WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #6

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE

AGENCY: Division of Health, Department of Health & Human Resources TITLE NUMBER: 64

AMENDMENT TO AN EXISTING RULE: YES X NO _____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 56

TITLE OF RULE BEING AMENDED: Infectious Medical Waste

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

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) SB 305

SECTION 64-5-2(f), PASSED ON March 10, 1999.

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON THE FOLLOWING DATE: July 1, 1999

Joan E. Ohl

Joan E. Ohl, Secretary

$9.00

DEPARTMENT OF HEALTH AND HUMAN RESOURCES
RULE PROMULGATION HISTORY ABSTRACT

Rule Title: 64 Infectious Medical Waste

Series Number: 56

Amendment of Existing Rule: X **New Rule:** __

Responsible Agency: Division of Health

Date Filed for Public Hearing or Comment Period: July 22, 198

Date of Public Hearing (if any):

Date Public Comment Period Ended: August 21, 1998

Date Agency-Approved Rule Filed with the Legislative Rule-Making Review Committee: September 10, 1998

Date of Filing of Modified Rule as Approved by the Legislative Rule-Making Review Committee: January 25, 1999

Date of Final Filing: April 29, 1999

Effective Date: July 1, 1999

Authorized by: S.B. 305 **(With amendments? Yes** __ **No** X**),**
Passed: March 10, 1999

Dates Emergency Rule in Effect (if any):

TITLE 64
LEGISLATIVE RULE
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 56
INFECTIOUS MEDICAL WASTE

§64-56-1. General.

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

1.2. Authority. – W. Va. Code §§20-5J-6(a) and 22-18-7(d). Related - W. Va. Code §§20-5J-1 et seq., 20-5K-1 et seq., and 22-18-1 et seq.

1.3. Filing Date – April 29, 1999.

1.4. Effective Date – July 1, 1999.

1.5. 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 in W. Va. Code §20-5J-2.

§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, or who proposes to do so, except as specified in Section 2.2 of this rule.

2.2. Exemptions.

2.2.a. 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.b. 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 means 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, and wastes from the production of biologicals and antibiotics likely to have been contaminated by an infectious agent.

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 whose act or process produces infectious medical waste.

3.7. Hospital. -- An institution which is primarily engaged in providing to patients in the institution, 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 impact in humans.

3.9. Infectious Medical Waste. --

3.9.a. 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.b. For the purposes of this rule, infectious medical waste includes the following materials:

3.9.b.1. Cultures and stock of microorganisms and biologicals;

3.9.b.2. Blood and blood products;

3.9.b.3. Pathological wastes;

3.9.b.4. Sharps;

3.9.b.5. Animal carcasses, body parts, bedding and related wastes;

3.9.b.6. Isolation wastes;

3.9.b.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.b.8. Waste contaminated by or mixed with infectious medical waste.

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

3.9.c.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.c.2. Human remains lawfully interred in a cemetery or in preparation by a licensed mortician for interment or cremation;

3.9.c.3. Used personal hygiene products, such as diapers, facial tissues and sanitary napkins;

3.9.c.4. Gauze and dressing material, containing small amounts of blood or other body secretions with no free flowing or unabsorbed liquid;

3.9.c.5. Hair, nails, and extracted teeth;

3.9.c.6. Waste generated by veterinary hospitals, except for waste meeting the criteria found in Sections 3.9.b.1, 3.9.b.4, or 3.9.b.5 of this rule; and

3.9.c.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.d. 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.e. 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. 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.

3.13. 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 of the federal Resource Conservation and Recovery Act of 1976, 42 U.S.C. § 6921 et seq., as amended, or any household waste as defined in the regulations promulgated pursuant to Subtitle C of that Act.

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, society, association, government body 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, 42 U.S.C. § 6921 et seq., 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. Permit Application and Approval Procedures for Non-Commercial Infectious Medical Waste Facilities.

4.1. This section applies only to non-commercial infectious medical waste facilities. 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 4.17 of this rule.

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

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

4.4. The owner of an infectious medical waste facility shall provide public notice of intent to apply for a permit.

4.4.a. Public notice shall be given by the following methods:

4.4.a.1. By mailing a copy of a notice to those persons whose names are included on a mailing list, maintained by the department of health and human resources, of people wishing to be notified of such requests; and

4.4.a.2. Any other method reasonably calculated to give actual notice of the action in question to the persons potentially affected by it, including press releases or any other forum or medium to elicit public participation.

4.5. The applicant for a permit for a non-commercial infectious medical waste facility shall maintain a public participation file. This file shall contain a summary of all comments and responses received during the pre-application public notification phase by the facility. This file shall be submitted to the secretary by the applicant with the application.

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

4.6.a. The name, mailing address, and location of the facility, using latitude and longitude to the nearest second, for which the application is submitted;

4.6.b. The name, address, telephone number and fax numbers of the owner of the facility, and if the owner is an individual or a partnership, the social security number or numbers of the owner or partners;

4.6.c. The name, address, telephone number and fax numbers of the manager of the facility, if different from the owner; and if the manager is an individual or partnership different from the owner, the social security number or numbers of the individual or partners;

4.6.d. Two copies of the proposed infectious medical waste management plan as required by Section 5 of this rule;

4.6.e. A copy of the public participation file; and

4.6.f. Information needed to demonstrate that the facility will be operated in compliance with this rule.

4.7. For new non-commercial 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:

4.7.a. The map scale and date;

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

4.7.c. The orientation of the map (north arrow);

4.7.d. The legal boundaries of the facility with the latitude and longitude to the nearest second for the site;

4.7.e. Access control (fences, gates); and

4.7.f. 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).

4.8. The secretary shall not begin the evaluation of a permit before receiving a complete application, as determined by the secretary. Within thirty (30) days of the secretary's receipt of a permit application, the completeness of the application shall be judged independently of the status of any other permit application or permit for the same facility or activity.

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

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

4.11. When the secretary determines an application for a new non-commercial infectious medical waste facility or a major change to an existing facility to be complete, he or she shall instruct the applicant or permittee to give public notice.

4.11.a. Public comment shall be conducted in accordance with the following guidelines:

4.11.b. Public notice shall be given by the following methods:

4.11.b.1. By mailing a copy of a notice to those persons whose names are included on a mailing list, maintained by the department of health and human resources, of people wishing to be notified of such requests; and

4.11.b.2. By publishing the public notice as a Class II legal advertisement in a qualified newspaper, as defined in W. Va. Code §59-3-1, serving the county where the facility will be located. That legal advertisement shall also be placed in newspapers of adjacent counties when a proposed facility is within two (2) miles of a county line. The cost of the publication will be the responsibility of the applicant who shall send a certification of publication to the secretary within twenty (20) days after publication; and

4.11.b.3. Any other method reasonably calculated to give actual notice of the action in question to the persons potentially affected by it, including press releases or any other forum or medium to elicit public participation.

4.11.c. All public notices issued shall contain the following information:

4.11.c.1. The name and address of the office processing the permit action for which notice is being given;

4.11.c.2. The name and address of the permittee or permit applicant, and if different, of the facility or activity regulated by the permit;

4.11.c.3. A description of the activities covered in the application, including the type of technology that will be used to treat infectious medical waste, the types, amounts, and origins of infectious medical waste to be handled, site improvements, and infectious medical waste handling methods;

4.11.c.4. The name, address, and telephone and fax numbers of a person from whom interested persons may obtain further information;

4.11.c.4.A. The availability of the application shall include, but not be limited to, copies placed at the courthouse of the county in which the facility is to be located, the city or town hall of any municipal government within two (2) miles of the proposed location of the facility, and the primary public library in the county.

4.11.c.4.B. Copies of the application shall be available from the secretary at no cost.

4.11.c.5. A general description of the location of the proposed permit area including streams;

4.11.c.6. A clear and accurate location map. A map of a scale and detail found in the West Virginia official state highway map is the minimum standard for acceptance. The map size shall be at a minimum two (2) inches by two (2) inches. Longitude and latitude lines and a north arrow shall be indicated on the map, and such lines will cross at or near the center of the proposed permit area;

4.11.c.7. A reference to the date of previous public notices relating to the permit;

4.11.c.8. That any interested person may submit a written comment on the application, and that such comments shall include a concise statement of the nature of the issues raised;

4.11.c.9. That any interested person may submit a written request for a public hearing, and that such request shall include a concise statement of the nature of the issues raised; and

4.11.c.10. That the secretary shall conduct a public hearing within forty-five (45) days in the county where the proposed facility is to be located whenever he or she receives a request.

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

4.11.d.1. Request additional information from the applicant; and

4.11.d.1.A. Reopen or extend the public comment period for thirty (30) days to give interested persons an opportunity to comment on the information or argument submitted; or

4.11.d.1.B. Require a public hearing.

4.11.e. In the event a public hearing is held:

4.11.e.1. Public notice of the hearing shall be given by the secretary at least thirty (30) days before the hearing;

4.11.e.2. A transcript of the hearing shall be available to the public from the secretary;

4.11.e.3. At the hearing, any person may make oral comments and submit written statements and data concerning the proposed major changes or new facility. Reasonable limits may be set on the time allowed for oral statements, and the written statements shall be submitted to the secretary no later than ten (10) days after the close of the hearing; and

4.11.e.4. The secretary shall act on the permit application within thirty (30) days after the date for the submission of written statements to the secretary.

4.11.f. In the event a public comment period is held, the secretary shall act on the permit application within thirty (30) days after the close of the comment period.

4.12. 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.

4.13. 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.

4.14. 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.

4.15. 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 or public comment reveals a situation which would endanger public health.

4.16. 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, That no prior approval is necessary in the case of a hospital which may in an emergency make an immediate change in its plan necessary to protect the safety and care of patients, employees or the public. In such an event, the hospital shall notify the secretary immediately followed by written notification within fifteen (15) days. 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. A major change consists of any of the following:

4.16.a. Installing a new unit for the treatment of infectious medical waste or replacing existing units not including improvements, as determined by the secretary, or repairs to existing units;

4.16.b. Changing the location of treatment; or

4.16.c. Permanently increasing the volume of infectious medical waste by at least

twenty percent (20%), if the amount of the increase is fifty (50) pounds or more.

4.17. 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.

4.18. Permits issued by the secretary for a non-commercial infectious waste facility are not transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation. An existing large quantity generator that changes ownership, however, may continue to operate under the previous owner's permit conditions until such time as the secretary can process the new permit application required by this section, provided the new owner sends the secretary a letter in which the new owner:

4.18.a. Advises the secretary of such change of ownership including any management changes; and

4.18.b. Agrees to be bound by the conditions and policies established in the infectious medical waste management plan for that facility by the previous owner until such time as a new management plan can be approved by the secretary.

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

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

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

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

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

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

5.2.d. Transportation method;

5.2.e. Manifest systems and labeling;

5.2.f. Disposal methods consistent with Section 10.4 of this rule;

5.2.g. The name, address, telephone and fax numbers and public service commission

or other permit or license number of any infectious medical waste transporter, if applicable;

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

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

5.2.l. A description of the procedures used to:

5.2.l.1. Prevent hazards in loading and unloading operations;

5.2.l.2. Prevent run-off from infectious medical waste handling areas to other areas of the facility or environment;

5.2.l.3. Prevent contamination of water supplies;

5.2.l.4. Mitigate effects of equipment failure and power outages; and

5.2.l.5. Prevent exposure of personnel to infectious medical waste;

5.2.m. Procedures for continuity of operations during a change of ownership;

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

5.3.b. 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.c. 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.d. Procedures for keeping records in accordance with Section 13 of this rule;

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

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

5.3.g. 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.g 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.a. 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.b. 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.c. 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.a. All infectious medical waste shall be packaged as required by this rule prior to storage, treatment, or transport.

6.2.b. 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.c. 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.c.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.b 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.c.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.b of this rule.

6.2.d. 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" or "regulated medical waste" 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.e. 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.f. 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 bags of different colors.

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

6.2.g.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.g.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.g.3. Swabbing or rinsing the container with a chemical sanitizer double the strength specified in Section 6.2.g.2 of this rule or a chemical with equivalent sanitizing capabilities.

6.2.h. Employers shall direct employees packaging infectious medical waste to use personnel protection equipment and shall provide training in its use.

6.3. Labeling Requirements.

6.3.a. 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.a.1. The name, address, business telephone and fax numbers of the generator;

6.3.a.2. The words "infectious medical waste" or "biomedical waste" or "biohazard" or "regulated medical waste";

6.3.a.3. The name, address, business telephone and fax numbers 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.a.4. The date on which the infectious medical waste was packaged.

6.3.b. 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.a of this rule for infectious medical waste. The following information shall be included on the label:

6.3.b.1. The name, address and business telephone and fax numbers of the generator;

6.3.b.2. The name, address, and business telephone and fax numbers of the facility at which the waste was rendered noninfectious;

6.3.b.3. The weight of the treated noninfectious medical waste and the method of treatment;

6.3.b.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.a. 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 of ten (10) gallons, whichever is less.

7.1.b. 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.c. 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.d. 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.e. 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 procedures for cleaning up a spill:

7.3.a. 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.b. Spray all broken containers of infectious medical waste with disinfectant;

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

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

7.3.e. Clean and disinfect non-disposable items and clothing;

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

7.3.g. 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.d 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 (sealing) 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 prior to transportation to an infectious medical waste management facility, even if refrigerated: Provided, that the total amount of storage time, including transportation to an infectious medical waste management facility, shall not exceed forty-five (45) days. Facilities that treat infectious medical waste on-site shall not store the infectious medical waste more than thirty (30) days.

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

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

9.3.b. 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.a. The international biohazard symbol;

9.6.b. The words "infectious medical waste", or "biomedical waste", or "biohazard" or "regulated medical waste";

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

9.6.d. 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.a. 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.b. Shall be designed and constructed so as to contain any spillage;

9.7.c. Shall be cleaned and disinfected following leakage or spills as provided in Section 6.2.g.3 of this rule;

9.7.d. Shall be cleaned and disinfected prior to using the conveyance for any other purpose as provided in Section 6.2.g.3 of this rule; and

9.7.e. 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.f. Separate, removable cargo-carrying containers are acceptable and if used, Sections 9.7.a through 9.7.e 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.a. The applicant's name;

9.10.b. The business address and telephone and fax numbers of the applicant, including both headquarters and local office;

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

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

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

9.10.g. The name and telephone and fax numbers of a person who may be contacted in the event of an accident or spill;

9.10.h. 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.i. 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 and fax 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.a. All infectious medical waste shall be treated by one of the following methods:

10.1.a.1. Incineration as described in Section 10.2 of this rule;

10.1.a.2. Steam treatment as described in Section 10.3 of this rule;

10.1.a.3. Discharge to a sanitary sewer as described in Section 10.4 of this rule; or

10.1.a.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.b. 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 solid waste incineration and as provided in subdivision 10.2.5 of this rule.

10.2. Incineration.

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

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

10.2.e. 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.f. 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.g. Facilities with incinerators in operation at the time this rule becomes effective may apply to the secretary for a waiver to Sections 10.2.b through 10.2.d 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.b through 10.2.d 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.a. A steam treatment process for infectious medical waste shall at all times maintain:

10.3.a.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.a.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.a.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.a.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.a.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.a.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.b. 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.b of this rule after treatment if recognizable.

10.3.c. 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.d. 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.d.1. The date, time and operator of each usage;

10.3.d.2. The type and approximate amount of waste treated;

10.3.d.3. The post-treatment reading of the temperature sensitive tape;

10.3.d.4. The dates and results of calibration; and

10.3.d.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.

Liquid 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.a. 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 or 10.4 of this rule.

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

10.5.c.1. A listing of the classes and amounts of infectious medical waste the

method could be employed to treat;

10.5.c.2. A copy of the detailed plans for the device used in the method;

10.5.c.3. A written summary of the proper operation of the method and device;

10.5.c.4. A copy of the operation and maintenance manual for the process or device;

10.5.c.5. Copies of approval and denial letters from other states where the process has been evaluated; and

10.5.c.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.

10.5.c.7. To evaluate alternative treatment technologies, the secretary shall use the procedures outlined in the following referenced manual that is incorporated in this rule: State and Territorial Association on Alternate Treatment Technologies, Technical Assistance Manual: State Regulatory Oversight of Medical Waste Treatment Technologies.

10.5.c.8. A non refundable alternative technology evaluation fee shall be submitted with the application in accordance with Table 64-56A at the end of this rule.

§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. The secretary may issue a permit only if he or she makes a specific finding that as to the medical waste stream the proposed facility will be consistent with the legislative findings and purpose stated in W. Va. Code §20-5J-2.

11.5. No person may establish, construct, operate, maintain, or allow the use of property for a commercial infectious medical waste management facility within:

11.5.a. The one-hundred (100) year flood plain;

11.5.b. Five hundred (500) feet of a dwelling, measured from the edge of the boundary of the facility, unless written permission is received from the owner of the dwelling;

11.5.c. 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.c.1. Wetlands;

11.5.c.2. Any endangered or threatened species of animal or plant;

11.5.c.3. Surface water;

11.5.c.4. Groundwater quality; or

11.5.c.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.

11.6.a. Prior to the issuance of a permit to operate a commercial infectious medical waste treatment facility, the intended operator shall obtain a performance bond payable to the Secretary in an amount established by the Secretary equal to the projected cost of operating the facility for sixty (60) days at full capacity.

11.6.a.1. The performance bond shall be paid to the secretary upon:

11.6.a.1.A. Closure of the facility, including voluntary closure and closure as a result of permit revocation or suspension, unless thirty (30) days before closure the operator has notified the secretary of closure and before closure has provided the secretary with certified mail receipts of its mailing of notices of closure to all its customers thirty (30) days before closure: Provided, That a performance bond payment made under this subparagraph shall be returned by the secretary upon verification that the operator provided the notices as required; or

11.6.a.1.B. Improper closure of the facility requiring corrective expenditures by the secretary.

11.6.a.2. A bond payment may be used by the secretary to correct an improper closure and to continue operation of a facility until its customers can be properly notified of the pending closure.

11.7. No person may own, construct, modify or operate a commercial infectious medical waste facility, nor may any person store, transport, treat or dispose of any infectious medical waste without first obtaining a permit from the secretary.

11.8. The owner of an infectious medical waste facility is responsible for insuring that the facility has a permit.

11.9. Pre-siting Notices.

11.9.a. In order to obtain approval to locate a commercial infectious medical waste facility, not under permit to operate as of April 12, 1997, an applicant shall, in accordance with W. Va. Code §20-5K-3, Procedure for Public Participation, file a pre-siting notice with the secretary, the division of environmental protection and the county commission or commissions and the local solid waste authority or authorities of the county or counties in which the facility is to be located. Such notice shall be available for public review, and shall include:

11.9.a.1. A description of the location at which the proposed facility may be sited;

11.9.a.2. Information concerning the anticipated size of the proposed facility;

11.9.a.3. An estimate of the volume, type, and origin of the infectious medical waste to be handled at the proposed facility;

11.9.a.4. A United States Geological Survey (USGS) topographic map showing the location and anticipated boundaries of each site being considered for the proposed facility;

11.9.a.5. A description of the technology that is to be used in the treatment of infectious medical waste;

11.9.a.6. The name, address and telephone and fax numbers of the owner or applicant of the proposed facility;

11.9.a.7. The name, address and telephone and fax numbers of the operator of the proposed facility, if different from the owner or applicant; and

11.9.a.8. Other information that the secretary may require.

11.9.b. The secretary shall mail a copy of the pre-siting notice to those persons whose names are included on a mailing list, maintained by the department of health and human resources, of people wishing to be notified of such pre-siting notices.

11.10. Permit Application Requirements. An application for a permit shall be submitted to the secretary in duplicate on forms prescribed by the secretary, and unless otherwise specified in this rule, shall include the following:

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

11.10.b. The name, address and telephone and fax numbers of the owner of the facility, and if the owner is an individual or a partnership, the social security number or numbers of the owner or partners;

11.10.c. The name, address and telephone and fax numbers of the manager of the facility, if different from the owner; and if the manager is an individual or partnership different from the owner, the social security number or numbers of the individual or partners;

11.10.d. A proposed infectious medical waste management plan as required by Section 5 of this rule. The infectious medical waste management plan shall be incorporated into the permit as part of the permit conditions;

11.10.e. A description of the legal documents upon which the applicant bases his or her legal right to enter and conduct operations on the facility permit area and whether that right is the subject of pending court litigation;

11.10.f. All application documents related to engineering and design plans and specifications as compiled, signed, and sealed by a professional engineer who is registered to practice in West Virginia;

11.10.g. Appropriate legible exhibits, including maps, figures, photographs, and tables, of appropriate scale to show all required details necessary to clarify information or conclusions;

11.10.h. Documentation of arrangements for permitted facilities to receive all treated waste and wastewater;

11.10.i. A treatment technology plan in accordance with the provisions of Section 10.3 through 10.5 of this rule;

11.10.j. 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;

11.10.k. A proposed design and a general discussion of the proposed operating procedures;

11.10.l. A notarized signature of the owner or principal officer verifying that the information contained in the application is true and correct to the best of that individual's knowledge and belief;

11.10.m. A review of land use zoning in the area with particular attention given to areas where zoning variances will be required, where agricultural impact statements may be

required, or where flood plain, river corridors, or wetlands are designated;

11.10.n. A description of the present land use within two (2) miles of the permit area. The description shall include, but not be limited to:

11.10.n.1. Impacts upon transportation facilities;

11.10.n.2. Impacts upon public and private water supplies;

11.10.n.3. Impact upon land use patterns;

11.10.n.4. Impacts upon agricultural, commercial and residential real estate values;

11.10.n.5. Impacts upon wildlife;

11.10.n.6. Impacts upon endangered or threatened species of animals or plants;

11.10.n.7. Impacts upon aesthetics;

11.10.n.8. Impacts upon socioeconomic conditions;

11.10.n.9. Impacts to water resources;

11.10.n.10. Impacts on sewage collection and treatment systems;

11.10.n.11. Impacts on local emergency response crews and firefighters;

11.10.n.12. Impacts upon known recreational, historical, archaeological, or environmentally unique areas; and

11.10.n.13. Other impacts as determined by the secretary.

11.10.o. A large-scale map with a minimum scale of one (1) inch equal to two hundred (200) feet and a maximum contour interval of ten (10) feet, or a 7.5 minute topographic map, showing the location of all of the following that occur either within the site boundaries or within two thousand five hundred (2,500) feet of the site;

11.10.o.1. Water supply wells;

11.10.o.2. Springs;

11.10.o.3. Wetlands (e.g., swamps, bogs, marshes);

11.10.o.4. Streams and drainages;

11.10.o.5. Public water supplies;

11.10.o.6. Other bodies of water;

11.10.o.7. Underground or surface mines;

11.10.o.8. Water quality monitoring points;

11.10.o.9. Occupied dwellings;

11.10.o.10. Roads;

11.10.o.11. Public buildings;

11.10.o.12. Sinkholes;

11.10.o.13. Property boundaries, including site property;

11.10.o.14. Current owners of record both surface and subsurface;

11.10.o.15. Easements or rights-of-way; and

11.10.o.16. One hundred (100) year flood plain boundary;

11.10.p. A description of present and proposed transportation routes and access roads, including any weight restrictions;

11.10.q. A description of buildings, treatment units, roads, and other structures to be constructed in conjunction with the facility, including the size of the construction and the number of miles of road to be constructed;

11.10.r. A description of emissions and discharges, such as dust, odors, gases, leachate, surface water runoff and collected groundwater associated with facility preparation, construction, operation and during and after closure of the facility; and

11.10.s. A non-refundable application fee according to the schedule shown in Table 64-56A at the end of this rule.

11.11. Modifications.

11.11.a. When a permit is modified, only the conditions subject to modification are reopened. All other conditions of the permit remain in effect for the duration of the permit.

11.11.b. The secretary may require additional information and, in the case of a major modification, may require submission of a new permit application.

11.11.c. Minor Modifications.

11.11.c.1. Modifications, except for major modifications as listed in this section, in the infectious medical waste plan may be made without notifying the secretary and shall be included in the next application for permit renewal.

11.11.c.2. Permits may be modified by the secretary at any time except for major modifications as listed in this section. Minor modification does not require the completion of the public notice procedures.

11.11.d. Major Modifications. A permittee shall submit an application for approval of a major modification before implementing the change. All major modifications shall be approved prior to implementation and require the opportunity for a public hearing as required by this rule unless an emergency is declared by the secretary. For the purpose of this section a major modification means:

11.11.d.1. The capacity of the commercial infectious medical waste facility will be increased over the permitted capacity by more than ten percent (10%);

11.11.d.2. The performance or operation of the surface water control system will be significantly affected;

11.11.d.3. A decrease in the quality or quantity of data from any environmental monitoring system will occur;

11.11.d.4. The amount or type of financial assurance will change;

11.11.d.5. The facility boundary will be significantly changed;

11.11.d.6. Authorization is being sought to construct an additional structure;

11.11.d.7. Different permitted facilities are being considered to receive treated waste or wastewater; or

11.11.d.8. Installing a new unit for the treatment of infectious medical waste or replacing existing treatment units not to include repair or improvements to existing units;

11.11.d.9. Changing the location of treatment;

11.11.d.10. Any other action that the secretary determines may present substantial endangerment to public health, safety or the environment; and

11.11.d.11. Other similar modifications as determined by the secretary.

11.11.d.12. Major modifications to an initial application for a new commercial

infectious medical waste facility require the applicant to undergo a new pre-siting process as described in Sections 11.9. through 11.12 of this rule.

11.11.d.13. Permit renewals that contain major modifications shall be treated as major modifications.

11.12. Permit Suspension or Revocation.

11.12.a. Suspension. A commercial infectious medical waste facility permit may be suspended by order of the secretary for any of the following reasons:

11.12.a.1. Violation of, or failure to adhere to, W. Va. Code Chapter 20, Article 5J, this rule, the terms and conditions of the permit, or any order of the secretary issued thereunder;

11.12.a.2. Interference with a representative of the secretary in the performance of his or her duties; or

11.12.a.3. Discovery of failure in the application or during the permit issuance process to fully disclose all significant facts or the permittee's misrepresentation of any significant fact at any time.

11.12.b. Revocation. A commercial infectious medical waste facility permit may be revoked by order of the secretary for any of the following reasons;

11.12.b.1. An attempt by an applicant or permittee to obtain or renew a permit by means of fraud, deceit or material misrepresentation;

11.12.b.2. Any deficiency at the facility constituting an imminent pollution, health, or safety hazard;

11.12.b.3. Persistent violation of W.Va. Code Chapter 20, Article 5J, this rule, permit terms and conditions, or orders issued by the secretary under that Code Article or this rule;

11.12.b.4. Discovery of failure in the application, or during the permit issuance process, to fully disclose all significant facts or the permittee's misrepresentation of any significant fact at any time;

11.12.b.5. Failure to maintain proper bonding; if for any reason a permittee fails to maintain proper bonding, the secretary shall issue a cease and desist order and revoke the permit and the permittee shall become fully liable for the amount of the bond; or

11.12.b.6. Any cause which would require disqualification pursuant to this rule from receiving a permit upon original application.

11.12.c. Effect of Permit Suspension or Revocation.

11.12.c.1. Suspension. All infectious medical waste processing, treatment, storing or transfer activities and the receipt of any infectious medical waste at the facility shall cease immediately upon receipt of an order of suspension. Activities at the facility may recommence only after expiration of the order of suspension or upon revocation of that order by the issuing authority.

11.12.c.2. Revocation. All infectious medical waste processing, treatment, storing or transfer activities and the receipt of any infectious medical waste at the facility shall cease immediately upon receipt of an order of revocation. The facility owner shall submit either an application for a permit to close the facility or an application for a new commercial infectious medical waste facility permit within the time specified in the order of revocation.

11.12.c.3. Environmental Monitoring and Control. Environmental monitoring and control activities specified in an order of suspension or revocation shall continue at the commercial infectious medical waste facility for the duration of such order or until the authority that issued that order approves the cessation of such activities.

11.15. Transfer of Facility.

11.15.a. Permits issued by the secretary are not transferable or assignable and shall automatically become invalid upon a change of ownership or upon suspension or revocation. An existing commercial facility that changes ownership may, however, continue to operate under the previous owner's permit conditions until such time as the secretary can process the new permit application required by this section, provided the new owner sends the secretary a letter in which the new owner:

11.15.a.1. Advises the secretary of such change of ownership including any management changes; and

11.15.a.2. Agrees to be bound by the conditions and policies established in the infectious medical waste management plan for that facility by the previous owner until such time as a new management plan can be approved by the secretary.

11.16. Application Review. Within thirty (30) days of receipt of a permit application, compliance schedule, closure plan, or major modification application, the secretary shall determine whether such application, schedule, or plan is complete and shall notify the applicant of his or her determination in writing. If the secretary determines that such application, schedule, plan or modification is not complete, the notification shall advise the applicant of the deficiencies that require remedy.

11.16.a. The secretary may not begin the evaluation of a permit before receiving a complete application, including any supplemental information requested.

11.16.b. The secretary may not issue a permit before receiving a complete application.

11.16.c. The secretary shall request formal comments from the county commission of the county in which the facility is proposed to be located and from any municipal government within two (2) miles of the proposed location, with any negative response to such application from any commission or municipal government to be considered by the secretary and specific findings made as to the concerns raised by such responses.

11.17. Public Participation. When the secretary determines an application for a new facility to be complete, he or she shall conduct a public hearing in the county where the proposed facility is to be located.

11.17.a. When the secretary determines an application for a major modification to be complete, he or she shall instruct the applicant or permittee to give public notice. The secretary shall conduct a public hearing in the county where the proposed facility is to be located whenever he or she receives a request.

11.17.a.1. Public hearings shall be conducted in accordance with the following guidelines:

11.17.a.2. Public notice of a public hearing shall be given at least thirty (30) days before the hearing. Public comment will be accepted during those thirty (30) days.

11.17.a.3. Public notice shall be given by the following methods;

11.17.a.3.A. By mailing a copy of a notice to those persons whose names are included on a mailing list, maintained by the department of health and human resources, of people wishing to be notified of such requests; and

11.17.a.3.B. By the applicant publishing the public notice as a Class II legal advertisement in a qualified newspaper, as defined in W. Va. Code §59-3-1, serving the county where the facility will be located. The secretary shall also require that legal advertisement be placed in newspapers of adjacent counties when a proposed facility is within two (2) miles of a county line. The cost of the publication will be the responsibility of the applicant who shall send a certification of publication to the secretary within twenty (20) days after publication; and

11.17.a.3.C. Any other method reasonably calculated to give actual notice of the action in question to the persons potentially affected by it, including press releases or any other forum or medium to elicit public participation.

11.17.a.4. All public notices issued shall contain the following information:

11.17.a.4.A. The name and address of the office processing the permit action for which notice is being given;

11.17.a.4.B. The name and address of the permittee or permit applicant, and if different, of the facility or activity regulated by the permit;

11.17.a.4.C. A description of the activities covered in the application, including the type of commercial infectious medical waste facility, the types, amounts, and origins of infectious medical wastes to be handled, site improvements, and infectious medical waste handling methods;

11.17.a.4.D. The name, address and telephone and fax numbers of a person from whom interested persons may obtain further information, including copies of the application;

11.17.a.4.D.1. The availability of the application shall include, but not be limited to, copies placed at the courthouse of the county in which the facility is to be located, the city or town hall of any municipal government within two (2) miles of the proposed location of the facility and all public libraries in the county.

11.17.a.4.D.2. Copies of the application shall be available from the secretary at no cost.

11.17.a.4.E. A brief description of the comment procedures and the date, time and place of the hearing, and other procedures by which the public may participate in the final permit decision;

11.17.a.4.F. A general description of the location of proposed permit area including streams;

11.17.a.4.G. A clear and accurate location map. A map of a scale and detail found in the West Virginia official state highway map is the minimum standard for acceptance. The map size shall be at a minimum two (2) inches by two (2) inches. Longitude and latitude lines and a north arrow shall be indicated on the map, and such lines will cross at or near the center of the proposed permit area;

11.17.a.4.H. A reference to the date of previous public notices relating to the permit;

11.17.a.4.I. For major modifications, the public notice shall state:

11.17.a.4.I.1. That any interested person may submit written comment on the application, and that such comments shall include a concise statement of the nature of the issues raised;

11.17.a.4.I.2. That any interested person may request a public hearing, and that such request shall include a concise statement of the nature of the issues raised; and

11.17.a.4.I.3. That the secretary shall conduct a public hearing in the county where the proposed facility is to be located whenever he or she receives a request.

11.17.a.5. An official transcript of the hearing shall be available to the public from the secretary.

11.17.a.6. 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.

11.17.a.7. If any data, information or arguments submitted during the public comment period raise substantial new questions concerning the proposed facility, the secretary shall:

11.17.a.7.A. Reopen or extend the public comment period to give interested persons an opportunity to comment on the information or argument submitted; or

11.17.a.7.B. Require an additional public hearing.

11.17.a.8. 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 minutes of all meetings held by the applicant and a copy of the applicant's written response to all written comment letters received during the written response period. This file shall be submitted to the secretary by the applicant at the end of the comment period.

11.17.a.9. Based on comments received at the public hearing or upon written recommendations received, the secretary may within thirty (30) days after the close of the public comment period, 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 comments received.

11.18. Permit Decision and Effective Date of Permit.

11.18.a. Within thirty (30) days of the close of the public comment period on an application for a new facility, or major modification of an existing permit, the secretary shall respond in writing to the comments received.

11.18.b. After comments have been responded to, the secretary shall issue a final permit decision. The secretary shall provide written notification of his or her decision to the applicant and to each person who has submitted written comments or requested notice of the final permit decision. For the purposes of this section, a "final permit decision" means the final decision of the secretary to grant, deny, revoke and reissue, or terminate a permit.

11.18.c. In the case of an application for a new facility, the secretary shall grant or deny the application as filed and as made available to the public pursuant to the provisions of this section. The secretary shall provide the reasons therefor in his or her written notification to the applicant. This notification shall also include reference to the procedures for appealing the final permit decision.

11.18.d. The secretary may refuse to grant a permit for any of the following reasons:

11.18.d.1. If an applicant or permittee has attempted to obtain or renew a permit by means of fraud, deceit or material misrepresentation;

11.18.d.2. Discovery of failure in the application or during the permit issuance process to fully disclose all significant facts or the permittee's misrepresentation of any significant fact at any time;

11.18.d.3. The secretary determines, based on comments and recommendations received, that the facility is incompatible with existing or proposed land use patterns, including, but not limited to: transportation facilities; public water supplies; water resources; agricultural, commercial and residential real estate values; aesthetics; socioeconomic conditions generally; or if it endangers public health, safety or well being.

11.18.e. A final permit decision shall become effective not less than thirty (30) days after the date of notice of the decision, unless an earlier date is requested by the applicant and agreed upon by the secretary.

11.19. A retailer of sharps to be used by individuals in their own medical treatment may establish a small commercial infectious medical waste management facility to be used solely for the treatment of sharps sold by and returned to the retailer for treatment. Such small commercial infectious medical waste management facility shall apply for and obtain a permit according to the provisions of Section 4 of this rule. In addition to the requirements of Section 4, the application shall include a letter describing the location and estimated volume of sharps to be treated and a certified letter from an approved 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 11.9 through 11.18 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.a. The name and address of the generator;

12.10.b. The weight of the waste received;

12.10.c. The date of receipt of the waste; and

12.10.d. 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 §§ 22-18-13 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 provi-

sions of relevant State law, this rule or permits issued under this rule.

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

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

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

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

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

Enforcement orders and related hearings are required to be conducted according to the provisions of W. Va. Code §§ 22-18-15, 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.a. 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.b. Seek an injunction in accordance with W.Va. Code §20-5J-9(b);

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

15.1.d. 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 § 22-18-16.

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 § 20-18-16 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.a. Bodily injury which involves a substantial risk of death;

16.5.b. Unconsciousness;

16.5.c. Extreme physical pain;

16.5.d. Protracted and obvious disfigurement; or

16.5.e. 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 §§ 22-18-17 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.a. 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.b. 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.c. 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.d. 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 § 22-18-20 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.a. 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.b. 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 provided for in Section 11.19 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
G. Alternative treatment evaluation fee	500.00

TECHNICAL ASSISTANCE MANUAL: STATE REGULATORY OVERSIGHT OF MEDICAL WASTE TREATMENT TECHNOLOGIES

April 1994

A Report of the State and Territorial Association on Alternate Treatment Technologies

Roger Greene, Rhode Island Department of Environmental Management, Diann J. Miele, M.S., Rhode Island Department of Health, and Nelson S. Slavik, Ph.D., President, Environmental Health Management Systems, Inc., were primarily responsible for facilitating consensus among participants during each of the three meetings that were held to discuss state review of medical waste treatment technologies.

Nelson S. Slavik, Ph.D., prepared this final document which reflects the discussions and consensus reached at these meetings.

The following state officials served as a steering committee for these meetings:

Charles H. Anderson
Louisiana Department of Health and Hospitals

Lawrence Chadzynski, M.P.H.
Michigan Department of Public Health

Robert M. Confer
New Jersey Department of Environmental Protection & Energy

Carolyn Dinger
Louisiana Department of Environmental Quality

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Rhode Island Department of Environmental Management

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Rhode Island Department of Health

Phillip R. Morris
South Carolina Department of Health and Environmental Control

Ira F. Salkin, Ph.D.
New York Department of Health

Wayne Turnberg
Washington Department of Ecology

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California Department of Health Services

A complete listing of all participants attending the New Orleans, Atlanta, and Washington, D.C. meetings may be found in Appendix D.

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EXECUTIVE SUMMARY

I. Introduction

The purpose of this report is to establish a framework or guideline that defines medical waste treatment technology efficacy criteria and delineates the components required to establish an effective state medical waste treatment technology approval process. The recommendations made in this report are an attempt to find commonality on many of the issues and criteria required in the medical waste treatment technology review process. Recognizing that all states may not totally agree with these recommended criteria or protocols, the guidelines developed should serve only to provide guidance to the states in the development of an approval process for medical waste treatment technologies.

The establishment of qualitative and quantitative parameters that ensure effective and safe medical waste treatment are required in defining treatment technology efficacy criteria and delineating the components necessary to establish an effective state medical waste treatment technology approval process. Recommendations are provided in this report for the following:

- Medical Waste Treatment Technology Efficacy Assessment
- Medical Waste Treatment Technology Approval Process
- Permitting and Site Authorization Issues
- Research and Development

II. Medical Waste Treatment Technology Efficacy Assessment Criteria

This report recommends that all medical waste treatment technologies meet the following microbial inactivation criteria:

> Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of B. stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater.

In meeting these criteria, selected pathogen surrogates which represent vegetative bacteria, fungi, parasites, lipophilic/hydrophilic viruses, mycobacteria, and bacterial spores are recommended. Formulas and methods of calculations are recommended and are based on microbial inactivation ("kill") efficacy as equated to "Log_{10} Kill", which is defined as the difference between the logarithms of the number of viable test microorganisms before and after treatment.

III. Process for Approving Medical Waste Treatment Technologies

This report recommends that both state and site approval be attained for the use of any medical waste treatment technology. Specific recommendations are provided for:

- State approval requirements of the technology to ensure that the technology is effective in safely inactivating microorganisms to specified criteria;
- Site approval requirements to verify that the sited equipment meets approved specifications and microbial inactivation requirements under actual operating conditions; and
- USEPA pesticide registration requirements, as applicable, for those medical waste treatment technologies that use chemicals as the microbial inactivator.

Additionally, the report recommends that parametric monitoring of the treatment process can substitute or replace biological indicator monitoring provided certain verification and monitoring parameters are achieved.

IV. Permitting and Site Authorization Issues

Several permitting and state authorization issues relating to alternate medical waste treatment technology approval are identified and discussed. Recommendations are provided for the following issues:

- User verification for microbial inactivation monitoring
- Commercial versus on-site facilities
- Previously approved technologies
- Small medical waste treatment devices
- Waste residue disposal
- Operator training
- Equipment operations plan
- Emergency and contingency response plan

V. Research and Development

This report recommends that each state view as optional its participation in experimental medical waste treatment research and development projects. For those states opting to participate in medical waste treatment technology research and development projects, issues recommended to be considered are the following:

- Process of establishing research and development variances, including limitations and allowances;
- Potential environmental emissions and occupational exposures;
- Treatment process residue disposal; and
- Agency funding and staffing.

This report also provides supplementary materials to assist a state in developing guidelines, an information request form, and microbial inactivation testing protocols. These materials are located in the Appendices A-C under the following headings:

- State Guideline for Approval of Medical Waste Treatment Technologies;
- Application for Evaluation and Approval of Medical Waste Treatment Technologies; and
- Example: Treatment Efficacy Testing Protocol for a Grinder/Chemical Medical Waste Inactivation Process.

GLOSSARY

"AOAC" refers to the Association of Official Analytical Chemists.

"ATCC" refers to the American Type Culture Collection.

"Biological Indicator(s)" means those microorganisms that are used as representative microbial agents in inactivation studies and testing.

"Cfu" refers to colony forming units.

"Challenge Load" means a medical waste load that has been constructed by composition (i.e., organic content, density, moisture/liquid content, or other physical or chemical composition) or amount to provide an appropriate challenge to the treatment process and microbial inactivating agent.

"Committee" refers to the State and Territorial Association on Alternate Treatment Technologies.

"FIFRA" refers to the Federal Insecticide, Fungicide, and Rodenticide Act.

"IEPA" refers to the Illinois Environmental Protection Agency.

"Log_{10}Kill" is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment.

"4 Log_{10}Reduction" is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population; i.e., a 99.99% reduction.

"6 Log_{10}Reduction" is defined as a 6 decade reduction or a 0.000001 survival probability in a microbial population; i.e., a 99.9999% reduction.

"Microbial Inactivation" is defined in Section 2.2 of this document

"Pathogen Surrogate(s)" means those microorganisms that are used as biological indicators in efficacy studies and testing that represent known microbial pathogens.

"Surrogate Load" means a waste load that has been constructed to represent a typical medical waste load by composition (i.e., organic content, density, moisture or liquid content, or other physical or chemical composition) and amount.

"Treatment" is defined as a mechanism (such as treatment, chemical, irradiation, etc.) which inactivates microbial organisms.

"USEPA" refers to the United States Environmental Protection Agency.

TECHNICAL ASSISTANCE MANUAL: STATE REGULATORY OVERSIGHT OF MEDICAL WASTE TREATMENT TECHNOLOGIES

1.0 INTRODUCTION

The development of new or modified medical waste treatment methods utilizing heat, chemicals, or irradiation has provided potential alternative solutions to the medical waste treatment/disposal problem. However, with the development of these medical waste treatment methods, the concern has arisen that these new technologies may also lead to potential environmental or occupational health and safety exposures. Only a limited number of states have attempted to quantitatively and qualitatively assess the efficacy and safety of these new treatment technologies. For those states that have adopted criteria, there is no universality of approach in the assessment of treatment technology efficacy and safety.

Establishing a uniform guideline or a standard set of efficacy criteria can result in potential benefits to the state approval process. A uniform approach may provide economic benefits through facilitating the state review process via similarity in approval requirements and the avoidance of state-by-state review duplication. Minimizing state liability in the review process is also a potential benefit of standardized, documented efficacy criteria and testing protocols. As another potential benefit, developing nationally recognized protocols and assessment criteria might also enhance facilitation and cooperation between federal and other state agencies integral to or peripherally involved in the review process.

In an attempt to standardize processes for medical waste technology review, several states that had actively participated in the programs authorized under the federal Medical Waste Tracking Act of 1988 organized and conducted a meeting in New Orleans, Louisiana on December 13 and 14, 1992. With the purpose of establishing a framework or guideline for a state approval process for medical waste treatment technologies, particularly those other than steam sterilization or incineration, this meeting initiated discussions on defining medical waste treatment technology efficacy criteria and delineating the components required to establish an effective state approval process. Although much was accomplished at this meeting, many issues remained unresolved.

With the objective of attaining committee consensus on the technical and administrative elements of treatment technology approval, a second meeting was held on February 25 and 26, 1993, in Atlanta, Georgia to continue the discussions initiated at the December 1992 meeting. At this meeting the committee recognized the need for establishing its identity to coordinate and support these activities. As such, the name "State and Territorial Association on Alternate Treatment Technologies" (STA^2T^2) was adopted for the purpose of defining the Committee and its objectives. The term "alternate" was defined as "other than steam sterilization or incineration".

The Atlanta meeting's agenda was based on attaining the committee's consensus on the technical and administrative elements of treatment technology approval. Specific topics addressed and discussed were as follows:

- Definition of the level of recommended microbial inactivation (i.e., Level II or Level III spore inactivation levels);

- Establishment of defined pathogen surrogates for microbial inactivation evaluation including:

  - Vegetative pathogen surrogates
  - Bacterial spore formers;

- Determination of the use of bacterial spore formers, as ultimate pathogen surrogates, including the determination of which spore formers should be used, for which treatment process, and at what level of required inactivation;

- Adoption of enumeration formulae for efficacy testing protocol quantification;

- Development of a comprehensive process approval application form;

- Development of specific process approval mechanisms for:

  - Commercial facilities
  - Health care facilities
  - Research and development projects
  - Small quantity treatment devices
  - Previously approved technologies;

- Development of criteria specifications and requirements for:

  - Waste residue disposal
  - Operator training
  - Challenge loads;

- Development of specific testing protocols for:

  - State permitting/licensing of the technology
  - Site permitting
  - User verification
  - Processes maintaining/not maintaining biological test indicator integrity;

- The timing and extent of USEPA FIFRA involvement in establishing efficacy criteria and protocols.

At the conclusion of the Atlanta meeting a report was prepared entitled "Recommendations for State Regulatory Oversight of Medical Waste Treatment Technologies" which summarized the issues and recommendations discussed during both the New Orleans and Atlanta meetings. This

report was distributed for review and comment to all state and territorial regulatory agencies involved in medical waste regulatory activities.

To gain additional input into the development of a uniform guideline for the assessment of medical waste treatment technologies, a third meeting was conducted on June 14-16, 1993, in Washington, D.C. with invited participants from all state and territorial medical waste regulatory agencies. The report prepared from the Atlanta meeting served as a basis of discussion. With invited input from all state and territorial representatives, the primary objective of the meeting was to seek consensus on the key topic areas listed above.

This report details the discussions and recommendations of the participants from the three meetings. It should be emphasized that the recommendations made in this report are an attempt to find commonality on many of the issues and criteria required in the medical waste treatment technology review process. As such, consensus agreement was sought on key issues to demonstrate support for the recommendations made in this report. However, consensus support for a recommendation does not necessarily imply unanimity for the position taken. Recognizing that all states may not totally agree with these recommended criteria or protocols, the guidelines developed through this series of meetings should serve only to provide guidance to states in the development of a review and approval process for medical waste treatment technologies.

Logistical support for all three meetings was provided by the USEPA. Roger Greene, Rhode Island Department of Environmental Management, Diann J. Miele, Rhode Island Department of Health, and Dr. Nelson S. Slavik, President, Environmental Health Management Systems, Inc., cofacilitated each of the meetings. A listing of all participants attending the New Orleans, Atlanta, and Washington, D.C. meetings is found in Appendix D.

2.0 MEDICAL WASTE TREATMENT TECHNOLOGY EFFICACY ASSESSMENT CRITERIA

The establishment of specific criteria that define medical waste treatment technology efficacy is required to consistently evaluate new or modified medical waste treatment technologies. A number of terms are used in the literature to denote the level of treatment that may be assigned to a medical waste treatment technology (e.g., decontaminate, sterilize, disinfect, render harmless, and kill). However, these terms are non-descriptive and do not provide any mechanism for measuring the degree of treatment efficiency. It is critical that terms and performance criteria be established that quantitatively and qualitatively define the level of microbial destruction required of any medical waste treatment process.

Currently, there are no federal or national efficacy standards for medical waste treatment technologies and only a limited number of states have attempted to establish treatment efficacy criteria. The need exists to develop nationally recognized standard treatment performance criteria and operating protocols which establish the qualitative and quantitative parameters that ensure effective treatment. This section provides recommended medical waste treatment technology efficacy assessment criteria and discusses the rationale for their recommendation.

2.1 Classification of Emerging Medical Waste Treatment Technologies

To develop approval protocols and performance criteria for medical waste treatment technologies, it is necessary to classify known or anticipated technologies based on their mode of microbial inactivation. Medical waste treatment categories can be represented through the following categories:

- Thermal (wet and dry heat, microwaving, infrared, laser, plasma pyrolysis)
- Chemical (chlorine, chlorine derivatives, ozone, enzymes)
- Irradiation (UV, Cobalt 60)
- Other treatment mechanisms designed for specific medical waste categories generated in small volumes (thermal/electrical).

For certain technologies, there may be a combination of inactivation modes used to inactivate microorganisms (i.e., chemical/thermal or chemical/irradiation). In addition to the treatment mode, there may also be - mechanical grinding introduced prior to, during, and/or at the end of the treatment process (Note: Grinding, shredding, and compaction are not viewed as treatment methods, but are used to facilitate the effectiveness of the treatment method or to render the waste destroyed, unrecognizable and nonfunctional). The total process by which the medical waste is treated will influence the selection of biological and physical indicators used in the testing and validation processes and will influence the protocols in which they are used.

2.2 Definition of Microbial Inactivation

Underlying the development of assessment protocols for approving an emerging medical waste treatment technology, is the establishment of efficacy criteria that provide a quantitative and qualitative measure of required performance. There is no consensus among the states on the level of microbial inactivation required of a medical waste treatment process. To properly define microbial inactivation requires that definitions established include both qualitative and quantitative aspects. From this perspective, definitions need to be established which qualitatively define microbial inactivation (i.e., form and type of microorganisms affected) and which quantify the required level of inactivation.

The terms sterilization and disinfection have provided some measure of prescriptive criteria as used in denoting sterilization or degree of disinfection required of medical instruments and supplies. Sterilization is commonly defined as the complete elimination or destruction of all forms of microbial life, including highly resistant bacterial endospores. Since complete elimination or destruction is difficult to prove, sterilization is usually expressed as a probability function in terms of the number of microorganisms surviving a particular treatment process. This function is usually expressed as a 6 Log_{10} reduction (defined as 6 decade reduction or a one millionth [0.000001] survival probability in a microbial population; i.e., a 99.9999% reduction) of the most resistant microorganisms to the sterilization process in question. Spore suspensions of resistant Bacillus species are often used as biological indicators for determining the efficacy of the sterilization process (i.e., B. stearothermophilus, thermal inactivation; B. subtilis, chemical inactivation; B. pumilus, irradiation inactivation).

Disinfection can be defined as a procedure that reduces the level of microbial contamination. How disinfection is defined is dependent on the process in which the disinfectant is used, what microorganisms are affected, and what level of microbial inactivation is achieved. In the definition proposed by Spaulding (see Selected Bibliography), disinfectants are labeled as low-, intermediate- or high-level, determined in part on the survivability of microbial groups (i.e., bacterial spores [most resistant], mycobacteria, non-lipid or small viruses, fungi, vegetative bacteria, and lipid or medium-sized viruses [least resistant]) after treatment. Low-level disinfectant processes cause the death of all bacteria except Mycobacterium tuberculosis and M. bovis, lipid-enveloped and medium-sized viruses (e.g., herpes simplex virus, cytomegalovirus, respiratory syncytial virus, hepatitis B virus, and human immunodeficiency virus), and fungi. Intermediate-level disinfectant processes do not necessarily kill bacterial spores but are effective against tubercle bacillus and fungi. However, intermediate-level disinfectant processes vary in their effectiveness against viruses with small non-lipid viruses (e.g., rhinoviruses) being significantly more resistant than medium-sized, lipid viruses. High-level disinfectant processes cause the death of all microbial life, except for high numbers of bacterial spores. Sporicidal capacity is an essential property of high-level disinfection, although the amount of sporicidal activity is not quantified in any definition.

It was agreed during the New Orleans meeting that there was a need to establish a separate classification system that would specifically denote levels of microbial inactivation required of

medical waste treatment. This classification system should quantitatively and qualitatively define the measure of required performance. To aid in the establishment of a separate classification system, the following categories of microbial inactivation were offered and discussed.

Level I - Inactivation of vegetative bacteria, fungi, and lipophilic virus

Level II - Inactivation of vegetative bacteria, fungi, all viruses, and mycobacteria

Level III - Inactivation of vegetative bacteria, fungi, all viruses, mycobacteria, and B. stearothermophilus spores at 10^4 or greater; or B. subtilis spores at 10^4 or greater with chemical treatment

Level IV - Inactivation of vegetative bacteria, fungi, all viruses, and mycobacteria, and B. stearothermophilus spores at 10^6 or greater

At the New Orleans meeting most participants generally favored Level III criteria for medical waste treatment technologies. Although there was considerable discussion at that meeting, no consensus had been reached on the qualitative and quantitative aspects of the Level II and III definitions and the conditions to be applied, if any, for relaxation of the Level III requirement to Level II.

A primary objective of the Atlanta meeting was to specifically define the qualitative and quantitative aspects of the microbial inactivation definitions and to assign their application. To meet this objective, discussions centered on:

- Defining microbial inactivation levels by representative microbial groups and by the amount of microbial inactivation required for each;
- Assigning representative pathogen surrogates to be used in the efficacy evaluation processes; and
- Assigning inactivation levels required of a medical waste treatment technology.

To assist the committee in further defining Levels I-IV, a summary was provided at the Atlanta meeting of USEPA sponsored research of emerging medical waste treatment technologies. Summarized were the treatment technologies evaluated, the surrogate organisms selected for testing and rationale for their selection, and in general, the results obtained from this research project. It was stated that the research material presented was not yet available for review since this material will serve as an appendix to the USEPA's "Final Report to Congress" when finalized.

Of particular interest to the committee was the availability of documentation that would support

the use of an ultimate pathogen surrogate (i.e., Bacillus stearothermophilus spores) that could be used to avoid the testing of representative pathogen surrogates from each of the microbial groups listed in the definitions above. As part of the USEPA sponsored study, comparative tests with vegetative bacteria, bacterial spores, fungal spores, and mycobacteria demonstrated that B. stearothermophilus and B. subtilis spores could be used to represent vegetative bacteria, fungi, and mycobacteria in evaluating both chemical and thermal (wet and dry heat) treatment systems.

No comparative testing, however, had been conducted with viruses or parasites. Without this supporting documentation for viruses and parasites, the committee could not recommend that B. stearothermophilus or B. subtilis be designated as an ultimate pathogen surrogate for efficacy testing. As such, the committee took the position to recommend that pathogen surrogates representing vegetative bacteria, fungi, parasites, viruses, mycobacteria, and bacterial spores be used to demonstrate efficacy of the treatment process. To determine if B. stearothermophilus and B. subtilis spores could be used in the future as pathogen surrogates representing all microbial groups, the committee recommended that further research be conducted to evaluate their relative resistance to representative parasitic agents (i.e., Giardia and Cryptosporidium) and viral agents (i.e., Polio 2, MS-2).

In defining microbial inactivation levels, each level will require characterization by (1) the microbial groups to be inactivated and (2) the level of microbial inactivation required for each group. In the categories depicted as Level I-IV above, each level represents a hierarchy of increasing treatment resistance where treatment resistance is defined by the type of microorganism requiring inactivation and/or the amount of inactivation required for that type of microorganism. The definition of these categories requires that all groups of pathogen surrogate microorganisms recommended for testing be included in the definition. To be consistent with the committee's recommendation that a representative microorganism be tested from each microbial group, the definitions of Levels II-IV were modified to include "parasites." Additionally, it was suggested that "all viruses" was too inclusive and it was recommended that all viruses be modified to "lipophilic/hydrophilic viruses." These changes are reflected in the definition for the Levels of Microbial Inactivation presented in Table I.

It should be noted that the inactivation levels defined in Table I are not to be construed as having any relationship with microbial inactivation requirements for microorganisms in Biosafety Levels I-IV as defined within guidelines set by the Centers for Disease Control in Biosafety in Microbiological and Biomedical Laboratories, (1993).

Inactivation of spores from both B. stearothermophilus and B. subtilis is also defined in Levels III and IV (Refer to Table 1). It was questioned whether these microorganisms were the most chemically or thermally resistant biological indicators. From information provided, the use of these microorganisms as the most resistant indicators to thermal and chemical agents is supported in the literature.

TABLE I - LEVELS OF MICROBIAL INACTIVATION

Level I - Inactivation of vegetative bacteria, fungi, and lipophilic viruses at a 6 Log_{10} reduction or greater

Level II - Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater

Level III - Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of B. stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater

Level IV - Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, mycobacteria, and B. stearothermophilus spores a 6 Log_{10} reduction or greater.

To avoid assigning a specific bacterial species for each specific treatment process, documentation was sought that would support the use of spores from just one bacterial species for both chemical and thermal treatment processes. In the USEPA sponsored studies comparing B. stearothermophilus and B. subtilis resistance to hypochlorite (1000 ppm available free chlorine) and glutaraldehyde (3000 ppm, 2% alkaline glutaraldehyde), the resistance of spores from both was comparable. Data also supported that B. stearothermophilus spores were slightly more resistant to dry heat than B. subtilis var. niger spores (the B. subtilis variety traditionally used to determine dry heat resistance). These data indicate that B. stearothermophilus can be used as the sole spore indicator for chemical treatment processes and as the sole spore indicator for both dry and wet heat thermal processes.

B. stearothermophilus spores, however, are more resistant to wet heat than spores from B. subtilis. Debate centered on whether spores from either species could be used interchangeably for wet or dry heat thermal processes even though B. stearothermophilus spores are more resistant to wet heat. It was argued that the use of spore inactivation in the definition serves two functions: (1) to demonstrate that bacterial spore formers (originating primarily from laboratory wastes) can be inactivated and (2) to provide a margin of safety beyond the inactivation of vegetative bacteria, fungi, viruses, parasites, and mycobacteria.

From the first perspective, both B. stearothermophilus and B. subtilis spores are used as indicators of medical product sterility because of their documented resistance to heat and chemicals. Inactivation of either of these highly resistant bacteria spores serves to demonstrate that any spores found in medical waste will also be inactivated. From the second perspective, B. subtilis and B. stearothermophilus spores both display significantly more heat resistance than

the microorganisms in the aforementioned microbial groups. The demonstration that highly resistant spores from either of these Bacillus species can be effectively destroyed ensures a margin of safety from the variables inherent in the treatment of medical waste (i.e., waste packaging, waste composition, waste density, and factors influencing the homogeneity of the treatment process).

On the basis of these arguments presented above, the committee recommended that either B. stearothermophilus or B. subtilis spores be used as biological indicators for chemical or thermal treatment processes. The question arose, however, to whether a higher level of inactivation would be required when using B. subtilis for wet heat treatment processes. It was argued that B. stearothermophilus and B. subtilis spores both have a documented high degree of thermal resistance. As such, higher inactivation levels required of B. subtilis spores for wet heat treatment processes were considered unnecessary to further demonstrate effective spore inactivation or an expanded margin of safety. In addition, it was argued that assigning different threshold inactivation levels for each defined biological indicator would set a bad precedent and lead to an overly and unnecessarily complex definition. The revision to allow the use of either B. stearothermophilus and B. subtilis spores as biological indicators for chemical or thermal treatment processes is reflected in the recommended definition for the Levels of Microbial Inactivation as presented in Table I.

The use of B. stearothermophilus or B. subtilis spores for demonstrating microbial inactivation by irradiation processes was also recommended. B. pumilus spores are used as the standard biological indicator to demonstrate irradiation efficacy in the sterilization of medical products. B. pumilus spores are, however, not as resistant to irradiation as the enteroviruses or the vegetative bacterium Deinococcus radiodurans. The use of an enterovirus (e.g., Polio 2 or Polio 3) or Deinococcus radiodurans can provide a more stringent measure of microbial inactivation than B. pumilus spores, making any requirement for this specific Bacillus species unnecessary for the purpose of providing an additional "margin of safety". To demonstrate that bacterial spores can be effectively inactivated, B. subtilis or B. stearothermophilus spores can serve as equivalent biological indicators. Inactivation of B. stearothermophilus or B. subtilis spores, although less resistant to irradiation than B. pumilus spores, serves to adequately demonstrate that any spores found in medical waste will also be inactivated.

Specific levels of inactivation are required of any adopted definition to quantitatively define the measure of required performance of a medical waste treatment technology. The definitions proposed by the committee state that inactivation is required of "vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria." Although implied but not specifically stated, this definition requires complete inactivation of the representative microorganisms tested in each of the microbial groups listed. Since complete inactivation is impossible to prove, it can be expressed as a probability function in terms of the number of microorganisms surviving a particular treatment process. In defining sterilization, this function is usually expressed as a 6 Log_{10} reduction. A 6 Log_{10} reduction is defined as a 6 decade reduction or a one millionth (0.000001) survival probability in a microbial population (i.e., a 99.9999% reduction). Using this definition as a basis for quantifying complete inactivation, the recommendation was made that

6 Log_{10} reduction be required of the representative microorganisms tested in each of the microbial groups listed (with the exception of B. stearothermophilus or B. subtilis spores). Table I - Levels of Microbial Inactivation incorporates these revisions.

For inactivation levels required of B. stearothermophilus or B. subtilis spores, the original definition stated that inactivation was required at "10^4 or greater" (i.e., 4 Log_{10} reduction or greater). It was questioned whether this level should remain as stated in the definition or be modified to be less or more stringent. In the USEPA sponsored studies it was demonstrated that of the medical waste treatment technologies studied, all could meet at least a 4 Log_{10} reduction of B. stearothermophilus or B. subtilis spores. The committee supported the level as defined in the original definition. Language however, was modified to replace "10^4 or greater" with "4 Log_{10} reduction or greater" to be consistent with the use of the definition of Log_{10} reduction. A 4 Log_{10} reduction is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population (i.e., a 99.99% reduction). The committee also revised the Level IV definition to replace "10^4 or greater" with "4 Log_{10} reduction or greater" to be consistent with the use of the definition of Log_{10} reduction. No further revision was suggested. These revisions are reflected in Table I.

Recommendations made by the committee for establishing a quantitative and qualitative definition for the Levels of Microbial Inactivation are incorporated into Categories I-IV of Table I. Summarizing, the committee recommended that:

- Pathogen surrogates representing vegetative bacteria, fungi, parasites, lipophilic/hydrophilic viruses, mycobacteria, and bacterial spores be used to demonstrate microbial inactivation;
- Either B. stearothermophilus or B. subtilis spores be used as biological indicators for chemical or thermal treatment or irradiation processes;
- A 6 Log_{10} reduction be required of the representative microorganisms tested in each of the microbial groups listed (with the exception of B. stearothermophilus or B. subtilis spores); and
- A 4 Log_{10} reduction level be required of B. subtilis or B. stearothermophilus spores.

Having quantitatively and qualitatively established a definition for the Levels of Microbial Inactivation, arguments were presented and discussed to determine the position of the committee on which category would serve as the benchmark criteria for medical waste treatment technology efficacy. Debate centered on the recommendation of Level II or Level III criteria. Arguments for recommending Level II criteria were as follows:

- Medical waste does not contain significant differences in amount and type of pathogens as household waste;

- Level II criteria provides a sufficient degree of microbial inactivation;
- Level III criteria may conflict with lesser inactivation criteria already defined by the state; and
- Level III or IV criteria can be applied, if necessary, to those medical waste streams requiring an additional margin of safety.

Arguments for recommending Level III criteria were as follows:

- Level III criteria serve as a margin of safety from the variables inherent in the treatment of medical waste (i.e., waste packaging, waste composition, waste density, and factors influencing the homogeneity of the treatment process);
- Segregation of some medical waste categories (i.e. laboratory cultures) requiring Level III treatment would be impractical if Level II criteria were in effect;
- Medical waste treatment equipment industry already achieves Level III criteria; and
- Level II or Level IV criteria may still be allowed dependent on the technology application or waste type processed.

It was the consensus (not unanimous) of the committee that Level III be required of all emerging medical waste technologies. The committee took the position that Level III criteria were to be established as a benchmark and as such, were applicable to all medical waste treatment devices. The committee realized that there might be circumstances under which a state may allow relaxation of the Level III requirement.

The committee rejected the allowance for exception :o Level II standards for those technologies that could be termed "counter-top" devices designed for a specific medical waste category. Relaxation from Level III to Level II criteria was not considered warranted on the basis of the equipment's:

- Inability to inactivate spores;
- Designation as a small quantity treatment device;
- Designation for treating minimally contaminated medical waste categories; or
- Exhibiting difficulty to demonstrate microbial inactivation through designated protocols (i.e., a needle thermal-destruction device).

The committee realized that there might be circumstances under which a state may allow relaxation of the Level III requirement. These exceptions would by necessity need to be made on a case-by-case basis, would require the equipment manufacturer to provide a rationale for relaxation, and would require adequate supporting documentation to substantiate that rationale.

The committee also debated if laboratory wastes (i.e. discarded cultures and stocks of pathogenic agents) should require sterilization (i.e. meet Level IV criteria) on the basis that these wastes may contain high concentrations of known pathogens. The committee took the position that Level III criteria remained the standard for all medical waste categories. The committee emphasized, however, that laboratories should be aware that cultures and stocks of disease-causing agents may require sterilization before disposal. In addition to guidelines set by the Centers for Disease Control in Biosafety in Microbiological and Biomedical Laboratories, (1993) and standards of the College of American Pathologists (CAP), some states require laboratory cultures to be incinerated or autoclaved (i.e., steam sterilized) before leaving the laboratory or before being disposed of. Although no specific recommendations for medical waste disposal are made under the Clinical Laboratory Improvement Amendments (CLIA), medical waste disposal practices are receiving increased scrutiny during routine inspections.

2.3 Representative Biological Indicators

In the absence of an ultimate pathogen surrogate to represent all defined microbial groups, the selection of pathogen surrogates representing vegetative bacteria, fungi, parasites, viruses, mycobacteria, and bacterial spores was considered necessary to define and facilitate any state approval process. Criteria defining surrogate selection should include that any surrogate recommended:

- Not affect healthy individuals;
- Be easily obtainable;
- Be an ATCC registered strain, as available;
- Be easily cultured and maintained; and
- Meet quality control requirements.

Microorganism strains obtained from the American Type Culture Collection (ATCC) and methods prescribed by the Association of Official Analytical Chemists (AOAC) assist in fulfilling these recommendations by (1) providing traceable and pure cultures of known characteristics and concentration and (2) providing recognized culturing protocols and detailed sampling and testing protocols.

Provided in Table II are the biological indicators recommended by the committee for testing microbial inactivation efficacy in medical waste treatment processes. The selection of these representatives was based on each microorganism:

- Meeting, where possible, the criteria established above;
- Representing, where possible, those organisms associated with medical waste; and
- Providing a biological challenge equivalent to or greater than that associated with microorganisms found in medical waste.

· Biological indicators selected to provide documentation of relative resistance to an inactivating agent should be chosen after evaluation of the treatment process as it relates to the conditions used during comparative resistance research studies described in the literature. Literature studies support the assertion that the degree of relative resistance of a microorganism to an inactivating agent can be dependent on various factors (i.e., pH, temperature). Conditions used in literature studies that demonstrate a relatively high degree of resistance of a particular microorganism may be significantly different to the conditions found within the treatment process. A comparison of the conditions used in the literature to those used in the treatment process should be made to determine if relative microbial resistance can be altered (i.e., lowered) as a result of treatment process conditions.

The committee emphasized that although the microorganisms selected represent pathogen surrogates, these selected surrogates may have the potential to be pathogenic under certain conditions. As such, the committee recommended that all testing be conducted using recognized microbial techniques. For those pathogen surrogates that still retain some higher degree of pathogenicity (e.g., Cryptosporidium, Giardia, and Mycobacteria), efficacy testing should be conducted only by qualified laboratory personnel.

TABLE II - RECOMMENDED BIOLOGICAL INDICATORS

Vegetative Bacteria	-	Staphylococcus aureus (ATCC 6538) Pseudomonas aeruginosa (ATCC 15442)
Fungi	-	Candida albicans (ATCC 18804) Penicillium chrysogenum (ATCC 24791) Aspergillus niger
Viruses	-	Polio 2, Polio 3 MS-2 Bacteriophage (ATCC 15597-B1)
Parasites	-	Cryptosporidium spp. oocysts Giardia spp. cysts
Mycobacteria	-	Mycobacterium terrae Mycobacterium phlei Mycobacterium bovis (BCG) (ATCC 35743)

Bacterial Spores	-	B. stearothermophilus (ATCC 7953) B. subtilis (ATCC 19659)

The committee recommended that one or more of the representative microorganisms from each microbial group be used in efficacy evaluation. Specific criteria for the selection of these microorganisms are provided below in Table III:

TABLE III - BIOLOGICAL INDICATOR SELECTION CRITERIA

Vegetative Bacteria	-	Staphylococcus aureus and Pseudomonas aeruginosa were selected to represent both gram-positive and gram-negative bacteria, respectively. Both are currently required by the Association of Official Analytical Chemists (AOAC) use-dilution method and both have been shown to be resistant to chemical inactivation.
Fungi	-	The selection of Candida albicans and Penicillium chrysogenum was based on reported data indicating these organisms representing yeast and molds, respectively, are the most resistant to germicides. Although Trichophyton mentagrophytes is the AOAC test organism for molds, Penicillium chrysogenum is reported to be more resistant to germicides. The inclusion of Aspergillus niger as an indicator organism was based on its familiarity as a common mold.
Viruses	-	Lipophilic (enveloped) viruses are less resistant to both thermal and chemical inactivation than the hydrophilic (nonenveloped) viruses. As such, enveloped viruses such as HIV, Herpes simplex virus and Hepatitis B virus are less resistant than enveloped viruses such as Poliovirus, Adenovirus, and Coxsackievirus. Polio 2 (attenuated vaccine strain) and Polio 3 virus were selected based on their relative higher chemical and thermal resistance. Additionally, the use of an enterovirus (e.g., Polio 2 or Polio 3) can provide a stringent measure of efficacy for irradiation treatment processes. MS-2 bacteriophage was selected as a Hepatitis virus surrogate in that this bacteriophage offers a comparable degree of chemical and thermal resistance, is safe to handle and easy to culture.

Parasites	-	Both Cryptosporidium spp. oocysts and Giardia spp. cysts are used as test organisms to demonstrate germicidal effectiveness. Cryptosporidium has been demonstrated to have a higher chemical resistance and Cryptosporidium spp. oocysts are more readily available than Giardia spp. cysts. Both are significantly pathogenic (both have an infectious dose of 10 cysts) and care is advised when using these microorganisms as parasitic biological indicators.
Mycobacteria	-	Mycobacterium phlei has a demonstrated measure of disinfectant resistance, is a rapid grower and is pigmented for easy identification. M. bovis (BCG) is used in the AOAC Tuberculocidal Method and is analogous to M. tuberculosis in that it is in the same group or complex. Individuals exposed to M. bovis (BCG, ATCC strain) may skin test convert although no actual infectivity or disease occurs. Risk of exposure would come from those mechanisms that grind the waste. Mycobacterium terrae is equivalent to M. tuberculosis in resistance to chemical inactivation. In Europe it is recommended for disinfectant testing. M. terrae does not grow as rapidly as M. bovis or M. tuberculosis.
Bacterial Spores	-	Both B. stearothermophilus and B. subtilis spores are commonly used as biological indicators for both thermal and chemical resistance. B. stearothermophilus spores exhibit more thermal and chemical resistance than spores from B. subtilis.

After discussion on the rationale for selection of the representative biological indicators presented above, consensus by the committee was attained on recommending the use of these biological indicator strains for treatment technology efficacy testing.

2.4 Quantification of Microbial Inactivation

Establishing the mechanisms to quantify the level of microbial inactivation is essential in developing the format and requirements of the guidance protocols. As presented and discussed, microbial inactivation ("kill") is equated to "Log_{10}Kill" which is defined as the difference between the logarithms of number of viable test microorganisms before and after treatment. This definition is translated into the following formula:

$$Log_{10}Kill = Log_{10}(cfu/g\ Introduced) - Log_{10}(cfu/g\ Recovered)$$

where:

Log_{10}Kill is equivalent to the term Log_{10} reduction;

"Introduced" is the number of viable test microorganisms introduced into the treatment unit;

"Recovered" is the number of viable test microorganisms recovered after treatment; and

"cfu/g" are colony forming units per gram of waste solids.

A Log_{10}Kill of 6 or greater is equivalent or less than a one millionth [0.000001] survival probability in a microbial population or a 99.9999% reduction or greater of that population.

Using the Level III definition recommended by the committee as shown in Table I, a Log_{10}Kill of 6 (e.g., 6 Log_{10} reduction) is required of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria and a Log_{10}Kill of 4 (e.g., 4 Log_{10} reduction) is required of B. stearothermophilus or B. subtilis spores. Employing the above equation to quantify microbial inactivation will require the consideration of the methods of biological indicator introduction and recovery. For those treatment processes that can maintain the integrity of the carrier (i.e., ampules, plastic strips) of the desired microbiological test strain, commercially available biological indicators of the required strain and concentration can be easily placed, recovered, and cultured to demonstrate efficacy. Quantification is evaluated by growth or no growth of the cultured biological indicator. For example, if an ampule that contained 1×10^4 B. stearothermophilus spores were treated, retrieved, and cultured, no growth would demonstrate a 4 Log_{10} reduction.

For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator carrier, quantitative measurement of efficacy requires a two-step approach. The purpose of the first step is to account for the reduction of microorganisms due to equipment design (i.e., dilution of indicator organisms or physical entrapment).

This first step, the "Control", is typically performed using microbial cultures (i.e., liquid suspensions) of predetermined concentrations necessary to ensure a sufficient microbial recovery at the end of this step. The microbial suspension is added to a standardized surrogate medical waste load that is processed under normal operating conditions without the addition of the microbial inactivation agent (i.e., heat, chemicals). Standard loads may vary depending on the various treatment challenges (i.e., high moisture content, high organic load, high density) required of the equipment. After processing, waste samples are collected and washed to recover the biological indicator organisms in the sample. Recovered microorganism suspensions are plated to quantify microbial recovery. The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the microbial inactivation agent. The required number of recovered viable indicator microorganisms from the "Control" must be equal to or greater than the number of

microorganisms required to demonstrate the prescribed Log reduction as defined in Level III (i.e., a 6 Log_{10} reduction for vegetative microorganisms and a 4 Log_{10} reduction for spores). See Appendix A (Section C3) and Appendix C for a detailed process description.

This step can be defined by the following equation:

$$Log_{10}RC = Log_{10}IC - Log_{10}NR$$

where:

$Log_{10}RC$ > 6 for vegetative microorganisms and > 4 for bacterial spores;

$Log_{10}RC$ is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) recovered in the non-treated processed waste residue;

$Log_{10}IC$ is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit; and

$Log_{10}NR$ is the number of "Control" microorganisms (in colony forming units per gram of waste solids) not recovered in the non-treated processed waste residue.

Rearranging the equation above enables the calculation of microbial loss due to dilution, physical manipulation, or residue adhesion during the treatment process. $Log_{10}NR$ represents an accountability factor for microbial loss and is defined by the following equation:

$$Log_{10}NR = Log_{10}IC - Log_{10}RC.$$

The second step ("Test") is to operate the treatment unit as in the "Control" run with the selected biological indicators, but with the addition of the microbial inactivation agent. After processing, waste samples are collected and washed as in the "Control" to recover any viable biological indicator organisms in the sample. From data collected from the "Test" and "Control", the level of microbial inactivation (i.e., "$Log_{10}Kill$") can be calculated by employing the following equation:

$$Log_{10}Kill = Log_{10}IT - Log_{10}NR - Log_{10}RT$$

where:

$Log_{10}Kill$ is equivalent to the term Log_{10} reduction;

$Log_{10}IT$ is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit. $Log_{10}IT = Log_{10}IC$;

$Log_{10}NR$ is the number of "Control" microorganisms (in colony forming units per gram of waste solids) not recovered in the non-treated processed waste residue; and

$Log_{10}RT$ is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) recovered in treated processed waste residue.

Appendix C (Section III) serves to illustrate the application of the equations presented above.

Formulas used in the discussion above for the quantification of microbial inactivation were modified from those used by Illinois EPA in their final regulations (June 1993) entitled "Potentially Infectious Medical Wastes" (see Selected Bibliography).

After discussion on the use and application of the formulas and calculations presented above, consensus by the committee was unanimous on recommending the use of the formulas and methods of calculation in the enumeration of medical waste treatment technology efficacy.

3.0 PROCESS FOR APPROVING MEDICAL WASTE TREATMENT TECHNOLOGIES

State approval of an emerging medical waste treatment technology is necessary to ensure that the technology can effectively and safely treat medical waste. From discussions, the completed approval process can be viewed as fulfilling, where applicable, three components:

- Approval of the technology by the state to ensure the technology is effective in safely inactivating microorganisms to specified criteria;
- Granting site approval to verify the sited equipment meets approved specifications and efficacy requirements under actual operating conditions; and
- USEPA FIFRA pesticide registration requirements, as applicable, for those medical waste treatment technologies that use chemicals as the microbial inactivator.

Each of these components requires information be supplied to states demonstrating that the treatment technology is effectively treating medical waste by established criteria and that the process is environmentally sound and occupationally safe. Information necessary for proper review of medical waste treatment technologies is provided for each component described below.

3.1 Biological Inactivation Efficacy: Establishing Protocols

Methodology employed to determine efficacy of the technology will, by necessity, need to be developed by the equipment manufacturer to assure the protocols are congruent with the treatment method. Protocols developed for efficacy testing should incorporate recognized standard procedures such as those found in Test Methods for Evaluating Solid Waste, Physical/ Chemical Methods and Standard Methods for the Examination of Water and Waste Water (see Selected Bibliography).

In establishing testing criteria to evaluate efficacy, the composition of the waste load(s) tested is critically important. Depending on the treatment mechanism, efficacy may vary with waste load composition (i.e., organic content, density, moisture or liquid content). Although the committee recognized that waste composition may affect efficacy results considerably, establishing specific requirements for challenge loads for all existing, pending, and future treatment technologies is not practical or necessarily all inclusive. The committee recommended that the equipment manufacturer prescribe those types of medical wastes that present the greatest challenge to efficacy of the equipment and present protocols that adequately evaluate efficacy under normal operating conditions. On submittal for evaluation by the state, the manufacturer's prescribed waste types and testing protocols could be accepted or modified at the discretion of the reviewing agency.

Dependent on the treatment process and efficacy protocols used, other factors may also influence the evaluation results. As such, the committee could not define specific protocols, but recommended that protocols evaluating medical waste treatment systems specifically delineate or incorporate:

- Waste compositions that typify actual waste to be processed;
- Waste types that provide a challenge to the treatment process;
- Comparable conditions to actual use (i.e., process time, temperature, chemical concentration, pH, humidity, load density, load volume);
- Assurances that biological indicators (i.e., ampules, strips) are not artificially affected by the treatment process;
- Assurances of inoculum traceability, purity, viability and concentration;
- Dilution and neutralization methods that do not affect microorganism viability;
- Microorganism recovery methodologies that are statistically correct (i.e., sample collection, number of samples/test, number of colony forming units/plate); and
- Appropriate microbial culturing methods (i.e., avoidance of microbial competition, the selection of proper growth media and incubation times).

Based on the results obtained from challenge load testing, the medical waste treatment technology may be limited in its application to not treating all categories or types of medical wastes. Physical or aesthetic characteristics may also predicate the limitations applied or the conditions of the equipment's use. If certain medical waste categories are excluded from the treatment process, the state should specify for the manufacturer (vendor) and the user of the equipment the waste segregation parameters that will be employed to prohibit the waste from treatment and the mechanisms of treatment/disposal to be utilized for these excluded wastes.

Consideration should also be given to the equipment's use in a particular setting when applying challenge load testing. The composition of the challenge load would be conceivably different and more challenging if a particular application treats a medical waste stream containing a higher proportion of a waste type or composition that is difficult to treat by that process. Conversely, challenge loads for technologies whose primary application is hospital medical waste, might be relaxed if that technology was applied only to waste generated by physician offices. Efficacy testing protocols may also require modification dependent on the size or throughput of the equipment. Multiple testing points might be required due to the waste volume processed or the treatment process.

The committee recommended that efficacy testing protocols and all results of any evaluations conducted, including original data, be included for evaluation by the state agency reviewing the application for treatment technology approval. The methodologies and protocols developed are especially critical for state evaluation of medical waste treatment processes that pulverize, grind, or shred the waste during the treatment process and do not allow intact retrieval of the biological test indicator. The complexity of these protocols is illustrated in Appendix C, "Example: Treatment Efficacy Testing Protocol for a Grinder/Chemical Medical Waste Inactivition Process".

To establish proper protocols that incorporate the recommended criteria above and meet any applicable recognized testing standards will, in most likelihood, require the equipment manufacturer to seek assistance from an independent laboratory. To ensure the required quality control and facilitate state review of the treatment process, the committee recommended that the qualified laboratory selected should:

- Be experienced in microbiological testing techniques and be familiar with required sampling and testing protocols;
- Be an accredited laboratory or have experience with product registration through the federal Food and Drug Administration (FDA) or the USEPA Office of Pesticide Programs; and
- Be equipped to meet FDA "Good Laboratory Practices" requirements.

3.2 Approval of Medical Waste Treatment Technologies

As a first step in the review process, information is required of the manufacturer to provide the state with the information it needs to properly assess the treatment technology proposed for approval. The state's use of a comprehensive information request form is essential in obtaining relevant information and in acquainting the manufacturer with the requirements and the responsibilities inherent in the review process. To meet these objectives, the form should at a minimum:

- Delineate state responsibilities and permitting requirements;
- Delineate manufacturer responsibilities and registration requirements;
- Request a detailed description of the medical waste treatment equipment to be tested, including manufacturer's instructions and equipment specifications, operating procedures and conditions, including, as applicable, treatment times, temperatures, pressures, chemical concentrations, irradiation doses, feed rates, and waste load composition;

- Request documentation demonstrating that the treatment method meets microbial inactivation criteria and required testing protocols, including a detailed description of the test procedures and calculations used in fulfilling designated performance standards verifying efficacy, of user verification methodology, and of microbial culturing protocols that ensure traceability, purity and concentration;

- Provide documentation of applicable emission controls for suspected pathological and toxics emissions; and

- Provide documentation for occupational safety and health assurance by describing the medical waste treatment equipment's safety systems such as warning signage, operating zone restrictions, lock-out procedures, and personal protection equipment requirements.

To assist the committee in developing a format for an information request form, information forms from the states of California, Michigan, and New Jersey were reviewed for their content. In addition to the information requested on these forms, the committee recommended that the following information also be requested:

- A more extensive discussion on available parametric controls (to verify efficacy and ensure operator non-interference in the treatment process);

- A discussion on energy efficiency and other potential benefits the treatment technology has to offer to the environment; and

- More detailed information relating to waste residues including their potential hazards/toxicities and their specific mode of disposal or recycling.

From the forms reviewed and the additional information requested by the committee, a recommended informational request form, termed an "Application for Evaluation and Approval of Medical Waste Treatment Technologies", was developed (See Appendix B).

In addition to fulfilling environmental and occupational safety requirements, all treatment technologies must meet Level III efficacy criteria. Demonstration that these criteria are met is the responsibility of the equipment manufacturer. In meeting these requirements the manufacturer must:

- Demonstrate that all required pathogen surrogates and resistant bacterial endospores (as recommended in Table II) are inactivated to Level III criteria under all required challenge waste load compositions;

- Develop and demonstrate that site approval and user verification testing protocols are workable and valid; and

- Demonstrate where technically practical, the relationship biological indicator data and data procured from real-time parametric monitoring equipment.

To assist in presenting the recommendations for efficacy review, an approval process guideline is presented in Appendix A.

3.3 Parametric Monitoring and Controls

Parametric monitoring of a medical waste treatment process can provide real-time data acquisition for assessing efficacy. However, correlation of the data acquired from the parametric monitoring device(s) with that of biological indicator studies is essential if parametric monitoring is to supplement or replace biological indicator monitoring. This demonstration is the responsibility of the manufacturer (vendor). To verify that a proper correlation has been established between the parametric monitoring device and biological indicator inactivation, the manufacturer (vendor) must demonstrate that parametric monitoring is:

- Correlated with biological indicator inactivation through documented efficacy studies linking microbial inactivation with the parameter(s) being monitored;

- Accurately monitoring the treatment agent and/or treatment conditions, as applicable (i.e., provide the limiting conditions that influence accurate monitoring); and

- Appropriate for the conditions that exist under operational circumstances.

Demonstration of the above components may allow the use of parametric monitoring for auditing treatment conditions or alerting the equipment operator of equipment malfunction or abnormal behavior. However, the use of parametric monitoring to substitute or replace biological indicator inactivation must require the device to additionally:

- Have tamper-proof controls or automatic factory-set controllers;

- Be integrated with the treatment unit to automatically shut-down or no longer accept or expel waste if treatment conditions are not maintained at specified performance levels;

- Be calibrated periodically as specified by the monitoring device's manufacturer; and

- Provide a tamper-proof recording of all critical operating parameters.

The committee recommended that parametric monitoring could substitute or replace biological indicator monitoring provided that all of the above conditions were achieved.

3.4 Site Approval for Medical Waste Treatment Technologies

The purpose of the site-approval process is to ensure that the treatment equipment sited is the same equipment and process approved by the state. Site approval may also require obtaining other state permits (i.e., solid waste treatment/disposal permits; emissions and discharge permits) in addition to those required under state medical waste regulations. Technology efficacy must also be demonstrated under actual operating conditions. However, the rigor of the biological indicator testing would be less than the testing required for technology approval, although tests conducted would be required to reflect the waste load compositions of waste treated. Effectiveness and reliability of the real-time monitoring systems must also be demonstrated to receive site approval. Additionally, agency review is necessitated to verify proper and safe operations, verify disposal of waste residues, and verify operator training.

Specifically, to fulfill microbial inactivation and information requirements recommended for site approval, the equipment user must:

- Demonstrate that required resistant bacterial endospores (as recommended in Table II) are inactivated to Level III criteria under typical waste load and challenge compositions;

- Verify that user verification protocols adequately demonstrate effectiveness of the treatment process;

- Verify the relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment (i.e., correlation of biological indicator inactivation with time and temperature via thermocouple monitoring);

- Document in a written plan,

  - Names or positions of the equipment operators
  - Waste types or categories to be treated
  - Waste segregation procedures required
  - Wastes types prohibited from treatment
  - Equipment operation parameters
  - Efficacy monitoring procedures
  - Operating documentation and record-keeping requirements
  - Contingency waste disposal plans
  - Personal protective equipment requirements

- Shut-down, clean-out and maintenance procedures
- Emergency response plans
- Operator training requirements; and

- Provide for state review,

  - Equipment model number and serial number
  - Equipment specification and operations manual
  - Certification that equipment is identical to state approved system
  - User's written plan
  - Certification documentation of operator training.

The state may want to visit the site of proposed operation to validate operations, or approve the site by reviewing the submitted information and documents. As a condition of site approval, the state should affirm its right to inspect the facility and affirm the right to revoke site approval if health and safety violations are discovered, if permit conditions are not being fulfilled, or if the facility is not adhering to its written plan.

Recommendations for the site approval process are presented in the approval process guideline in Appendix A.

3.5 USEPA Pesticide Use Registration

The use of a chemical agent in any treatment process may involve pesticide registration with the USEPA Pesticide Registration Office under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The USEPA Pesticide Registration Office's involvement in the regulatory process is dependent on advertising claims made by the medical waste treatment equipment's manufacturer (vendor). If claims are made that specify a level of microbial inactivation by term (i.e., kills pathogens, disinfects), registration with the USEPA Pesticide Registration Office is required.

Registration for a label claim will require the manufacturer (vendor) to submit efficacy studies of the process for review. Currently, the only label claim allowed for any medical waste treatment technology is the claim of "sanitizer", which is defined as "an antimicrobial agent that is intended for application to inanimate objects or surfaces for the purpose of reducing the microbial count to safe levels."

Several questions remain to be addressed concerning the involvement of the USEPA Pesticide Registration Office in the medical waste treatment technology review process. These questions are summarized as follows:

- For what advertising claims (and by which media, e.g, newspaper, product labels, etc.) should federal pesticide registration be required for chemical treatment processes?

- What are the specific guidelines and protocols required or what information is necessary for efficacy assessment review by USEPA Pesticide Registration Office?

- What are the quality assurance/quality control requirements required for pesticide registration?

- What potential conflicts may arise from the microbial inactivation guidelines recommended by the committee and those claims allowed by the USEPA Pesticide Registration Office?

It was recommended that the committee continue its dialogue with the USEPA Pesticide Registration Office to ensure consistency in the regulatory review process.

4.0 PERMITTING AND STATE AUTHORIZATION ISSUES

Although the review process for medical waste treatment technology approval is primarily concerned with ensuring safe and effective medical waste treatment, several permitting issues were identified and discussed by the committee. Recommendations are summarized below for each issued discussed.

4.1 User Verification: Biological Inactivation Efficacy Monitoring

User verification methodology is necessary to periodically verify to the equipment user and the state that the treatment unit is functioning properly, that proper operating procedures are used, and that performance standards are achieved. User verification protocols will employ biological indicators in addition to available verified parametric monitoring. Protocols used will have previously been approved by the state to assure the protocols are congruent with the treatment method/mechanism.

Specifically, to fulfill microbial inactivation and documentation requirements recommended for user verification, the state operating protocol will require that the equipment user to:

- Demonstrate on a periodic basis that required resistant bacterial endospores (as recommended in Table II) are inactivated to Level III criteria under standard operating procedures;
- Document the frequency of biological and/or parametric monitoring; and
- Document and record all biological indicator and critical parametric monitoring data.

Although no formal verification of compliance with these recommendations was prescribed, the committee noted that numerous regulatory agencies (i.e., the federal Occupational Safety and Health Administration, the state department of health, the state environmental agency) and accrediting associations (i.e., Joint Commission on Accreditation of Healthcare Organizations, College of American Pathologists) would serve to provide oversight. User verification requirements recommended are contained in the "State Guideline for Approval of Medical Waste Treatment Technologies" presented in Appendix A.

4.2 Commercial Versus On-Site Facilities

Commercial and on-site facilities (i.e., hospitals) can be typically distinguished by the increased volume of waste throughput from commercial facilities. As such, additional process controls, efficacy monitoring, and permitting might be necessitated to ensure that microbial inactivation is maintained and that environmental and occupational/public health and safety concerns are met.

As a facility applying for a commercial medical waste treatment permit, additional requirements may be imposed under other solid or special waste treatment/disposal regulations. As such, cooperative efforts between permitting agencies or divisions are necessitated to ensure the facility is meeting its environmental health and safety responsibilities. To assist in identifying the potential commercial application of a medical waste treatment technology, the committee recommended that the potential use of the technology be indicated in technology review information supplied to the state by the equipment manufacturer.

4.3 Previously Approved Technologies

With rapid evolution of emerging medical waste treatment technologies and with the establishment of more restrictive efficacy criteria, previously granted approvals become an issue. Within the framework of the approval or permitting process, some mechanism should be established that requires previously approved technologies to meet current efficacy criteria. A number of options should be available to the state to allow previously approved mechanisms to continue with the realization that at some point, previously approved technologies will have to meet current standards. The committee discussed several options that would allow the state to periodically review all medical waste treatment technologies to determine if they were fulfilling current standards of performance.

Option One involved the granting of approval for a technology with the provision that any modification to the equipment would require reapplication for approval under current standards. As an example, the State of New York Department of Health in its approval letter includes the following statement:

> "This approval is granted for this specific system used in your efficacy studies and should not be construed as a general endorsement of the technology employed or any other unit or system. Any modifications of the system will require separate approval of the Department and may involve further efficacy testing."

Option Two limits the granted site or use permit to a specific time period (e.g., 3 or 5 years). At the time of renewal, the unit must demonstrate that it meets the efficacy criteria and other permit conditions at the levels prescribed in the new standards.

As a third option, the state could mandate that on the issuance of the new medical waste efficacy standards, pre-existing equipment subject to regulation would be required to comply with current efficacy standards within a set time period. Following compliance, the user would have the option to replace the existing equipment with approved technology, retrofit the equipment to meet current standards, or take the equipment out of service. Incorporation of additional provisions as stated in Option One or Option Two with those in Option Three would ensure that technology meeting current standards would remain in compliance with future, more restrictive regulations.

Steam sterilizers or autoclaves were discussed as to whether they should be included as an "emerging treatment technology." It was noted that the steam sterilization process has been used for decades to sterilize medical products, biological products, and medical or biohazardous waste and is generally recognized as a traditional sterilization process. Accordingly, many states presently do not consider steam sterilization to be a new technology and do not require any additional approval as such. It was recommended by the committee that steam sterilization not be included as an "emerging treatment technology" and thus, not be subject to registration and technology approval requirements. Site and operation permits would still be necessitated, as required, under applicable state regulations.

The committee, however, did recognize that the steam sterilization process is subject to waste load variables and operator control which could lead to inadequate processing of the waste. To assist in documenting that the process is effective, the equipment operator should:

- Adopt standard written operating procedures which denote:

  - sterilization cycle time, temperature, and pressure
  - types of waste acceptable
  - types of containers and closures acceptable
  - loading patterns or quantity limitations;

- Document times/temperatures for each complete sterilization cycle;

- Use time/temperature sensitive indicators to visually note the waste has been decontaminated;

- Use biological indicators placed in the waste load (or simulated load) periodically to verify that conditions are met to achieve decontamination; and

- Maintain all records of procedure documentation, time-temperature profiles, and biological indicator results.

4.4 Small Medical Waste Treatment Devices

As stated previously, the committee took the position that Level III criteria were applicable to all medical waste treatment devices, including small "counter-top" devices. It was recognized by the committee that registration of all small medical waste treatment devices by the authorized state regulatory agency would be a significant effort in states which do not already have generator and disposal facility registration requirements. To minimize the state's effort, it was suggested that the equipment's manufacturer (or vendor) take responsibility in fulfilling siting requirements as a condition of technology approval. As such, the manufacturer would provide during the technology approval process, all information required for site approval for a typical

site for which the equipment is designed. Information required of the small treatment device manufacturer would be similar to the information required of all medical waste treatment equipment manufacturers, but would include all materials and documents required for the user to ensure proper equipment use, operational safety, and treatment technology efficacy. These materials and documents would include:

- An operations and maintenance manual;
- Information on proper use, safety precautions and the implications of potential misuse;
- Efficacy testing instructions;
- A training/education manual; and
- Available service agreements/programs.

On installation of the treatment device, the manufacturer would complete a record of the buyer, the location, and the results of on-site challenge testing at the time of purchase. This information would be submitted annually to the state by the manufacturer as the notification record of site registrations of equipment installed that previous year. The committee recommended that small medical waste treatment devices be specifically identified on initial application for technology approval.

4.5 Waste Residue Disposal

The disposition of waste residues was an environmental concern expressed by many on the committee. To ensure that waste residues are properly identified and disposed of, the committee recommended they be addressed at both the technology approval stage and equipment siting stage of the review process. During the technology approval process, information on the characteristic(s) of the waste residues, the mechanism(s), and the mode(s) of their disposal should be provided by the manufacturer. This information should include:

- A description of residues (i.e., liquid, solid, shredded, hazardous constituents);
- Waste designation (i.e., hazardous, special, general);
- Disposal mechanisms (i.e., landfilling, incineration, recycling); and
- Recycling efforts, if anticipated (i.e., waste types, amounts, percentages, name and location of recycling effort).

During the siting stage of the review process, specific information on residue disposal should also be required. This information should include all of the above information, but also specifically state with attached documentation the actual mechanism and location of disposal. To avoid recycling being used as a mechanism to potentially avoid regulatory permitting requirements and to assure that recycling efforts are legitimate, the state should request the following information from the on-site or commercial facility:

- The types of waste residue to be recycled;
- The amounts of waste residue to be recycled;
- The percentage of the total waste and waste residue to be recycled;
- The recycling mechanism used; and
- The location of the recycler.

Previously untreated medical wastes used in the development and testing of prototypical equipment should continue to be considered as potentially infectious and as such, be disposed of as untreated medical waste. To minimize environmental and occupational exposures that may result from using untreated medical wastes, it was recommended that prototypical equipment be tested using non-infectious or previously treated medical waste (i.e., treated by an approved process such steam sterilization) that has been inoculated with recommended pathogen surrogates. Waste residues generated could then be disposed of as general solid waste after verification of microbial inactivation.

4.6 Operator Training

Mandated operator training was recommended (as appropriate: small treatment devices may be excluded from this recommendation) as a requirement for process approval because of its potential affect on both efficacy and operator safety. To assure proper operation of the treatment process, the manufacturer would be required to provide an operator training program which would include:

- Training and education materials adequately describing the process, process monitors, and safety precautions and controls;
- Contingency plans in the event of abnormal occurrences (e.g., power failure, jamming, inadequate chemical concentrations) and emergencies (e.g., fire, explosion, release of chemical or biohazardous materials);
- Shut-down, clean-out and maintenance procedures;

- Personal protective equipment requirements; and

- A listing of all potential occupational safety and health risks posed by the equipment and its use.

The proposed "ASME Standard for the Qualification and Certification of Medical Waste Incinerator Operators" (September 1992) was reviewed for its potential applicability as a guideline for developing required elements for operator training. Although the committee agreed that the proposed standard was far too extensive for emerging medical waste treatment equipment operations, certain components might provide the basis for an operator training program for medical waste treatment technologies.

4.7 Equipment Operations Plan

The proposed "ASME Standard for the Qualification and Certification of Medical Waste Incinerator Operators" (September 1992) offers elements for inclusion into an equipment operations plan. Using this proposed standard as a guide, the following components are recommended for incorporation into an equipment operations plan:

- A description of all mechanical equipment, instrumentation, and power controls;

- A description of systems' operations including: acceptable waste types, loading parameters, process monitors, treatment conditions, and disposal;

- A description of all parametric controls and monitoring devices, their appropriate settings, established ranges and operating parameters as correlated with biological indicators, and calibration requirements;

- A description of the methods required, both to ensure process monitoring instrumentation is operating properly and to prevent tampering with controls;

- A description of methods and schedules for periodic calibration of process monitoring instrumentation;

- A description of proper mechanical and equipment responses, including identification of system upsets (e.g., power failure, jamming, inadequate treatment conditions) and emergency conditions (e.g., fire, explosion, release of chemical or biohazardous materials);

- A description of personal protective equipment requirements for routine, abnormal, and emergency operations;

- A thorough description of all potential occupational safety and health risks posed by the equipment and its use;

- Specific responsibility assignments for operators:

  - Collecting and organizing data for inclusion into the operating record;
  - Evaluating any discrepancies or problems;
  - Recommending actions to correct identified problems; and
  - Evaluating actions taken and documenting improvement.

4.8 Emergency and Contingency Response Plan

The development of a separate plan to assist the operating facility in properly responding to an unplanned, emergency, or abnormal event was recommended by the committee. The development of the plan will by necessity, be a shared responsibility between the manufacturer (vendor) and the equipment's user. The primary objectives of this emergency and contingency response plan are:

- To prevent or minimize biological and/or chemical agent release to the environment;

- To prevent or minimize biological and/or chemical agent exposure to the equipment operator or other support or maintenance personnel; and

- To develop contingency medical waste treatment or disposal alternatives for untreated or inadequately treated waste.

The plan should take into consideration those events that result in:

- Failure in the treatment technology (e.g., inadequate chemical agent concentration, temperature);

- Mechanical failure (e.g., jammed shredder, inadequate steam pressure);

- Equipment shut-down in mid-cycle;

- Spill or release of biological or chemical agents; and

- Accumulation of untreated or inadequately treated medical waste.

As the equipment designer, the manufacturer (vendor) should provide evidence of a failure mode and effect analysis to prevent or minimize inadequate treatment and biological/chemical exposures caused by equipment, process design, process control, and process monitoring failures. This analysis should examine all possible and expected effects of failures, specifying in detail the nature of the effect and causes of action to be taken to prevent biological/chemical exposures. The analysis must examine the effects of failure related to:

- All process controls and process monitoring devices, their appropriate settings, and established ranges and operating parameters;
- All parametric controls and associated monitoring devices, their appropriate settings, and established ranges and operating parameters as correlated with biological indicators, and calibration requirements;
- Proper mechanical and equipment responses, including identification of system upsets or malfunction (e.g., power failure, jamming, inadequate treatment conditions) and emergency conditions (e.g., fire, explosion, release of chemical or biohazardous materials);
- The methods required, both to ensure process and parametric monitoring devices are operating properly and to detect tampering with the devices;
- The methods and schedules for periodic calibration of process and parametric control and monitoring instrumentation; and
- Equipment/inadequately treated waste decontamination procedures required in the event of a mid-cycle shut-down.

The equipment user has the responsibility of incorporating the manufacturer-supplied information into a descriptive written emergency and contingency response plan. Additional information to be provided in the plan should at a minimum include:

- A description of all potential occupational safety and health risks posed by the equipment and its use;
- A description of proper responses for system upsets and emergency conditions;
- A description of personal protective equipment requirements for routine, abnormal, and emergency operations;
- A description of proper medical response if required; and
- A pre-designated disposal method and site for untreated or inadequately treated medical waste if an equipment failure precludes use of the treatment equipment.

5.0 RESEARCH AND DEVELOPMENT

The issue of state responsibility and regulation in the research and developmental phase of medical waste technologies was raised. It was recognized that there was a need to develop new technologies, but time, staffing and funding of the permitting state agency might preclude the state's involvement in a research and development project. Concerns raised in state involvement with research and development projects included:

- The process of establishing research and development variances, including limitations and allowances;
- The knowledge of and permitting of potential environmental emissions and safety considerations;
- Treatment process residue disposal; and
- Agency funding and staffing.

Because of the above concerns, it was the consensus of the committee that each state view as optional its participation in experimental medical waste treatment research and development projects. For those states opting to participate in medical waste treatment technology research and development projects, the concerns raised above were discussed.

To provide a framework for discussion, the committee reviewed language currently proposed by the State of Illinois Environmental Protection Agency (IEPA) for "Experimental Permits" for medical waste treatment technologies. Language as proposed states that the "Agency may issue Experimental Permits" provided that the "applicant can provide proof that the process or technique has a reasonable chance for success." Additionally the IEPA requires evidence that "environmental hazards are minimal" and requires a "description of the type of residuals anticipated and how they will be managed and disposed of." As proposed, the Experimental Permits are to be granted for two years with a one-time renewal based on submittal of application of renewal and a report summarizing equipment performance, efficacy results, and management of residual materials.

In the discussion that followed, the question was raised of how proof can be provided that the equipment has a "reasonable chance of success." It was suggested that proof may consist of data acquired from scaled-down prototypical models or from analogous technologies that have a proven track record. It was noted from the prior discussion that IEPA stated it may issue Experimental Permits allowing the IEPA discretion in granting an experimental permit. To minimize concerns that research and development of a medical waste treatment technology may pose environmental and occupation risks, an application form similar to that required of a technology seeking formal approval might be submitted. The form would request available environmental and occupational safety data in addition to equipment specifications, residue management and disposal, and any available preliminary efficacy data and protocols.

To further minimize environmental and occupational safety concerns that might arise during research and development, it was recommended that the prototypical equipment be tested using non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended pathogen surrogates. Waste residues generated could then be disposed of as general solid wastes on verification of microbial inactivation. Non-treated medical wastes used during research and development would require agency-approved treatment after testing.

Concern that the research and development permit might be used as a mechanism to operate a commercial waste treatment venture was also raised. It was suggested that to avoid this possibility the following statements be adapted into guidance document language:

- Research and Development permits are to be granted for a period of two years with a one-time renewal;
- Granting of a Research and Development permit does not assure future site approval at that site on state approval of the process;
- Research and Development permitted facilities cannot accept waste for monetary gain; and
- Research and Development permitted facilities must have any experimentally treated medical waste treated by a state approved medical waste treatment process before disposal or recycling.

Funding of the additional costs incurred by the state as a result of the increased oversight activities associated with a research and development project was also a concern. It was emphasized that the additional requirements of time, staff, and expertise to monitor and review the experimental technology would require that some mechanism (e.g., set fee or time and materials) be established to reimburse the state for these activities.

6.0 RECOMMENDATIONS FOR FUTURE ACTIVITIES

It was the committee's hope that these discussions and resultant report would be useful in establishing a nationally recognized foundation for the review and approval of emerging medical waste treatment technologies. To provide future support for the development and implementation of a nationally recognized guideline, the committee recommended:

- The establishment of a research program to evaluate the thermal, chemical and irradiation resistance of B. subtilis and B. stearothermophilus spores relative to all representative microbial groups for the determination of their use as ultimate pathogen surrogates for medical waste treatment technology efficacy testing;

- The establishment of criteria and procedures for emergency and contingency response to ensure adequate equipment decontamination and operator safety in the event of a mid-cycle shut-down or other abnormal occurrence;

- The establishment of criteria and testing procedures to monitor the potential release of biological aerosols from alternative medical waste treatment equipment;

- Establishment of a clearinghouse to create a network for:

  - Future regulatory activities
  - Integration of technology approvals/denials
  - Information on equipment failures
  - Development of emergency equipment decontamination protocols
  - Provision of access to technical expertise and documentation
  - Assistance to manufacturers in the approval process
  - Protocol review/assessment/development/continuity;

- Continued committee discussion and interaction with the USEPA Office of Pesticide Programs as that office further develops its registration requirements and protocols for medical waste treatment technologies using chemical agents; and

- The expanded integration of health and safety oversight of medical waste treatment activities by state regulatory agencies and professional accrediting associations to include defined oversight responsibilities and inspector training programs.

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APPENDIX A

STATE GUIDELINE FOR APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

PREFACE

This guideline summarizes the discussions and results of the State and Territorial Association on Alternate Treatment Technologies. It should be emphasized that the recommendations provided by the Association and adopted by the participating states are an attempt to find commonality on many of the issues and criteria required in the medical waste treatment technology review process. Recognizing that all states may not totally agree with these recommended criteria or protocols, this guideline can serve as a foundation or model for the development of state guidelines or regulations. It is also recognized that definitions, terms, and regulatory methodologies used within the framework of this guideline may not be compatible with granted legislative authority or existing regulatory language. As such, this guideline may require revision to conform with specific state statutes and regulatory requirements.

STATE GUIDELINE FOR APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

A. DEFINITION OF MICROBIAL INACTIVATION

A1. Inactivation is required to be demonstrated of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; a 6 Log_{10} reduction is defined as a 6 decade reduction or a one-millionth (0.000001) survival probability in a microbial population (i.e., a 99.9999% reduction).

A2. Inactivation is required to be demonstrated of B. stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater; a 4 Log_{10} reduction is defined as a 4 decade reduction or a 0.0001 survival probability in a microbial population (i.e., a 99.99% reduction).

B. REPRESENTATIVE BIOLOGICAL INDICATORS

B1. One or more of the following representative microorganisms from each microbial group shall be used to determine if microbial inactivation requirements are met:

a) Vegetative Bacteria

- Staphylococcus aureus (ATCC 6538)
- Pseudomonas aeruginosa (ATCC 15442)

b) Fungi

- Candida albicans (ATCC 18804)
- Penicillium chrysogenum (ATCC 24791)
- Aspergillus niger

c) Viruses

- Polio 2 or Polio 3
- MS-2 Bacteriophage (ATCC 15597-B1)

d) Parasites

- Cryptosporidium spp. oocysts
- Giardia spp. cysts

e) Mycobacteria

- Mycobacterium terrae

- Mycobacterium phlei
- Mycobacterium bovis (BCG) (ATCC 35743).

B2. Spores from one of the following bacterial species shall be used for efficacy evaluation of chemical, thermal, and irradiation treatment systems:

a) B. stearothermophilus (ATCC 7953)
b) B. subtilis (ATCC 19659).

C. QUANTIFICATION OF MICROBIAL INACTIVATION

C1. Microbial inactivation ("kill") efficacy is equated to "Log_{10} Kill" which is defined as the difference between the logarithms of the number of viable test microorganisms before and after treatment. This definition is equated as:

$$Log_{10}Kill = Log_{10}(cfu/g\ "I") - Log_{10}(cfu/g\ "R")$$

where:

Log_{10}Kill is equivalent to the term Log_{10} reduction;

"I" is the number of viable test microorganisms introduced into the treatment unit;

"R" is the number of viable test microorganisms recovered after treatment; and

"cfu/g" are colony forming units per gram of waste solids.

C2. For those treatment processes that can maintain the integrity of the biological indicator carrier (i.e., ampules, plastic strips) of the desired microbiological test strain, biological indicators of the required strain and concentration can be used to demonstrate microbial inactivation. Quantification is evaluated by growth or no growth of the cultured biological indicator.

C3. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator (i.e., chemical inactivation/grinding), quantitative measurement of microbial inactivation requires a two step approach: Step 1, "Control"; Step 2, "Test." The purpose of Step 1 is to account for the reduction of test microorganisms due to loss by dilution or physical entrapment.

a) Step 1:

1) Use microbial cultures of a predetermined concentration necessary to ensure a sufficient microbial recovery at the end of this step.

2) Add suspension to a standardized medical waste load that is to be processed under normal operating conditions without the addition of the treatment agent (i.e., heat, chemicals).

3) Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.

4) Plate recovered microorganism suspensions to quantify microbial recovery. (The number of viable microorganisms recovered serves as a baseline quantity for comparison to the number of recovered microorganisms from wastes processed with the treatment agent).

5) The required number of recovered viable indicator microorganisms from Step 1 must be equal to or greater than the number of microorganisms required to demonstrate the prescribed Log reduction as specified in Section A (i.e., a 6 Log_{10} reduction for vegetative microorganisms or a 4 Log_{10} reduction for bacterial spores). This can be defined by the following equations:

$$Log_{10}RC = Log_{10}IC - Log_{10}NR$$

or

$$Log_{10}NR = Log_{10}IC - Log_{10}RC$$

where:

$Log_{10}RC$ > 6 for vegetative microorganisms and > 4 for bacterial spores and where:

$Log_{10}RC$ is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) recovered in the non-treated processed waste residue;

$Log_{10}IC$ is the number of viable "Control" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit;

$Log_{10}NR$ is the number of "Control" microorganisms

(in colony forming units per gram of waste solids) which were not recovered in the non-treated processed waste residue. $Log_{10}NR$ represents an accountability factor for microbial loss.

b) Step 2:

1) Use microbial cultures of the same concentration as in Step 1.

2) Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the treatment agent.

3) Collect and wash waste samples after processing to recover the biological indicator organisms in the sample.

4) Plate recovered microorganism suspensions to quantify microbial recovery.

5) From data collected from Step 1 and Step 2, the level of microbial inactivation (i.e., "Log_{10} Kill") is calculated by employing the following equation:

$$Log_{10}Kill = Log_{10}IT - Log_{10}NR - Log_{10}RT$$

where:

$Log_{10}Kill$ is equivalent to the term Log_{10} reduction;

$Log_{10}IT$ is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) introduced into the treatment unit. $Log_{10}IT = Log_{10}IC$;

$Log_{10}NR$ is the number of "Control" microorganisms (in colony forming units per gram of waste solids) which were not recovered in the non-treated processed waste residue;

$Log_{10}RT$ is the number of viable "Test" microorganisms (in colony forming units per gram of waste solids) recovered in treated processed waste residue.

D. EFFICACY TESTING PROTOCOLS

D1. Methodology employed to determine treatment efficacy of the technology will need to assure required microbial inactivation and assure the protocols are congruent with the treatment method. Protocols developed for efficacy testing shall incorporate, as applicable, recognized standard procedures such as those found in USEPA "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods" and APHA et al., Standard Methods for the Examination of Water and Waste Water.

D2. The state agency reviewing medical waste treatment technologies (the "Agency") shall prescribe those types and compositions of medical wastes that present the most challenge to treatment effectiveness under normal operating conditions of the equipment reviewed.

D3. Dependent on the treatment process and microbial inactivation mechanisms utilized, protocols evaluating medical waste treatment systems shall specifically delineate or incorporate, as applicable:

a) Waste compositions that typify actual waste to be processed;

b) Waste types that provide a challenge to the treatment process;

c) Comparable conditions to actual use (i.e., process time, temperature, chemical concentration, pH, humidity, load density, load volume);

d) Assurances that biological indicators (i.e., ampules, strips) are not artificially affected by the treatment process;

e) Assurances of inoculum traceability, purity, viability and concentration;

f) Dilution and neutralization methods that do not affect microorganism viability;

g) Microorganism recovery methodologies that are statistically correct (i.e., sample collection, number of samples/test, number of colony forming units/plate); and

h) Appropriate microbial culturing methods (i.e., avoidance of microbial competition, the selection of proper growth media and incubation times).

E. TECHNOLOGY APPROVAL PROCESS

E1. To initiate the technology review process, the manufacturer (vendor) shall complete and submit the "Evaluation of Medical Waste Treatment Technology: Information Request Form" to the Agency. The manufacturer (vendor) shall:

a) Provide a detailed description of the medical waste treatment equipment to be tested including manufacturer's instructions and equipment specifications, operating procedures and conditions including, as applicable, treatment times, pressure, temperatures, chemical concentrations, irradiation doses, feed rates, and waste load composition;

b) Provide documentation demonstrating the treatment method meets microbial inactivation criteria and required testing protocols including a detailed description of the test procedures and calculations used in fulfilling required performance standards verifying microbial inactivation, of user verification methodology, and of microbial culturing protocols which ensure traceability, purity and concentration;

c) Provide information on available parametric controls/monitoring devices, verifying microbial inactivation and ensuring operator non-interference;

d) Provide documentation of applicable emission controls for suspected emissions;

e) Provide information relating to waste residues including their potential hazards/toxicities and their specific mode of disposal or recycling;

f) Provide documentation providing occupational safety and health assurance; and

g) Provide information on energy efficiency and other potential benefits the treatment technology has to offer to the environment.

E2. The manufacturer (vendor) shall demonstrate that all required pathogen surrogates and resistant bacterial endospores are inactivated to criteria specified in Section A and Section C under all Agency specified challenge waste load compositions.

E3. The manufacturer (vendor) shall develop and demonstrate that site approval and user verification testing protocols are workable and valid.

E4. The manufacturer (vendor) shall demonstrate where technically practical, the relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment.

E5. The manufacturer (vendor) shall develop contingency response plans and protocols for use in the event of an emergency, accident, or equipment malfunction. The manufacturer (vendor) shall demonstrate that developed protocols are effective in providing operator safety from physical, chemical, or biological exposures during and after the event including decontamination procedures.

E6. The manufacturer (vendor) shall demonstrate evidence of USEPA pesticide registration for those treatment processes that employ a chemical agent to inactivate microorganisms.

E7. Upon demonstration to the Agency's satisfaction, technology approval is granted only under the conditions specified in the manufacturer's instructions and equipment specifications, operating procedures and conditions including, as applicable, treatment times, temperatures, pressure, chemical concentrations, irradiation doses, feed rates, and waste load composition. Revisions to these equipment and operating conditions, as warranted relevant to the Agency, will require re-application for approval to the Agency.

F. SITE APPROVAL PROCESS

F1. To fulfill microbial inactivation requirements and information requirements for site approval, the equipment user shall:

a) Demonstrate that the equipment sited is the same equipment and process approved by the Agency as specified in Section E.

b) Demonstrate that required resistant bacterial endospores are inactivated as specified in Section A2 criteria under typical waste load and Agency specified challenge compositions;

c) Verify that user verification protocols adequately demonstrate microbial inactivation; and

d) Verify the relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment.

F2. The site facility shall provide a written operations plan that includes:

a) The names or positions of the equipment operators;

b) The waste types or categories to be treated;

c) Waste segregation procedures required;

d) Wastes types prohibited for treatment;

e) Equipment operation parameters;

f) Microbial inactivation monitoring procedures;

g) Shut-down, clean-out and maintenance procedures;

h) Personal protective equipment requirements; and

i) Operator training requirements.

F3. The site facility shall provide a written emergency and contingency response plan that includes:

a) A description of proper responses, including identification of system upsets (i.e., power failure, jamming, inadequate treatment conditions) and emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials);

b) A description of personal protective equipment requirements for routine, abnormal, and emergency operations; and

c) A description of all potential occupational safety and health risks posed by the equipment and its use.

F4. The site facility shall submit to the Agency for their review:

a) Equipment model number and serial number;

b) Equipment specification and operations manual;

c) Certification that equipment is identical to the state authorized system;

d) A copy of the facility's operations plan;

e) A copy of the facility's emergency and contingency response plan; and

f) Certification documentation of operator training.

F5. As a condition of site approval, the Agency shall have a right to inspect the facility and the right to revoke site approval if health and safety violations are discovered, if permit conditions are not being fulfilled, or if the facility is not adhering to its written plans.

F6. Any modifications to the medical waste treatment unit may require re-approval by the Agency and may involve further efficacy testing.

G. USER VERIFICATION

G1. To verify that the medical waste treatment unit is functioning properly and that performance standards are achieved, the equipment user shall:

a) Demonstrate that required resistant bacterial endospores are inactivated to criteria as specified in Section A2 under standard operating procedures using protocols that have previously been approved by the Agency as specified under Section E and F;

b) Demonstrate adherence to the frequency of biological monitoring specified by the Agency; and

c) Document and record all biological indicator and parametric monitoring data.

G2. To document microbial inactivation for steam sterilizers and autoclaves, the equipment operator shall:

a) Adopt standard written operating procedures which denote:

1) Sterilization cycle time, temperature, pressure

2) Types of waste acceptable

3) Types of containers and closures acceptable

4) Loading patterns or quantity limitations;

b) Document times/temperatures for each complete sterilization cycle;

c) Use time-temperature sensitive indicators to visually denote the waste has been decontaminated;

d) Use biological indicators placed in the waste load (or simulated load) periodically to verify that conditions meet microbial inactivation requirements as specified in Section A2; and

e) Maintain all records of procedure documentation, time-temperature profiles, and biological indicator results.

G3. Medical waste incinerators are to be operated, maintained, and monitored as specified in applicable site and operating permits.

H. SMALL MEDICAL WASTE TREATMENT DEVICES

H1. All small medical waste treatment devices shall fulfill the requirements necessary for technology approval and shall meet the microbial inactivation requirements as defined in Section A.

H2. Technology and siting approval are the responsibility of the manufacturer or equipment vendor. The manufacturer (vendor) shall provide to the Agency:

a) All information required for technology approval as defined in Section E;

b) All information required of site approval for a typical site for which the equipment is designed as defined in Section F; and

c) All materials and documents required of the user to ensure proper use, safety, and effective treatment. These materials and documents would include:

1) An operations and maintenance manual;

2) Information on proper use and potential misuse;

3) Microbial inactivation testing instructions;

4) Training/education manual; and

5) Available service agreements/programs.

H3. The manufacturer (vendor) shall furnish the user of the treatment device:

a) An operations and maintenance manual;

b) Information on proper use and potential misuse;

c) Microbial inactivation testing instructions;

d) Training/education manual; and

e) Available service agreements/programs.

H4. Upon the installation of the treatment device, the manufacturer shall compile a record of the buyer, the location, and the results of on-site challenge testing at time of purchase. This information shall be submitted annually to the Agency by the manufacturer (vendor) as the notification record of site registrations of equipment installed that previous year.

I. PREVIOUSLY APPROVED TECHNOLOGIES

I1. Medical waste treatment equipment which is subject to these registration and technology approval requirements that has been installed and operated before January 1, 1994, shall comply with current efficacy standards by (date). By (date), pre-existing medical waste treatment equipment shall have been modified to meet current standards, taken out of service, or replaced by approved equipment.

I2. Steam sterilizers, autoclaves, and incinerators are not included within the category of "emerging treatment technologies" and are not subject to these registration and technology approval requirements. Site and operation permits are still necessitated, as required, under applicable state regulations.

J. WASTE RESIDUE DISPOSAL

J1. Information on the characteristic(s) of all waste residues (liquids and solids), and the mechanism(s) and mode(s) of their disposal shall be provided by the manufacturer on the "Application for Evaluation and Approval of Medical Waste Treatment Technologies." This information shall include:

a) Description of residues (i.e., liquid, solid, shredded, hazardous constituents);

b) Waste designation (i.e. hazardous, special, general);

c) Disposal mechanism (i.e. landfilling, incineration, recycling); and

d) Recycling efforts, if anticipated, (i.e., waste types, amounts, percentages, name and location of recycling effort).

J2. Information on waste residue disposal shall be provided by the user facility as required under site approval (Section F). This information shall include:

a) All information requested in Section J1;

b) The disposal site (name and address);

c) The mechanism of disposal (i.e. landfilling or incineration); and

d) The amounts of residue(s) anticipated to be disposed of (e.g., volume and weight per week).

J3. If residue(s) are to be recycled, the following information shall be provided by the user facility as required under site approval (Section F). This information shall include:

a) The types of waste residue to be recycled;

b) The amounts of waste residue to be recycled;

c) The percentage of the total waste and waste residue to be recycled;

d) The recycling mechanism used; and

e) The name and location of the recycler.

J4. Previously untreated medical wastes used in the development and testing of prototypical equipment shall be considered potentially infectious and will be required to be disposed of as untreated medical waste.

J5. Prototypical equipment testing using non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended pathogen surrogates can be disposed of as general solid waste after verification of microbial inactivation.

J6. All liquid and solid waste residues will be disposed of in accordance with applicable state and local regulations.

K. OPERATOR TRAINING

K1. To assure proper operation of the treatment process, the manufacturer (vendor) shall provide to the user as part of the treatment equipment purchase an operator training program which shall include:

a) A description of all mechanical equipment, instrumentation, and power controls;

b) A description of system operations including waste types acceptable,

loading parameters, process monitors, treatment conditions, and residue disposal procedures;

c) A description of all parametric controls and monitoring devices, their appropriate settings as correlated with biological indicators, and calibration requirements;

d) A description of proper responses, including identification of system upsets (i.e., power failure, jamming, inadequate treatment conditions) and procedures to be followed during emergency conditions (i.e., fire, explosion, release of chemical or biohazardous materials);

e) A description of the procedures for equipment shut-down and clean-out for maintenance or other purposes;

f) A description of personal protective equipment requirements for routine, abnormal, and emergency operations; and

g) A description of all potential occupational safety and health risks posed by the equipment and its use.

K2. The facility shall develop a written equipment operations plan which shall include:

a) Delegation of responsibility for safe and effective equipment operation to operating personnel;

b) A description of operating parameters that must be monitored to ensure microbial inactivation;

c) A description of all process monitoring instrumentation and established ranges for all operating parameters;

d) A description of the methods required to ensure process monitoring instrumentation is operating properly;

e) A description of methods and schedules for periodic calibration of process monitoring instrumentation; and

f) A description of the procedures for equipment shut-down and clean-out for maintenance or other purposes.

K3. The facility shall develop a written contingency and emergency response plan to include:

a) A description of all potential occupational safety and health risks posed by the equipment and its use;

b) A description of proper responses for system upsets and emergency conditions;

c) A description of personal protective equipment requirements for routine, abnormal, and emergency operations;

d) A description of proper medical response if required; and

e) A pre-designated disposal site for untreated or inadequately treated medical waste if a mechanical failure precludes use of the treatment equipment.

K4. The facility shall document and keep on record copies of all training for at least 3 years.

L. RESEARCH AND DEVELOPMENT

L1. The Agency may issue an Experimental Permit for medical waste treatment processes or techniques that are undergoing research and development if the applicant can provide evidence that:

a) Environmental impact is minimal; and

b) Occupational exposures are minimal.

L2. The Agency's "Evaluation of Medical Waste Treatment Technology: Information Request Form" shall be submitted and shall contain environmental and occupational safety data in addition to equipment specifications, residue management and disposal, and any available preliminary microbial inactivation data and protocols.

L3. All equipment testing shall preferably use non-infectious or previously treated medical waste (i.e., treated by an approved process such as steam sterilization) that has been inoculated with recommended pathogen surrogates listed in Section B. Waste residues generated can be disposed of as general solid wastes upon verification of microbial inactivation. Untreated medical wastes used in the development and testing of prototypical equipment shall be considered potentially infectious and will be required to be disposed of as untreated medical waste.

L4. All Experimental Permits have a duration not to exceed two years with a one-time renewal.

L5. Granting of an Experimental Permit does not assure future site approval on state approval of the process.

L6. Facilities with experimental permits cannot accept waste for monetary gain.

APPENDIX B

APPLICATION FOR EVALUATION AND APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

The "Application for Evaluation and Approval of Medical Waste Treatment Technologies" is provided as a guidance document to assist state agencies in reviewing new medical waste treatment technologies. The document is intended to serve only as a model for state development of initial application forms by providing a general format of pertinent technology review questions. Definitions and terms used in this document may require revision to conform with specific state legislative and regulatory requirements.

APPLICATION FOR
EVALUATION AND APPROVAL OF
MEDICAL WASTE TREATMENT TECHNOLOGY

Name of Company			
Name of Applicant (Must be an individual[s] Name)			
Trade Name of Device		**Model Number**	
Applicant Address - Street			
City	**State**	**ZIP code**	**Applicant Telephone Number**

Department Use Only

Date Application and questionnaire received	**Date Completed**

Note: The review and assessment process will not commence until all information required is submitted and received.

D1058 3/93

APPLICATION FOR EVALUATION AND APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES:

Complete the following questionnaire and return it along with the application. Please include any additional support data which maybe applicable. Use additional paper if necessary. Reference with the related section and number(s).

A. GENERAL

A1. Is the treatment technology best suited for on-site use at the point of generation, or is it adaptable for use as a commercial or regional treatment process receiving waste from several generators?

On-site_____ Commercial/Regional_____ Both_____

A2. Is this treatment technology specified for use at small generator facilities such as physician, dental, or veterinary offices or clinics?

Yes_____No_____

A3. Has this treatment technology been approved/disapproved in any other state? If so, please indicate which states have issued a decision and submit copies of approvals/disapprovals.

A4. Has the use of this equipment ever resulted in any environmental or occupational safety violation (federal, state, or local)?

A5. Has the use of this equipment ever resulted in any injuries, of any kind, or transmissions of any disease to any person? Describe all such instances.

A6. Have you reviewed all applicable state solid and medical waste regulations for medical waste acceptance, treatment, and disposal?

A7. Have you inquired as to whether any other permits are required? Please enclose agency response and requirements with your application. List all required permits and enclose copies of any permit approvals.

NOTE: Local governments or other agencies may require permits.

B. LEVEL OF TREATMENT

B1. Does the level of microbial inactivation achieved by the treatment process meet the following definition?

"Inactivation of vegetative bacteria, fungi, lipophilic/hydrophilic viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater; and inactivation of B. stearothermophilus spores or B. subtilis spores at a 4 Log_{10} reduction or greater."

Yes___ No___ If no, specify where the definition is unfulfilled.

C. CHARACTERIZATION OF PROPOSED TREATMENT PROCESS

C1. Please check the appropriate categories that best describe the methods of this proposed technology. Proposed treatment technologies may incorporate several of the categories listed below.

Chemical	____	Heat	____
Mechanical	____	Shredder	____
Microwave	____	Grinder	____
Hammermill	____	Irradiation	____
Plasma Arc	____	Radiowave	____
Encapsulation	____		

Other (specify)_____

D. WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS

Please identify if the proposed system is compatible or non-compatible with the following types of waste.

	Type of Waste	Compatible	Non-compatible
D1.	Cultures and stocks of infectious agents and associated biologicals	____	____
D2.	Liquid human and animal waste including blood and blood products and body fluids	____	____
D3.	Pathological waste	____	____

D4. Contaminated waste from animals ____ ____

D5. Sharps ____ ____

D6. Other _____ ____ ____

Please refer to the state medical waste regulations for further definition of the medical waste categories and prescribed medical waste management requirements.

D7. What waste characteristics present the most challenge to the proposed treatment process:

Organic materials ____

Liquids ____

Density/compaction ____

Other characteristics ____ Specify: _____

_____

D8. Describe by composition (i.e., material and percentage) those medical wastes that would pose the most challenge to the proposed technology. Why?

D9. Describe the physical or chemical components of medical wastes that would interfere, cause mechanical breakdown, or compromise the treatment process or microbial inactivation efficacy.

E. MICROBIOLOGICAL TEST PROCEDURES

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeasts, parasites, lipophilic/hydrophilic viruses, and mycobacteria at a 6 Log_{10} reduction or greater. Bacterial spores shall be inactivated at a 4 Log_{10} reduction or greater. A representative from each of the following microbial groups is required for testing.

E1. Listed below are several test organisms which have been used as microbiological indicators to determine the effectiveness of a given treatment method. If there are any data either to support or refute the inactivation of any of the biological indicators using the proposed treatment process under normal operating conditions, please check the appropriate space next to the indicator.

NOTE: If protocols utilized by the applicant to generate microbial inactivation data are deemed unacceptable by the Department, the Department reserves the right to request that the applicant resubmit data generated from Department-approved protocols. If data has not yet been procured to support the inactivation of the listed biological indicators below, please contact the Department before initiating efficacy testing to ensure research protocols are in accordance with the Department's requirements.

Vegetative Bacteria

- Staphylococcus aureus (ATCC 6538) ___
- Pseudomonas aeruginosa (ATCC 15442) ___

Fungi

- Candida albicans (ATCC 18804) ___
- Penicillium chrysogenum (ATCC 24791) ___
- Aspergillus niger ___

Viruses

- Polio 2 or Polio 3 ___
- MS-2 Bacteriophage (ATCC 15597-B1) ___

Parasites

- Cryptosporidium spp. oocysts ___
- Giardia spp. cysts ___

Mycobacteria

- Mycobacterium terrae ___
- Mycobacterium phlei ___
- Mycobacterium bovis (BCG) ATCC 35743) ___

Bacterial Spores

- B. stearothermophilus (ATCC 7953) ___
- B. subtilis (ATCC 19659) ___

E2. Were the results certified by an independent public health or certified testing laboratory? Yes____ No____

If yes, indicate the name, address, and telephone number of the certifying laboratory and attach the test protocol, results and an explanation of any available data not supporting the reduction factors referenced above.

F. BY-PRODUCTS AND DISCHARGES OF THE TREATMENT PROCESS

F1. Please indicate all by-products and discharges (to air, water, or land) which may be generated as a result of this alternative treatment technology.

Stack Emissions___ Heat___ Slag___ Vapors or Fumes___

Ash___ Liquid___ Smoke___ Aerosols___

Leachate___ Dust___ Odor___ Steam___

Chemical Residues___

Other, specify_____

F2. If any of the above by-products or discharges are indicated, how will they be controlled?

F3. If there are no by-products or discharges indicated, how was this determined?

F4. Are any of these by-products or discharges USEPA-listed hazardous wastes (40 CFR Part 261), biohazardous, etc.? No___ Yes___. If yes, explain necessary controls, personal protective equipment, storage, disposal, etc.

G. ENVIRONMENTAL EFFECTS OF THE TREATMENT PROCESS

G1.	Are any negative effects on the environment anticipated from the use of the treatment process and/or disposal of the treated waste from the treatment process?
G2.	What environmental, occupational, and/or public health hazards would be associated with a malfunction of the treatment process? Specify.
G3.	If the treatment process includes the use of water, steam, or other liquids, how will this waste discharge be handled (i.e., sewer, recycled, etc.)? Specify.
G4.	What are the physical characteristics of the waste residues generated from the treatment process (i.e., wet, dry, shredded, powdered, etc.)? Specify.
G5.	How will the treated medical waste from this process be disposed of (i.e., landfill, incineration, recycled, etc.)? Specify.
G6.	Are any by-products classified as hazardous waste (40 CFR Part 261)? Yes___No___- Complete Item A6.

H. OCCUPATIONAL HAZARDS

H1.	What are the potential hazards associated with the treatment process?
H2.	What hazard abatement/reduction strategies will be used in during the operation of this treatment process (include engineering controls, person protection equipment, etc.)?
H3.	What training will the operator(s) of the treatment process receive?

I. CRITICAL FACTORS OF THE TREATMENT PROCESS

I1. **What** are the critical factors that influence the specific treatment technology? **Specify.**

I2. **What** are the consequences if these factors are not met? Specify.

I3. **Explain** the ease and/or difficulty of operation of the medical waste treatment **system.** Specify.

I4. **What** type of ongoing maintenance is required in the operation of the treatment **system?** Specify.

Maintenance Manual Attached? Yes___ No___

I5. **What emergency measures** would be required in the event of a malfunction? **Specify.**

I6. **How** are these measures addressed in an emergency plan or in the operations **protocol?**

I7. **What is the maximum amount** of waste to be treated by this process per cycle?

I8. **How long is a cycle?**

J. CHEMICAL INACTIVATION TREATMENT PROCESSES

J1. If the treatment process involves the use of chemical inactivation:

a) What is the name of the active ingredient?

b) What concentrations must be used and maintained?

c) At what pH is the chemical agent active?

d) What is the necessary contact time?

e) If there is any incompatibility with specific materials and surfaces, specify.

f) What is the pH of any end products (i.e., liquid effluents)?

g) List any additional factors or circumstances that may interfere with the chemical's inactivation potential.

J2. What is the active life of the chemical agent after it has been exposed to air or contaminated medical waste?

J3. Have studies been conducted relative to the long-term effectiveness of the chemical agent while in use? If yes, please attach a copy of the study and test results.

J4. What health and safety hazards may be associated with the chemical (present and long-term)? Specify.

MSDS Attached? Yes___ No___

J5. Is the chemical agent registered for this specific use with the Environmental Protection Agency (USEPA) Pesticide Registration Division? Yes___ No___

If yes, provide the USEPA registration number_____ and a copy of the EPA-approved label instructions for use.

J6. Is the spent chemical agent classified as a hazardous waste by USEPA (40 CFR Part 261) or by other state criteria? Yes___ No___ If yes, specify whether by USEPA or by which state(s)_____.

J7. Is an environmental impact study for the chemical agent available? Yes___ No___ If yes, attach a copy of this information.

K. QUALITY ASSURANCE AND VERIFICATION OF MICROBIAL INACTIVATION

K1. How is the quality assurance of the treatment process addressed? Specify.

K2. What is the recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system? Specify.

K3. Other than the biological indicators listed in Section E, what other indicators, integrators, or monitoring devices would be used to show that the treatment unit or process was functioning properly? (Please describe and explain.)

K4. How is it determined that the processed waste has received proper treatment? (Check the appropriate item.)

Temperature indicator:	visual only___	continuous___	both___
Pressure indicator:	visual only___	continuous___	both___
Time indicator:	visual only___	continuous___	both___
Chemical concentration indicator:	visual only ___	continuous ___	both ___

Other: Please specify_____

K5. How have the treatment process monitors been correlated with biological indicators to ensure effective and accurate monitoring of the treatment process? Specify.

K6. What is the established process monitor calibration schedule, and what is its frequency of calibration?

K7. How are the process monitors interfaced to the system's operations to effect proper treatment conditions? Explain.

K8. How are the process monitor controls secured to prevent operator over-ride of the process before treatment is adequately affected? Explain.

K9. What failure mode and effect analyses have been performed on the treatment system? Specify and provide.

L. POST-TREATMENT RESIDUE DISPOSAL, RECLAMATION OR RECYCLING

L1. How will the treated medical wastes from this process be disposed of:

Burial in an approved landfill____

Incineration____

Recycled____

L2. If the wastes are to be recycled, provide additional evidence regarding this strategy.

L3. If the wastes are to be recycled, what percentage of the treated waste will be recycled? How will the remainder of the treated waste be disposed of?

M. POTENTIAL ENVIRONMENTAL BENEFITS

M1. Has an energy analysis been conducted on the proposed technology?

Yes___ No___ If yes, specify and provide results of that analysis.

M2. Has an economic analysis been performed on the proposed technology?

Yes___ No___ If yes, specify and provide results of that analysis.

_____

M3. How does this treatment technology improve on existing medical waste treatment and disposal methods? Specify.

M4. What is the potential of this proposed technology for waste volume reduction? Specify._____

N. OTHER RELEVANT INFORMATION AND COMMENTS

All approvals or denials received from other states, counties or agencies concerning any aspect of equipment operation and efficacy; as well as all safety, competency or training requirements for the users/operators, etc. must also be included.

APPLICATION FOR EVALUATION AND APPROVAL OF MEDICAL WASTE TREATMENT TECHNOLOGIES

CERTIFICATION STATEMENT

I certify that the information requested and contained in this document is accurate and complete and that all existing documentation requested in this application for this system or similar systems is provided. The Vendor, identified below, agrees to provide [state agency] all results of all studies conducted by or for any state, company, agency or country, or any other person as defined at [state regulation], which the vendor conducts, or is in any way aware of, to determine the operational performance of any aspect of the equipment for which authorization to operate in this state is requested on the filing this application. I am aware that regulated medical waste management systems to be operated in this state for regulated medical waste treatment and/or destruction must be identical to the system described in this application for authorization to operate in this state and for which operational data is presented in the application for [state agency] review. Any and all changes in the system and related equipment after this application submittal and [state agency] review and authorization to operate must be submitted in writing to [state agency] prior to use. The [state agency's] permitting conditions or other agency's authorizations granted to operate this system to treat and/or destroy regulated medical waste will be reviewed by [state agency] periodically to ensure specifically authorized regulated medical waste technology systems meet currently accepted standards for regulated medical waste management. [State Agency] may modify system operational or performance requirements for systems that received prior authorizations to operate, if warranted to protect human health and the environment.

I am further aware that on reviewing the completed application and the required attachments, [state agency] may have additional questions and require submissions of data and other information deemed necessary regarding this or related medical waste disposal systems. Failure to provide all existing requested information will result in delays in processing the request for authorization to operate. Failure to provide all required information as outlined in the application, or willfully withholding information, may be cause for [state agency] to deny or rescind authorization to operate if [state agency] determines that the information not submitted would have been in any way relevant to its review of this technology.

NAME OF SYSTEM/EQUIPMENT	**MODEL NUMBER**
NAME OF CERTIFYING PERSON (must be a corporate officer)	**TITLE**
SIGNATURE OF CERTIFYING PERSON (must be a corporate officer)	**DATE**
NAME OF PERSON COMPLETING APPLICATION	**TITLE**
NAME OF VENDOR (COMPANY)	**TELEPHONE**
NAME OF DIVISION	**FAX**
ADDRESS	
CITY, STATE & ZIP CODE	

APPENDIX C

EXAMPLE:
MICROBIAL INACTIVATION TESTING PROTOCOL FOR A GRINDER/CHEMICAL MEDICAL WASTE INACTIVATION PROCESS

PREFACE

The following protocol is provided as an example of the steps and procedures required to determine the level of microbial inactivation of a system that cannot ensure or provide integrity of the biological indicator carrier (i.e., test strip, ampule) through the treatment process to recovery. This protocol is not intended to be all inclusive or meet all the variables or constraints associated with the multiplicity of medical waste treatment technologies. However, the protocol includes the components and the processes that require consideration to ensure the data recovered and numeric calculations made accurately represent the true microbial inactivation level of the treatment process.

This example provides a protocol for a chemical inactivation/ grinding medical waste treatment process that does not allow the retrieval of the biological indicator carrier. For each step in the protocol, an explanation or note is offered (in brackets) to provide rationale or background for the step or process described. For the protocol provided, adherence to good microbial and laboratory practices is essential for researcher and equipment operator safety and for the generation of accurate data.

EXAMPLE:
MICROBIAL INACTIVATION TESTING PROTOCOL FOR A
GRINDER/CHEMICAL MEDICAL WASTE TREATMENT PROCESS

I. Materials

A. Bacillus stearothermophilus spores as a suspension of 2×10^{10} initial inoculum. NOTE: B. stearothermophilus spores were chosen as the spore of choice due to the thermophilic nature of B. stearothermophilus and its ability to optimally grow at elevated temperatures. Culturing collected waste samples at 60°C using B. stearothermophilus spores as a biological indicator reduces the number of potential cross contaminants that might arise on a culture plate. A spore suspension of 2×10^{10} initial inoculum was chosen to provide an adequate number of recoverable spores for determining a 4 Log_{10} reduction. Determination of this concentration may require trial runs to ascertain the recovery concentrations.

B. Surrogate waste load constructed to contain by weight: 5% organic material and 95% plastics, cellulose, and glass. Total weight of sample to be between 15 and 20 pounds. NOTE: The surrogate waste load used in this example was constructed to represent the typical medical waste composition that would be treated by this system at the user site location. Surrogate waste loads may also be constructed to replicate medical waste loads which challenge the efficacy of the system. The sample weight of the load was selected as being representative of the feed rate and typical loading conditions of the unit. Weight loads should be constructed to mimic conditions of actual use.

II. Protocols

A. Control Run

1. Add 2×10^{10} B. stearothermophilus spore suspension to surrogate waste load. The spore suspension should be added as to not expose the researcher or equipment operator to the biological indicator. To minimize potential exposures and to adequately disperse the spore suspension throughout the load, the spore suspension could be transferred into four or more separate plastic screw-capped tubes. These tubes could subsequently be equally dispersed throughout the surrogate waste load.

2. Load inoculated surrogate waste into the previously cleaned (decontaminated) treatment unit and run unit without chemical inactivation agent. [The unit should be previously decontaminated to minimize cross contamination from spores originating from previous efficacy testing.]

3. Collect ten one (1) gram samples during the duration of the run (i.e., collect samples at the beginning of waste discharge through final discharge). NOTE: The amount, number and collection frequency of the sample collection will be determined previously by trial runs. The important consideration for this determination is to ensure that during the span of the run, the test data collected provide an accurate reflection of the level of microbial inactivation for the entire load.

4. Place the 1-gram samples immediately upon collection into pre-weighed (combination weight of both liquid and tube) plastic screw cap tubes containing an appropriate neutralizing solution and vortex vigorously for 5 minutes. NOTE: This step is required to neutralize chemical agent activate at the time the waste exits the unit and is necessary to determine actual microbial inactivation the treatment process and minimize the inclusion of residual chemical activity that might be present. The amount, concentration, and exposure time of the selected neutralizing agent must be pre-determined so as to neutralize the specific chemical agent without inhibiting growth of the biological indicator. Collection tubes are pre-weighed, including neutralizing agent, to determine the weight of the actual waste sample collected.

5. Construct an approximate 10-gram composite sample from the 10 representative samples collected in Step 3. [This step provides for the evaluation of the level of microbial inactivation of the entire load without assaying each individual sample taken above.]

6. Decant, sieve, and filter as required to separate solid waste material from the neutralizing liquid. Save liquid effluent. [This step is required to wash bacterial spores from the collected waste sample. Protocols involved in this rinsing step will be determined by trial runs to ascertain the best mechanisms to adequately rinse and separate the solid waste components from the liquid rinse.]

7. Wash and vortex solid materials a second time with neutralizing buffer. Decant, sieve, and filter as required to separate solid waste material from liquid. Combine liquid effluent with that obtained in Step 6. [This step provides an extra wash to collect from the waste as many of the spores as possible.]

8. Filter liquid through Millipore™ filtration unit or equivalent to concentrate retrieved spores on membrane filter. Wash filter with 10 mls of citrate or other appropriate buffer. [This step concentrates retrieved spores to equal the number of spores from 10 grams waste/10 mls buffer or by factoring, the number of spores from 1 gram waste per 1 ml buffer. For example,

plating one ml of the liquid would result in the number of cfu on the plate to be equal to the number spores per one gram of waste.]

a) Triplicate plate 0.1 ml from the 10 ml concentrate in Step 8 above; this dilution represents Plate A. [This step equates to a total dilution of 1:10.]

b) Add 1.0 ml of the 10 ml concentrate in Step 8 above to 9.0 mls of buffer solution (this represents a 1:10 serial dilution and is represented as Dilution Tube B). Triplicate plate 0.1 ml of Dilution Tube B; this dilution represents Plate B. [This step equates to a total dilution of 1:100.]

c) Add 1.0 ml of Dilution Tube B above to 9.0 mls of buffer solution (This represents an additional 1:10 serial dilution and is represented as Dilution Tube C). Triplicate plate 0.1 ml of Dilution Tube C; this dilution represents Plate C. [This step equates to a total dilution of 1:1000).

d) Add 1.0 ml of Dilution Tube C above to 9.0 mls of buffer solution (This represents an additional 1:10 serial dilution and is represented as Dilution Tube D). Triplicate plate 0.1 ml of Dilution Tube D; this dilution represents Plate D. [This step equates to a total dilution of 1:10,000).

B. Test Run

1. Follow protocols in II A. except run the treatment unit with specified chemical inactivation agent concentrations.

2. Upon washing the membrane filter in Step II.8 with 10 mls of buffer:

a) Triplicate plate 1 ml of buffer in Step 2 above via the pour plate method (i.e., 1 ml of spore concentrate into 10-12 mls of liquid agar. Vortex and pour into plate; this represents Plate A^1. [This step equates to no dilution factor, i.e., this number represents the number of spores per gram of waste.]

b) Triplicate plate 0.1 ml of buffer in Step 2 above via the pour plate method (i.e., 0.1 ml of spore concentrate into 10-12 mls of liquid agar. Vortex and pour into plate; this represents Plate B^1. [This step equates to a 1:10 dilution factor.]

c) Add 1.0 ml of the buffer in Step 2 above to 9.0 mls of buffer solution [this represents a 1:10 serial dilution and is represented as Dilution Tube C^1]. Triplicate plate 0.1 ml of Dilution Tube C^1; this dilution represents Plate C^1. [This step equates to a total dilution of 1:100.]

III. Calculations

Using the equations found in Section C3 of "State Guideline for Approval of Alternate Medical Waste Technologies", the following calculations are performed:

A. Calculate initial inoculum in spores per gram waste.

1. 2×10^{10} spores/15 lbs. waste =
2×10^{10} spores/6.8×10^{3} grams waste =
3×10^{6} spores/gram waste = inoculum = IC

$IC = 3 \times 10^{6}$

B. Calculate number of spores recovered.

1. Step One "Control" Data:

	a	b	c
Plate A -	TMTC*	TMTC	TMTC
Plate B -	TMTC	TMTC	TMTC
Plate C -	TMTC	TMTC	TMTC
Plate D -	200 cfu**	210 cfu	190 cfu

*Too Many To Count
**Colony Forming Units

Accounting for the dilution factor of 10,000 for Plate D, the average recovery of viable "Control" spores per gram equals 200 x 10,000 or 2,000,000 spores/gram or 2×10^{6} spores/gram.

$RC = 2 \times 10^{6}$

2. Step Two "Test" Results:

	a	b	c
Plate A[1] -	50 cfu	48 cfu	52 cfu
Plate B[1] -	5 cfu	4 cfu	6 cfu
Plate C[1] -	1 cfu	0 cfu	0 cfu

The average recovery of viable "Test" spores per gram equals 50 spores per gram (no dilution factor).

$RT = 5 \times 10^1$

C. Calculate Log_{10} Reduction.

1. Step One "Control" Results:

$Log_{10}RC = Log_{10}IC - Log_{10}NR$; where

$Log_{10}RC = Log_{10}(2 \times 10^6 \text{ spores/gram}) = 6.301$
$Log_{10}IC = Log_{10}(3 \times 10^6 \text{ spores/gram}) = 6.477$
$Log_{10}NR = Log_{10}IC - Log_{10}RC$
$Log_{10}NR = 6.477 - 6.301 = 0.176$

$Log_{10}NR = 0.176$

2. Step Two "Test" Results and Log_{10}Kill Calculation:

a) $Log_{10}Kill = Log_{10}IT - Log_{10}NR - Log_{10}RT$, where:

$Log_{10}IT = Log_{10}IC = 6.477$
$Log_{10}NR = 0.176$
$Log_{10}RT = Log_{10}(5 \times 10^1) = 1.699$

b) Log_{10} Reduction (Log_{10}Kill), where:

$Log_{10}Kill = 6.477 - 0.176 - 1.699 = 4.602$

$Log_{10}Kill = 4.602$

APPENDIX D

LIST OF PARTICIPANTS IN ROUNDTABLE DISCUSSIONS IN NEW ORLEANS, ATLANTA, AND WASHINGTON, D.C.

FEDERAL AGENCIES

Centers for Disease Control and Prevention

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Chief, Special Wastes Section
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Office of Solid Waste
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64-56

H. B. 2544

Bill-Health, Infectiou

(By Delegates Hunt, Linch, Compton, Faircloth, Jenkins and Riggs)

[Introduced Feburary 1, 1999; referred to the Committee on Health and Human Resources then the Judiciary.]

A BILL to amend and reenact section one, article five, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, relating to authorizing the division of health to promulgate a legislative rule relating to infectious medical waste.

Be it enacted by the Legislature of West Virginia:

That section one, article five, chapter sixty-four of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted, to read as follows:

ARTICLE 5. AUTHORIZATION FOR DEPARTMENT OF HEALTH AND HUMAN RESOURCES TO PROMULGATE LEGISLATIVE RULES.

§64-5-1. State board of health; division of health.

(a) The legislative rule filed in the state register

on the eighteenth day of November, one thousand nine hundred ninety-six, authorized under the authority of section three, article thirty-two, chapter sixteen of this code, modified by the division of health to meet the objections of the legislative rule-making review committee and refiled in the state register on the sixteenth day of December, one thousand nine hundred ninety-seven, relating to the division of health (asbestos abatement licensing, 64 CSR 63), is authorized.

(b) The legislative rule filed in the state register on the first day of August, one thousand nine hundred ninety-seven, authorized under the authority of section eight, article thirty-three, chapter sixteen of this code, modified by the division of health to meet the objections of the legislative rule-making review committee and refiled in the state register on the sixteenth day of December, one thousand nine hundred ninety-seven, relating to the division of health (breast and cervical cancer diagnostic and treatment fund, 64 CSR 69), is authorized.

(c) The legislative rule filed in the state register on the first day of August, one thousand nine hundred ninety-seven, under the authority of section ten, article five-j, chapter sixteen of this code, modified by the

director of the division of health to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-third day of January, one thousand nine hundred ninety-eight, relating to the division of health (clinical laboratory technician and technologist licensure and certification, 64 CSR 57), is authorized.

(d) The legislative rule filed in the state register on the twenty-second day of December, one thousand nine hundred ninety-seven, authorized under the authority of section two, article thirteen-c, chapter sixteen of this code, relating to the division of health (drinking water treatment revolving fund, 64 CSR 49), is authorized.

(e) The legislative rule filed in the state register on the fourth day of June, one thousand nine hundred ninety-seven, authorized under the authority of section seven, article one, chapter sixteen of this code, modified by the division of health to meet the objections of the legislative rule-making review committee and refiled in the state register on the sixteenth day of December, one thousand nine hundred ninety-seven, relating to the division of health (sewage systems, 64 CSR 9), is authorized with the following amendment:

On page 7, subsection 5.1. following the sentence which ends "local health department offices." by inserting the following: "*Provided,* That the director shall issue a permit for the installation of a National Sanitation Foundation Class I home aeration unit to be installed on a single family dwelling unit when no other approved system can be installed."

(f) The legislative rule filed in the state register on the tenth day of September, one thousand nine hundred ninety-eight, authorized under the authority of section six-a, article five-j, chapter twenty, of this code, modified by the division of health to meet the objections of the legislative rule-making review committee and refiled in the state register on the twenty-fifth day of January, one thousand nine hundred ninety-nine, relating to the division of health (infectious medical waste, 64 CSR 56), is authorized.

NOTE: The purpose of this bill is to authorize the Division of Health to promulgate a legislative rule relating to Infectious Medical Waste.

Strike-throughs indicate language that would be stricken from the present law, and underscoring indicates new language that would be added.