requirements of a major generator for what is an exception is unreasonable. It would be more appropriate to allow up to three months of exceeding the limit of the SQG per year before forcing them to adhere to the large generator requirements.

Another approach might be to state that if an SQG's average monthly poundage exceeds the 50-pound limit by 25 percent over a 12-month

Received 10/3/91

Renumber 10.2.4 as 10.2.4.1.
Add a semicolon ";" and the word "or" at the end of 10.2.4.1.
Insert the following after the word "or":

"10.2.4.2. Carbon monoxide emissions shall be continuously monitored downstream of the final combustion chamber but prior to release to the air. Continuous monitoring records shall be maintained for a period of three (3) years."

Section 10.2.5. provides that incinerator ash shall be analyzed monthly for total organic carbon (TOC) and annually for metals. For the small incinerators ash is removed about once per quarter. The company would prefer not to shutdown the incinerator for the TOC analysis. This section should be revised to address infrequent ash cleanouts. Due to the nature of our incineration operation an annual composite analysis for TOC will be sufficient. The following language is suggested:

"10.2.5.1. Owners and operators of incinerators which are used to burn small quantities of medical infectious wastes shall analyze the ash sample annually for total organic carbon content."

Section 10.2.6. This section will require incinerator operator certification and payment of an operator fee. Section 4.15, which exempts small quantity generators, should be revised to exempt small quantity generators which also incinerate medical infectious waste in permitted hazardous waste management units. The following language is suggested:

"4.15. Small quantity generators who generate infectious medical wastes in the provision of health services in their own office are not required to obtain a permit and are exempt from Section 10.2.6., operator certification and operator fees."

Section 10.2.6 should be revised as follows:

"10.2.6 Two (2) years following the effective date of this rule, all owners and operators of infectious medical waste incinerators, except as provided by Section 4.15., shall provide written registration to the secretary. The secretary shall....."

WEST VIRGINIA UNIVERSITY HOSPITALS

October 1, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health & Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, WV 25305

Dear Ms. Howard,

Please consider the following comments concerning the September 3, 1991 Department of Health proposed rules for infectious medical waste.

1. The proposed rules were formulated and developed utilizing HB2141 as a basis. The regulations of other states have also been considered as well as comments received from several constituencies. The process has been very healthy and the department should be commended on its efforts. Entities currently involved with proper infectious waste handling, treatment, etc. will, in most cases, be only minimally affected by these regulations.

2. The use of the words "infectious waste" is a misnomer and most misleading greatly affecting public perception. The definition of infectious waste in the Medical Waste Act states that it must be "capable of producing infectious disease", meaning potentially infectious. Most health care/infection control persons would agree that less than 1% of what is included in this definition is truly "capable of producing infectious disease". Current good common practice in healthcare segregates, handles and treats potentially infectious materials as the law requires. This should continue as the proposed rules require. However, the proposed rules reinforce negative public perception by extensively utilizing the term "Infectious Waste" when meaning "Potentially Infectious Waste". I recommend, as other states have adopted, substituion of the term "Regulated Medical Waste". This simple revision will more accurately and appropriately describe what is in those red bags and provide a better basis for educating those not knowledgeable with the industry.

3. For large generators of regulated medical waste the labeling requirement to include date and weight on individual containers will greatly increase the cost and serve no known advantage. When storage and transportation is performed on a bulk basis, dating and weighing the entire load on a bulk basis should be allowed. Other labeling requirements as indicated in the proposed rules are appropriate.

Facilities Management Department
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period, then they would be considered large generators and would be required to adhere to those guidelines.

MEDICAL PARK WHEELING, WEST VIRGINIA 26003 304-243-3000
SKILL, SERVICE, HOPE AND LOVE

WHEELING HOSPITAL

September 30, 1991

Ms. Kay Howard
Director, Regulatory Department
Department of Health and Human Resources
Room 204, Building 3
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305

Re: Proposed Infectious Medical Waste Rule
Public Hearing October 3, 1991

Dear Ms. Howard:

I am writing in reference to the proposed rules on infectious waste. Wheeling Hospital offers the following comments:

1) We believe that incineration should be permitted for a group of hospitals that may want to create a regional infectious waste facility. The proposed rules contain no mechanism for hospitals to band together and establish a non-commercial regional infectious waste facility. The rules should be changed exempting hospitals from having to follow the requirements of a commercial medical waste management facility.

2) We believe there should be provisions in the rules to allow a hospital to accept infectious medical waste from another hospital for ninety days under temporary conditions. Examples of temporary conditions could be repairs to incinerator, refractory relining of incinerator, and modifications to incinerator.

3) Under transportation requirements:

   a) We agree with rule 9.7.3 that vehicles shall be cleaned and disinfected following leakage or spills.

   b) We disagree with rule 9.7.4 that vehicles shall be cleaned and disinfected prior to using the conveyance for any other purpose. If the infectious waste is properly packaged and there is no leakage or spill, then the vehicle should not have to be cleaned and disinfected prior to any other use.

   c) We disagree with rule 9.7.5 that vehicles shall not be used to transport food, foodstuffs, food additives, food containers, or any substances to be ingested by people or animals or applied to food or feed. If the vehicle has been properly cleaned and disinfected, there should be no reason why the vehicle could not then be used to transport food and foodstuff.

4. The requirements for treatment of regulated medical waste by steam (autoclaving) are much more stringent than necessary. The time of steam treatment as indicated in the proposed rules should be reduced by 50% to conform with commonly used processing times that obtain sufficient kill rates.

5. Alternative treatment methods must be encouraged, however must be carefully reviewed. The proposed rules appear to have sufficient safeguards, however it must be recognized that EPA guidelines for testing protocols are non-existent at this time. The reliance upon the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for registering disinfectants is also not appropriate because of the microbiological nature of infectious organisms. Alternate testing mechanisms must be allowed. To allow alternate treatment methods to be developed, and regulated, the discretion of the Secretary of Health must be stressed.

Thank you for considering these comments.

Sincerely,

Robert J. Carubia
Facilities Management

RJC/bp

xc: Dr. Joseph Shock

I appreciate the opportunity to comment on the proposed rules. I would hope the Department of Health and Human Resources would consider these comments in finalizing rules and regulations. While we share your concern that infectious medical waste should be properly handled and disposed of, we would hope that the rules and regulations also be practical and not significantly create problems and unneeded expense for health care facilities.

Very truly yours,

L. E. Boddorf
Assistant Administrator

LEB/lr

4) Rule 4.1 refers to certain facilities that are exempt by Sections 2.1, 2.2, or 4.15 of this rule. We are unable to locate rule 4.15. Perhaps rule 4.15 was omitted from the rules or is a misprint.

5) Rule 5.2.6 refers to disposal methods consistent with Section 10.4 of this rule

and

Rule 5.7 refers to disposal of infectious medical waste in this State is prohibited, except as described in Section 10.4 of this rule.

Section 10.4 is the Sanitary Sewer.

We believe the reference to Section 10.4 is in error as there are other methods of treatment - 10.2 Incineration, 10.3 Steam Sterilization and 10.5 Alternate Methods in addition to 10.4 Sanitary Sewer.

6) Rule 10.2.5 requires incinerator ash to be tested monthly for total organic carbon content. We believe testing monthly is an excessive requirement and added cost. We suggest annual testing as adequate.

7) Annual Permit Fees:

   a) We believe the annual fee of $250 for a transportation vehicle for "on site" hospitals should be reduced to zero.

   b) We believe the annual fees for hospitals are excessive. They should be reduced, based on bed size, to a maximum of $500.

   c) We would suggest that infectious waste facilities that are located on contiguous property only be required to obtain one permit. In our particular case, Wheeling Hospital operates an acute care hospital, a nursing facility, and a dialysis facility which are operationally distinct. However, all the waste is disposed of by Wheeling Hospital and never leaves the Wheeling Hospital Medical Campus. One permit for the disposal of all waste at Wheeling Hospital would make much more sense than three separate permits.

8) With reference to rule 5.4, the secretary may grant a period of no more than two (2) years to develop a proposal to modify or upgrade the treatment process being used. We understand the EPA will publish draft rules and regulations next year that may be more stringent than State regulations. Two years may not be enough time for a facility to decide. We suggest this be changed to no more than two (2) years after the EPA rules are final.

PUBLIC HEARING

BEFORE THE WEST VIRGINIA DEPARTMENT OF

HEALTH AND HUMAN RESOURCES

In Re: PROPOSED INFECTIOUS WASTE RULE

Transcript of proceedings had and testimony adduced at a hearing on the 3rd day of October, 1991, at 10:00 a.m., at the West Virginia State Capitol Complex, Conference Room C, Charleston, Kanawha County, West Virginia.

PHYLLIS HAYNES EDENS
CERTIFIED COURT REPORTERS
2135 KAY NEVA LANE
CHARLESTON, WEST VIRGINIA 25312
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BEFORE: MR. JOSEPH SCHOCK
MS. KAY HOWARD
MR. JOSEPH WYATT

SPEAKERS: MR. FRANK CRABTREE
DR. HARRY NEWELL
MS. LILLIAN MORRIS
MR. ROBERT FOSTER
MR. JOHN ROACH
MR. RICHARD STEVENS
MR. ALBERT TIECHIE
MR. GIL DELAURA

I N D E X

MS. HOWARD: Good morning, my name is Kay Howard, and we are here this morning to conduct a public hearing on a proposed infectious medical waste rule. I should mention for the record, today is October 3, 1991.

Before I go on, I would like to introduce three people to you.

At my left here is Mr. Joe Schock, who is Director of the Office of Environmental Health Services, and to his left is Mr. Joe Wyatt, who is in charge of our infectious medical waste program.

Our purpose today is to conduct a public hearing concerning this proposed infectious medical waste rule. We are here to listen to your comments rather than to engage in any on-the-spot debate at this hearing.

I would like to remind you or inform you, as the case may be, that all the comments we receive are part of a public record, whether they are written or spoken.

If comments are written, you do not have to read them in order to have them entered into the record. I can assure you we do read and respond to all the comments that are made.

We may not agree with all the comments, but

we certainly consider them.

I would also like to introduce you, we are taping this, and we also have a court reporter here on my right, Shelia Miller, who is listening and doing the things that court reporters do to have everything recorded.

We only have seven persons who have identified at the present time that they would like to speak, but you can decide as the hearing progresses if you want to speak, that is fine.

Since it is such a small number of people, I am not going to impose a strict time limit. I would like to ask you to please be brief and to try to restrict yourself to no more than five minutes worth of speaking.

Your comments should address the role and not digress to other issues. I have no further remarks to make at this point.

I believe that Mr. Schock wants to make a few remarks, and then after he speaks, I will entertain questions about the conduct of the hearing or any other pertinent matters you may have questions about as best I can.

MR. SCHOCK: Thank you, Kay. The proposed

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

It is based on the legislative provisions of House Bill 2141, the West Virginia Medical Act, which was enacted in the last legislative session.

The guiding force of the act was the policy statement of the Medical Waste Subcommittee of the Joint Committee on Government and Finance. This statement serves as the preamble to the proposed rule.

The Medical Waste Subcommittee consisted of representation from infection control. Terry Lee with C.A.M.C., I see you are here.

The pollution control commission of the West Virginia Hospital Association, Gill Delaura, is here with us today. The West Virginia Medical Association, George Rider, is with us today.

The dental association, two environmentalists, and we have Missy Wolverton, who is on that committee, and myself.

Since the passage of House Bill 2141, we

have had the opportunity to have a series of meetings with the veterinarians, physicians, dentists, morticians, the haulers, and a great number of meetings with various representatives of the hospital groups, because we were most anxious to get their input into the proposed rule.

We tried, as best we could, to word the rule to avoid the need for interpretation. We have received about 17 formal sets of comments so far, and much of them related to clarification of certain provisions of the rule.

One of the things that I am learning as we are going through and developing the rule is that it is almost impossible to word a piece of legislation or a rule so tight that it requires no interpretation whatsoever.

When I talk with my counterparts in the other states, it is quite common to develop an administrative "Q" and "A" that is sent out from time-to-time.

I found every meeting was a learning experience for our staff and for the other participants.

We were most anxious to find out what procedures are being followed that comply with the proposed rule and what procedures were not. We need to share

experiences.

In order to have a successful program, I think all professions need to work together, whether we are a major medical facility or small quantity generators, haulers, landfill operators, and, of course, we in state government, including the Air Pollution Control Commission, D.N.R., and Health and Public Service Commission.

I thank you for your interest and concern, and I look forward to hearing your comments. Thank you.

MS. HOWARD: Any questions?

(No response.)

MS. HOWARD: I intend to just follow the sign-up sheets which I have picked up in more or less random order, with one exception.

Mr. Frank Crabtree is going to appear for the Public Service Commission and has a commitment elsewhere and has asked to be allowed to speak first, and if there is no objection, I would like to start off with Mr. Crabtree.

(No response.)

MS. HOWARD: Thank you.

(THEREUPON came Mr. Frank Crabtree.)

MR. CRABTREE: Good morning, my name is Frank

Crabtree. I am Director of the Transportation Division of the Public Service Commission.

Mr. Schock phoned me a while back and expressed some concern that had been expressed to him concerning the Public Service Commission's involvement in the transportation of infectious medical waste.

As most of you know probably, the Public Service Commission does regulate the commercial carriage of property in this state and that has evolved to include solid waste over the years.

Solid waste, as we know, is being broken down into various components through evolutionary process and refined laws and rules over the years as well, and infectious waste is now a category of its own in this state.

Infectious waste cannot be deposited in any state landfill at present, as you know.

However, the Public Service Commission has been given statutory authority to regulate infectious medical waste carriers in House Bill 2141 specifically.

We believe it existed in the general jurisdiction before that, but in 2141, it was spelled out.

It also spelled out in 2141, I am speaking

specifically of 20-5J-10, I believe it is, it spells out that the Public Service Commission shall grandfather in certain of those carriers that we believe, to our best interpretation, that were transporting infectious medical waste as of the effective date of the bill, which was February 23 of this year.

The P.S.C. was given six months to do that, and by August 23, the Commission had grandfathered in those carriers that we believed had met the statutory conditions of the grandfathering, and there were several.

There are several more at the Commission at this point with applications pending for infectious medical waste authority that have not been grandfathered.

So at present in this state, there are counties with no carrier that has been authorized by the Public Service Commission to commercially transport infectious waste.

I give you one more variable in this scene of regulated haulers out there, and that is the existence of a case in federal court.

That case was brought by medical waste haulers who are primarily domiciled outside the state of

West Virginia who come into West Virginia and haul waste back out to a disposal facility.

In last August of 1990, these two companies went to the federal district court for the southern district here in Charleston and obtained an injunction against the Public Service Commission to prevent us, to stop us from regulating their activity until it could be determined whether our activity is a burden on interstate commerce, if it is not permissible under the constitution.

So the state of affairs concerning the regulation of the transportation of infectious medical waste is in limbo, to be frank with you, at this point.

We did implement 2141 as it pertained to us and have grandfathered in certain carriers, and as I mentioned, although we have not grandfathered in carriers that encompass the entire state at this point, there are applications pending before the commission for a certificate for all infectious waste that would, indeed, cover the entire state several times over, as a matter of fact, and those are basically just pending.

The Public Service Commission has been waiting for some of these rulings from federal court to

determine its jurisdiction.

The Commission at this point has not determined when it will act on those applications specifically, because of the federal court case.

So when Mr. Schock contacted me a few days ago, he expressed concern that some carriers had brought up that some of the state was, indeed, unserved by commercial carriers, that there were generators that had no carrier out there that had been authorized by the Public Service Commission, and he asked me to respond to that today, and I will try to be more brief about that response.

It is our understanding that there are a number of carriers out there with no Public Service Commission authority that are, indeed, transporting this waste commercially.

The same carriers may well be out-of-state corporations or instate.

I think there are probably both that are doing this, and in the meantime, the Public Service Commission, again to be frank, does not feel it can stop these carriers at this point until the case is resolved in federal court.

So the particular suggestion of some carriers that Mr. Schock's office would be, rather than the Public Service Commission, would be willing to grant temporary authority to some of these carriers, and as some of you know, the Commission speaks only through its orders officially, I cannot speak for the three-member Commission specifically only to say that I will carry this concern to them, and perhaps in the context of the cases pending before the Commission, they will be able to answer that.

I don't have any specific answer except to tell you generally the Commission is aware of the situation, that there are counties with no P.S.C. authorized carrier and that are generating infectious medical waste without an authorized carrier, that is a Public Service Commission authorized carrier.

I brought with me today a few copies -- there are a few more here.

This particular document contains a map of West Virginia showing you by carrier where the Commission has grandfathered in existing carriers, pursuant to 2141.

The second map in there shows you the carriers, the number of applications pending and what

carriers have those pending before the Commission by county.

Then attached to the back of that is a docket of P.S.C. cases, specifically cases pending that involve an application for authority to transport infectious medical waste.

To reference why this should become part of this particular public meeting, I should point out that the proposed rules would require a commercial carrier of infectious waste in the state to obtain Public Service Commission Authority, if applicable, prior to transportation.

That would be a requirement that they would be held accountable for, I would presume, in the context of the health rules, so if, indeed, the rules are finalized in their present form, and if, indeed, the case in federal court I told you about is decided in favor of the Commission eventually, then it is our position that the provision would kick-in for purposes of enforcement.

It is up in the air right now, and I cannot be more specific without going into the details of the cases pending, and I'm not inclined to do that.

My opposing counsel is out there in the

audience, and I don't really want him to have an opportunity for equal time on that, but, of course, he shall if he wants to. I would entertain questions.

MR. SCHOCK: If a carrier comes to me and requests a permit from the Health Department --

MS. HOWARD: Identify yourself.

MR. SCHOCK: Joe Shock, Office of Environmental Health Services.

If a carrier comes to me and wants to be permitted under our proposed rule, which they are required to do, and they are not licensed by the P.S.C., does that put me in any kind a legal difficulty, because, frankly, the case you are talking about conceivably can go through an appeal process that could last 12 to 24 months or something like that, I'm not really sure how long.

MR. CRABTREE: There is some reluctance on my part, Mr. Schock, to try to guess on either the Commission or federal court, but as a practical matter, I do not believe the Commission would hold a carrier responsible for a requirement of a P.S.C. certificate in the context of any kind of enforcement case or in the context of your rules until the case I told you about is settled in federal

court.

MS. HOWARD: Please identify yourself and who you are representing, if you are representing someone.

MS. SMITH: My name is Sloan Smith, and I represent the West Virginia Solid Waste Haulers Association, and the company I work for is General Refuse Service.

You mentioned that you might entertain the idea of temporary authority.

The way I understand it, though, you have three applications before you right now that are statewide applications for temporary authorization.

All you need to do is act on those temporary authorities, and I think the state would pretty much be taken care of until this is settled also.

MR. CRABTREE: It is my understanding there are at least three applications pending for temporary authority, maybe only three statewide. There may be other applications covering parts of the state for temporary authority as well.

Yes, I think that possibly the Commission might use those pending cases as a vehicle.

At this point, everything has been put on hold for a year, basically while we were briefing some law

in federal court and the court was deciding how it was to conduct the upcoming hearing in this case, so it was a long process, but that would be one vehicle, I think that is true.

MS. HOWARD: Excuse me just a moment, is there an Angela Edens here? If so, we have a message.

(No response.)

MS. HOWARD: Is there anyone else that wishes to ask Mr. Crabtree a question?

I don't want to let this hearing get too far into actions of the P.S.C., because the topic really is the proposed rule on infectious medical waste. No other questions?

(No response.)

MS. HOWARD: Thank you.

(Mr. Crabtree stands aside.)

MS. HOWARD: Next then I would like to call Doctor Harry Newell. Is Doctor Newell here?

(THEREUPON came Doctor Harry Newell.)

MR. NEWELL: Mr. Schock, Mr. Wyatt and other interested people, we, as veterinarians --

MS. HOWARD: Identify yourself.

MR. NEWELL: I am Doctor Harry Newell, and I represent the West Virginia Veterinarian Medical Association.

We, as veterinarians, realize that we are covered under these rules and regulations, and hopefully, we will comply as requested and as demanded.

We do have some concern in relation to how certain vaccines and certain sharps will be disposed of relative to sales to lay people.

Specifically, it appears in the last month or two that several drug stores, and Kroger, in particular, a grocery chain, is involved in the sale and distribution of small animal vaccines.

Feed stores, for years, have been involved in the sales of large animal or food animal vaccines, and they are producing sharps, obviously, but specifically in regard to the small animal products, you have a rabies product which is an attenuated product, which could revert and could be an infectious product if not properly handled.

I'm talking about the syringe residue leptospirosis, which produces a disease in humans called Wiel's disease.

There is another product that is in the canine distemper vaccine commonly, Brucellosis, which is a very variable vaccine commonly only dispensed through veterinarians, but it is not unusual to find products which are specifically designed to be distributed to veterinarians to find their way through lay channels.

The Strain 19 Brucellosis vaccine, which Brucellosis causes a high fever, Strain 19 is for variables in the virus itself. It is found in milk and meat products.

Lyme disease is a new disease, and a new vaccine is available, and veterinarians have a concern about these.

There are other vaccines, and I do not intend to enumerate all of them, but we wonder if under 2-2-1, whether exempt under individual households.

It says a member of a household during self-health care, and it appears this paragraph would apply, and it appears that it might be covered under paragraph 11-16, where it appears that this paragraph states that if you are dispensing these type of products, then you shall collect the residue of these products and then you shall dispose of these products, and this is not true, Joe?

So my reason to be here today is to point out that veterinarians do have a concern about the distribution of these products.

Actually as early as two months ago, veterinarians had little concern about this, because it was not a common procedure, but within the last month or two, it has become a major cause of concern to veterinarians, and we would like to call your attention to these problems.

I would have to say that as veterinarians, we feel that we have been treated fairly relative to the rules and regulations, and we will comply to the rules and regulations as outlined. Thank you. Are there any questions?

MS. HOWARD: Please, if you speak, identify yourself and stand so people can hear you.

MS. LANDFREED: I'm Sandra Landfreed with the Office of Health Facility Licensing and Certification. These vaccines are alive, is that what you said?

DR. NEWELL: Some of them are. At the present time, the Lyme disease is not a live vaccine. The rabies vaccine is a live vaccine. The lepto vaccine is a live vaccine, and the Strain 19 is not a live vaccine.

The Lyme vaccine, I believe at the present time, is only produced under a killed product.

Obviously, they are attenuated vaccines, but any attenuated vaccine can be attenuated down to where it will produce an immunity but not produce the disease.

It always has the opportunity to revert back to where it will not only produce the immunity but it will also produce the disease.

(Doctor Newell stands aside.)

MS. HOWARD: The next name I find is Lillian Morris.

(THEREUPON came Ms. Lillian Morris.)

MS. MORRIS: Good morning, my name is Lillian Morris. I am Safety Director at Charleston Area Medical Center and responsible for waste management planning.

I appreciate the opportunity to comment on the proposed rules today. The process for promulgating the proposed infectious medical waste rule has been a long and arduous one.

The Department of Health and Human Resources is to be commended for the collaborative method used in development of the proposed rule.

However, it is our considered opinion that the proposed rule places unnecessary restrictions and requirements on the health care industry without providing the community with significant benefits.

In addition, the rule does not support or encourage health care facilities to work together for the effective and efficient management of infectious medical waste for our communities.

Many activities required by this rule are unnecessary and extremely costly for the appropriate and safe management of infectious medical waste.

It should be emphasized that there is no factual information to indicate infectious waste causes negative environmental occurrences.

The rule has inappropriately applied techniques for management of hazardous chemicals to the management of infectious waste.

We support the proper and responsible management of infectious waste but submit that over-regulation provides no additional protection or benefit to the public for the cost that must be incurred.

Due to the restrictions this rule places on

generators of infectious waste having on-site treatment facilities and the liability it generates, many hospitals may find it necessary to limit acceptance of infectious waste from others in the health care community needing assistance, such as doctors' offices, ambulance and rescue services, dentists, public health clinics and others.

Today hospitals with waste management facilities provide this assistance to other health care providers. The assistance should be fostered and supported by the regulations, not penalized.

It is the goal of West Virginia health care facilities to provide safe, efficient, and effective management of infectious medical waste from generation to disposal.

As a community neighbor, we share community concern and are sensitive to the impact our activities may have on our environmental.

The West Virginia Medical Waste Act emphasizes the concept of local and on-site management of medical waste.

It must be pointed out that the rules discourage the health care community from combining efforts

to achieve the best management solution, because it lacks a mechanism for joint ventures for waste management.

Without a mechanism that encourages health care facilities to work together to establish the most effective management system, West Virginia will continue to be, as it is today, a major exporter of waste to other states.

Concern for effective waste management and increasing regulations are encouraging health care facilities to take an ever-increasing look at our management practices.

Hospitals view themselves as partners with the Health Department and others in defining today's activities and planning for tomorrow's needs. It is our desire to work toward this goal.

We would ask that the Department of Health and Human Resources seriously re-evaluate the language and restrictions contained in the proposed draft regulations before filing of the rules.

It is our belief that health care facilities in the state of West Virginia will be adversely affected in both time and money without the benefit of protecting the

public health and the environment from a waste stream that has had no demonstrated environmental damage. Thank you.

MS. HOWARD: Thank you.

(Ms. Morris stands aside.)

MR. HOWARD: Mr. Bob Foster.

(THEREUPON came Mr. Robert Foster.)

MR. FOSTER: My name is Robert L. Foster, and I am Chairman of the West Virginia Manufacturers Association Environmental Safety and Health Committee.

I am speaking today on behalf of the Manufacturers Association regarding the proposed Title 64, Series 56 Infectious Medical Waste regulation filed September 3, 1991.

My oral comments are brief, and I will present you with written comments.

Basically, our association is concerned the regulation, as written, might not allow the manufacturers who have hazardous waste generators to continue to burn their medical waste that is generated from their infirmaries in the incinerators they have in some of the plants.

Although there is a paragraph in the regulation that says infectious medical waste contaminated

with hazardous waste can be treated as hazardous waste, I'm not too sure exactly what that language really means.

Does that mean they have to mix chemical waste with contaminated waste --

In any case, we are concerned that the waste will not be allowed to continue to be burned in the existing hazardous waste incinerators located in some of our member company plants.

Most of our companies, our manufacturers will be small-quantity generators. They do generate less than 50 pounds per month of volume.

However, there are a couple that may occasionally need to be over the 50 pounds limitation, and we would like to see that 50-pound limitation increased to between 50 and 100 pounds.

The Manufacturers Association would also request favorable consideration in allowing medical waste to be stored in areas that have equivalent containment systems as specified in 8.8 of the regulations.

Some of our members have two or more plants in the same general area, and we would, therefore, like to see section 9.3.2 to be revised to allow transportation

consolidation for disposal of small quantities of medical waste generated at nearby common parent company plants without all the transportation and application permits and the paper work associated with transporting these small quantities to a common facility where it could be disposed of.

Again, on behalf of the Manufacturers Association, I express my appreciation for the opportunity to present this statement and submit our written comments.

(Mr. Foster stands aside.)

MS. HOWARD: The next person would be Mr. John Roach. Mr. Roach, if you will come forth, and please be sure and identify yourself and who you represent.

(THEREUPON came Mr. John Roach.)

MR. ROACH: My name is John Roach, and I am an attorney. I represent DeRoyal Industries. We have previously submitted, although its timely arrival was not assured, several written comments for your consideration.

Basically, our comments deal with our particular product, which we call a trace cart. This actually is the baby of the trace cart, which is larger. This is a 12-inch waste cart.

We also have a bigger brother, which is 20 inches and the mama, or shall we say the mother of all trace carts, which is a 40-inch trace cart.

These products are designed for the safe containment of both sharps and non-sharps products, and that is where are concern rests in regards to these regulations, particularly the sixth section of the regulations concerning packaging.

It is not altogether clear to us whether or not, in the scheme of the regulations, whether you must use a plastic bag internally with your containment system or whether a device or product such as ours, which is leak proof and puncture resistent, might also serve both or eliminate the need of the plastic bag.

Secondly, we believe that for products which are designed, as is ours, and which have the structural integrity that ours does that this product should be utilized without the need for the use of a corrugated or fiberboard container.

It is not altogether clear to us under the regulations, I believe it is 6.2 and 6.3, whether or not a polyethylene or polystyrene containment system, such as

ours, is an equivalent container or device when compared to fiberboard or cardboard containment.

So we would suggest that the regulations, either through the interpretative process or through actual language changes, make provision for a containment device such as this with which when sealed is leak proof and puncture resistant and virtually impossible to open.

Perhaps an ax would do it, but under normal conditions, it is virtually impossible to open, so we would present that for your consideration and offer you the baby of the family.

MR. SCHOCK: I am going to take it home and fill it full of beer.

MR. ROACH: Don't put the lid on because you may never get to the beer.

MR. SCHOCK: I've got three young grandkids, and they would just love to play in that.

MS. HOWARD: I'm going to move it away, so that I don't get disposed of as infectious medical waste.

(Mr. Roach stands aside.)

MS. HOWARD: The next person will be Mr. Richard Stevens. Please identify who you are and who you are

speaking on behalf of.

(THEREUPON came Mr. Richard Stevens.)

MR. STEVENS: My name is Richard Stevens. I am the Executive Director for the West Virginia Dental Association.

I am pleased with the opportunity to just briefly comment on the proposed rules and regulations regarding the management of disposable of infectious waste.

These regulations had in the beginning, I believe almost two years ago, in December of '89, the goal of all interested parties at the Department of Health, as well as health providers and others who are involved in either management or disposal of infectious waste, a common goal, that goal of reducing to the maximum extent possible within our resources available to us in this state the proper management and disposal of infectious waste.

Of course, dentists, dental offices are covered under the regulations.

The profession of dentistry has for several years voluntarily been taking steps and procedures to minimize the exposure of infectious materials and waste to the public.

We have been very pleased over the last two years to have been working with the Department of Health in drafting these regulations, and as far as the profession of dentistry is concerned, we find them satisfactory and in keeping in the interest of everyone. Thank you.

MS. HOWARD: Thank you, Mr. Stevens.

(Mr. Stevens stands aside.)

MS. HOWARD: Moving right along here, Mr. Albert Tiechie.

(THEREUPON came Mr. Albert Tiechie.)

MR. TIECHIE: My name is Albert Tiechie, and I am here to represent Beckley Hospital, Beckley, West Virginia. I have submitted some written comments, and since that time, have revised them.

I offer to you the revised copy. I have reviewed the rule and have concerns regarding the section on transportation of infectious medical waste.

I would like to note at Beckley Hospital, we autoclave 95 percent of the infectious med. waste that we produce, so we transport very little. We do have occasion to transport some.

I have offered some alternative wording,

because I just personally think you should not shoot holes in somebody's hard work without offering some alternatives. I think you should offer something to use for a substitute.

Section 971 through 975 deals with vehicles used to transport infectious medical waste. The backhauling of food substance should not be permitted and is, indeed, prohibited by section 975.

However, the present wording will require our hospital and probably others who are rural hospitals to acquire an additional vehicle, as food substance and infectious waste can never be transported by the same vehicle.

The two tasks are mutually exclusive for the life of the vehicle by section 975, and disinfection is not an available alternative.

In a small facility, one truck is often used for many different purposes, and on occasion may transport small amounts of infectious waste and on other occasions may transport a small amount of food substances.

I would like to offer an addition possibly under 9.7.1.1, which would satisfy the intent of the rule, to protect the public health, but cause much less hardship

and/or expense for smaller institutions.

The wording I would propose is that separate removable cargo carrying portions are acceptable, and if used, shall comply with 9.7.1 through 9.7.5, in lieu of the entire vehicle.

What would this do? This addition would allow institutions that have multi-use vehicles, i.e. small trucks, to obtain a container section, a separate container section for the vehicle that would be dedicated to the transportation of infectious med. waste and secured in or on the vehicle only when this occurs.

All other requirements would still apply to the entire vehicle. This provision will eliminate the possibility of backhauling of food substances in any container, including trailer sections of tractor trailers that has been used for infectious waste.

Preventing the simultaneous transport of infectious waste and food substances using the separate container sections can be accomplished by adding the following clause to section 975 after the words food or foods, simultaneous to the transport of infectious medical waste.

Making these small changes will protect the public health, but it will preclude the need for the purchase of additional vehicles.

It is possible that instead of hauling this small amount of infectious waste ourselves, we could contract and have it done.

That is certainly an alternative, and I would like to point out from an environmental standpoint, that it is a 6,000 foot trip for our facility to the disposal facility that we use for some five percent of our waste.

It is a hundred miles round trip for the nearest contractor that handles our infectious med. waste, so for public health, it is much more advantageous to transport 6,000 feet, as opposed to 100 miles.

This would also minimize the cost related to compliance with the rule.

The vehicle could then be used for occasional transportation of food substance without risking any exposure to infectious waste which is then transported in an entirely separate container.

It should be noted, as most of you probably

know, that all food is normally delivered to hospitals by suppliers, but there will always be extraordinary circumstances where a small pick-up is required.

I hope you will consider these comments in the draft of the final rule. I do not think these additions weaken the rule, and they will be very helpful to the smaller institutions. Thank you.

MS. HOWARD: Thank you.

(Mr. Tiechie stands aside.)

MS. HOWARD: The last person I have signed up to speak is Mr. Gil Delaura.

(THEREUPON came Mr. Gil Delaura.)

MR. DELAURA: My name is Gil Delaura. I am Vice President and General Counsel for the West Virginia Hospital Association. Good morning, I will be try to be brief.

I know some people think it is impossible for a lawyer to be brief. There are a couple of brief comments. First of all, the Association wishes to thank the Department of Health.

Obviously, the Department is facing a major challenge in implementing the Medical Waste Act, and we wish to express our appreciation for the patience and dedication

and collaborative effort which has been consistently exhibited by the Department since the passage of the infectious waste legislation.

Two comments, one, I want to read into the record a paragraph or two from an article in the New England Journal of Medicine, Volume 325, Number 8, by Doctor Rutala, R-U-T-A-L-A, and by Doctor Weber, W-E-B-E-R, University of North Carolina, Chapel Hill.

Both of these individuals have spent years in studying medical and infectious waste.

One or two brief comments for the record, quote, "Most proponents of state and federal medical waste legislation have claimed that medical waste poses a threat to human health and must therefore be strictly regulated."

"However, the alleged health hazards of our current medical waste disposal practices have not been demonstrated."

"The potential for infection from contact with medical waste, other than sharps, is virtually non-existent."

"Contaminated sharps are the only form of medical waste that have been associated with the

transmission of infectious disease."

"This is not surprising, given the intrinsic capability of sharps to disrupt the integrity of the skin and introduce infectious agents into the wound."

"All the reports describing the transmission of infectious agents by contaminated sharps have occurred in settings of occupational health care, however, and none have been associated with environmental injuries occurring after the disposal of the waste outside the hospital."

"There is no epidemiologic evidence that hospital waste disposal practices have caused disease in the community."

The second paragraph, which I think is important for some people in this group, refers to many things in the newspapers about red bags in landfills and the sky is falling, et cetera, because somehow there happens to be a red bag from some health care facility or from somewhere that ended up in a landfill.

The Association historically has supported the law and regulation from D.N.R. which says hospitals and other health care facilities and generators of infectious medical waste cannot put red bags in a landfill.

We support that, but, again, to set the record straight, I think it is important to realize, and I think it is important for the citizens of West Virginia to clearly understand, that when we talk about contamination and the danger of infection in landfills, we are really talking about generators from the community property.

As the article states in the New England Journal of Medicine, quote, "Household waste contains, on average, 100 times more microorganisms with pathogenic potential for humans than medical waste."

"From our daily experience with household waste and decades of waste removal and burial in landfills, we can deduce that the incremental health risk from the less microbially contaminated medical waste are nominal."

Let me get this out for the record, if I may. I would request that the entire article be put into the record. I do have some extra copies if anyone is interested in them, not many, but I do have a few.

The second thing I would like to briefly comment on concerns one point in the regulations dealing with non-commercial medical waste management facilities.

The proposed rule does not encourage the

formation of non-commercial medical waste facilities on a local and regional level.

For example, hospitals located within the same city or town may be able to realize economies of scale by combining together in an efficient manner their waste disposal.

Under this rule, they will be probably highly unable to do so.

Hospitals in rural areas in our state already under financial duress will find themselves in a precarious position if they are forced to dispose of infectious medical waste exclusively by use of commercial haulers.

An unpinnable financial dilemma may develop for both urban and rural hospitals.

Keep in mind that hospitals will have to show some amount of leadership in being able to accept infectious medical waste generated by other generators in the community, such as doctors' offices, public health clinics, primary care clinics, dental offices.

The Department should develop standards which encourage, as opposed to discourage, local joint

efforts among health care providers in responsible disposal of infectious waste.

That concludes my comments. I have written comments to follow-up here at this point. Thank you very much.

MS. HOWARD: Thank you, Mr. Delaura.

(Mr. Delaura stands aside.)

MS. HOWARD: Now is there anyone who has decided in the meanwhile that they would like to speak who has not previously spoken. I would like to give those persons a chance at this time.

(No response.)

MS. HOWARD: I don't see any hands up. Is there anyone who has already spoken that wishes to say something else?

DR. NEWELL: I would like to ask a question, please.

MS. HOWARD: We'll try, Dr. Newell.

DR. NEWELL: It's an easy question. I would like to ask Mr. Schock, are the proposed rules that we are discussing here now, are they now in effect?

MS. HOWARD: They are not in effect at this point.

They are scheduled probably to go into effect next week.

We certainly have to, I think, consider the possibility for making amendments to the rule which would go into effect on an emergency basis next week.

I'm not quite sure what the timing of any possible amendments would be.

Of course, the rule will also concurrently approximately be submitted to the Legislature for its review, and the emergency filing is only of temporary duration. Any other questions?

(No response.)

MS. HOWARD: Well, it has been a very short public hearing. I do declare the public hearing closed.

(WHEREUPON, the hearing concluded at 11:00 a.m.)

REPORTER'S CERTIFICATE

STATE OF WEST VIRGINIA

COUNTY OF KANAWHA, to wit:

I, the undersigned, SHELIA MILLER, do hereby certify that the foregoing is, to the best of my skill and ability, a true and accurate transcript of all the testimony as set forth in the caption hereof.

Given under my hand this _____ day of October, 1991.

Certified Court Reporter