Regulated Medical Waste Management Regulations

CHAPTER 120.

REGULATED MEDICAL WASTE MANAGEMENT REGULATIONS.

Regulated Medical Waste Management Regulations

PART I.

Definitions.

9 VAC 20-120-10. Definitions.

9 VAC 20-120-10. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise. Chapter 14 (§ 10.1-1400 et seq.) of Title 10.1 of the Code of Virginia defines words and terms that supplement those in this chapter. The Virginia Solid Waste Management Regulations, 9 VAC 20-80-10 et seq., define additional words and terms that supplement those in the statutes and this chapter. When the statutes, as cited, and the solid waste management regulations, as cited, ~~define a word or term differently~~ conflict, the definitions of the statutes are controlling.

"Act" or "regulations" means the federal or state law or regulation last cited in the context, unless otherwise indicated.

"Alternative treatment method" means a method for the treatment of regulated medical waste that is not incineration or steam sterilization (autoclaving).

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"Approved sanitary sewer system" means a network of sewers serving a facility that has been approved in writing by the Virginia Department of Health, including affiliated local health departments. Such sewer systems may be approved septic tank /drainfield systems and on-site treatment systems, or they may be a part of a collection system served by an NPDES permitted treatment works.

"Associated" means two or more firms that share staff members, management, directors, and assets or engage in joint ventures. Holding companies and part owners are associated parties.

"Ash" means the residual waste material produced from an incineration process or any combustion.

"ASTM" means the American Society for Testing and Materials.

"Autoclave tape" means tape that changes color or becomes striped when subjected to temperatures that will provide sterilization of materials during treatment in an autoclave or similar device.

"Blood" means human blood, human blood components, and products made from human blood.

"Board" means the Virginia Waste Management Board.

"Body fluids" means ~~any~~ liquid emanating or derived from humans ~~or animals and not limited to~~ including blood; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; ~~and~~ semen and vaginal secretions; amniotic fluid; urine; saliva in dental procedures; and any other body fluids that are contaminated with blood, and any other liquids emanating from humans that may be mixed or combined with body fluids.

"Closure" means the act of securing a regulated medical waste management facility pursuant to the requirements of these regulations.

"Closure plan" means the plan for closure prepared in accordance with the requirements of this chapter.

"Commonwealth" means the Commonwealth of Virginia.

~~"Conflict" means that provisions of two documents, such as regulations or a permit, do not agree and both provisions cannot be complied with simultaneously. If it is possible for both provisions to be complied with, no conflict exists.~~

"Container" means any portable enclosure in which a material is stored, transported, treated, ~~disposed of,~~ or otherwise handled.

~~"Contamination" means the degradation of naturally occurring water, air, or soil quality either directly or indirectly as a result of human activity; or the transfer of disease organisms, blood or other matter that may contain disease organisms from one material or object to another.~~

"Contaminated" means the presence or the reasonably anticipated presence of blood or other body fluids on an item or surface, or within and item.

"Contingency plan" means a document setting out an organized, planned and coordinated course of action to be followed in the event of a fire, explosion, or release of regulated medical waste or regulated medical waste constituents that could threaten human health or the environment.

"CWA" means the Clean Water Act (formerly referred to as the Federal Water Pollution Control Act), 33 USC § 1251 et seq.; PL 92-500, PL 93-207, PL 93-243, PL 93-592, PL 94-238, PL 94-273, PL 94-558, PL 95-217, PL 95-576, PL 96-148, PL 96-478, PL 96-483, PL 96-510, PL 96-561, PL 97-35, PL 97-117, PL 97-164, PL 97-216, PL 97-272, PL 97-440, PL 98-45, PL 100-4, PL 100-202, PL 100-404, and PL 100-668.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy human pathogens on a surface or item to the point where they are no longer capable of transmitting disease and the surface or item is rendered safe for handling, use, or disposal.

"Department" means the Virginia Department of Environmental Quality.

"Director" means the Director of the Department of Environmental Quality or his designee.

"Discard" means to throw away or reject. When a material is soiled, contaminated or no longer usable and it is placed in a waste receptacle for disposal or treatment prior to disposal it is considered discarded.

"Discharge" or "waste discharge" means the accidental or intentional spilling, leaking, pumping, pouring, emitting, emptying, or dumping of regulated medical waste into or on any land or state waters.

"Disposal" means the discharge, deposit, injection, dumping, spilling, leaking, or placing of any ~~regulated~~ solid waste into or on any land or water so that such ~~regulated medical~~ solid waste or any constituent of it may enter the environment or be emitted into the air or discharged into any waters, including ground waters.

"Disposal facility" means a facility or part of a facility at which ~~regulated medical~~ solid waste is intentionally placed into or on any land or water, and at which the ~~regulated medical~~ solid waste will remain after closure.

"Domestic sewage" means untreated sanitary wastes that pass through a sewer system.

"Empty" means wastes have been removed from a container using the practices commonly employed to remove materials of that type. In all such cases liquid blood and body fluids shall be removed.

"EPA" means the U.S. Environmental Protection Agency.

"Etiologic agents" means the specific organisms defined to be etiologic agents in ~~49 CFR 173.134.~~ 42 CFR 72.3. In general, etiologic agents as defined in 42 CFR 72.1, means a viable microorganism or it's toxin which causes, or may cause, human disease.

"Federal agency" means any department, agency, or other instrumentality of the federal government, any independent agency, or establishment of the federal government including any government corporation and the Government Printing Office.

"Generate" means to cause waste to become subject to regulation. When regulated medical waste is first discarded it must be appropriately packaged in accordance with this regulation. At the point a regulated medical waste is discarded it has been generated.

Note: Timeframes associated with storage and refrigeration are no longer linked to the "date of generation".

"Generator" means any person, by site location, whose act or process produces regulated medical waste identified or listed in Part III of this chapter or whose act first causes a regulated medical waste to become subject to this chapter.

"Hazardous material" means a substance or material ~~that has been determined by the United States Secretary of Transportation to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce and~~ that has been so designated under 49 CFR 171 and 173.

"Hazardous waste" means any solid waste defined as a "hazardous waste" by the Virginia Hazardous Waste Management Regulations.

"Highly leak resistant" means that leaks will not occur in the container even if the container receives severe abuse and stress, but remains substantially intact.

"Health Care Professional" means a medical doctor or nurse practicing under a license issued by the Department of Health Professions.

"Highly puncture resistant" means that punctures will not penetrate the container even if the container receives severe abuse and stress, but remains substantially intact.

~~"Limited small clinic" means an office where fewer than 10 health care professionals practice, no surgical procedures are performed, and is under the total administrative control of one or more of those practitioners. A person practicing under a license issued by the Department of Health Professions is a health care professional.~~

"Motor vehicle" means a vehicle, machine, roll off container, tractor, trailer, or semi-trailer, or any combination of them, propelled or drawn by mechanical power and used in transportation or designed for such use.

"Nonstationary health care providers" means those persons who routinely provide health care at locations that change each day or frequently. This term includes traveling doctors, nurses, midwives, and others providing care in patients' homes, first aid providers operating from emergency vehicles, and mobile blood service collection stations.

"NPDES" or "National Pollutant Discharge Elimination System" means the national program for issuing, modifying, revoking, reissuing, terminating, monitoring, and enforcing permits pursuant to §§ 307, 402, 318, and 405 of ~~CWA~~ Clean Water Act. The term includes any state or interstate program that has been approved by the Administrator of the United States Environmental Protection Agency.

"Off-site" means any site that does not meet the definition of on-site as defined in this part. Areas of a facility that are not on geographically contiguous property. Outside of the boundary of the site.

"On-site" means the same or geographically contiguous property, which may be divided by 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~~ entrance and exit to the facility are controlled by the owner or the operator of the facility. Noncontiguous properties owned by the same person but connected by a right-of-way that he controls and to which the public does not have access, is also considered on-site property.

"Owner" means the person(s) who own(s) a regulated medical waste management facility or part of a regulated medical waste management facility.

"Package" or "outside package" means a package plus its contents.

"Packaging" means the assembly of one or more containers and any other components necessary to assure compliance with minimum packaging requirements under VRGTHM or this chapter.

"Permit by rule" means provisions of this chapter stating that a facility or activity is deemed to have a permit if it meets the requirements of the provision.

"Permitted waste management facility" or "permitted facility" means a regulated medical waste treatment~~,~~ or storage~~, or disposal~~ facility that has received a permit in accordance with the requirements of the chapter.

"Physical construction" means excavation, movement of earth, erection of forms or structures, the purchase of equipment, or any other activity involving the actual preparation of the regulated medical waste management facility.

~~"Principal corporate officer" means either:~~

~~1. A president, secretary, treasurer, or vice president of the corporation in charge of a principal business function, or any other person who performs similar policy, or decision making function for the corporation, or~~

~~2. The manager of one or more manufacturing, production, or operating facilities employing more than 250 persons or having gross annual sales or expenditures exceeding $25 million (in second quarter 1980 dollars), if authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.~~

~~"Principal executive officer" means either:~~

~~1. For a federal agency:~~

~~a. The chief executive officer of the agency; or~~

~~b. A senior executive officer having responsibility for the overall operations of a principal geographic unit of the agency (e.g., regional administrators of EPA).~~

~~2. For a state agency: The chief executive officer of a department, board, commission, hospital, educational institution, or an authority.~~

~~3. For a municipality: The chief executive officer of a county, city, or town.~~

"Processing" means preparation, treatment, or conversion of regulated medical waste by a series of actions, changes, or functions that bring about a decided result.

~~"Publicly owned treatment works" or "POTW" means any device or system used in the treatment (including recycling and reclamation) of municipal sewage or industrial wastes of a liquid nature that is owned by a state or municipality (as defined by § 502(4) of the CWA).~~

~~"Putrescible waste" means regulated medical waste that contains material capable of being decomposed by microorganisms.~~

"RCRA" means the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (42 USC § 6901 et seq.), the Hazardous and Solid Waste Amendments of 1984, and any other applicable amendments to these laws.

"Regulated medical waste" means solid wastes defined to be regulated medical wastes in Part III of this chapter.

"Regulated medical waste management" means the systematic administration of activities that provide for the collection, source separation, storage, transportation, transfer, processing, treatment, and disposal of regulated medical wastes whether or not such facility is associated with facilities generating such wastes or otherwise.

"Regulated medical waste management facility" means a solid waste management facility that manages regulated medical waste.

"Safe sharps program" means a program supported by a city, county, town or public authority, which is intended to enhance the safe disposal of sharps discarded by private individuals.

"Sanitary sewer system" means a system for the collection and transport of sewage, the construction of which was approved by the Department of Health or other appropriate authority.

"Secondary container" means a storage device into which a container can be placed for the purpose of containing any leakage from the original container.

"Section" means a subpart of this chapter and when referred to all portions of that part apply.

"Sharps" means needles, scalpels, knives, ~~glass,~~ syringes with attached needles, pasteur pipettes and similar items having a point or sharp edge or that are likely to break during transportation and result in a point or sharp edge.

"Shipment" means the movement or quantity conveyed by a transporter of a regulated medical waste between a generator and a designated facility or a subsequent transporter.

"Site" means the land or water area upon which a facility or activity is physically located or conducted, including but not limited to adjacent land used for utility systems such as repair, storage, shipping, or processing areas, or other areas incident to the controlled facility or activity.

"Solid waste" means any garbage, refuse, sludge and other discarded material, including solid, liquid, semisolid or contained gaseous material, resulting from industrial, commercial, mining and agriculture operations, or community activities, but does not include (i) solid or dissolved material in domestic sewage, (ii) solid or dissolved material in irrigation return flows or in industrial discharges which are sources subject to a permit from the State Water Control Board, or (iii) source, special nuclear, or by-product material as defined by the Federal Atomic Energy Act of 1954, as amended 42 USC §§ 2011-2284. The definition of solid waste is further clarified in the Virginia Solid Waste Management Regulations 9 VAC 20-80-140.

"Solid waste management" means ~~the systematic administration of activities that provide for~~] the collection, source separation, storage, transportation, transfer, processing, treatment, and disposal of solid wastes ~~whether or not such facility is associated with facilities generating such wastes or otherwise~~ or resource recovery.

"Spill" means any accidental or unpermitted ~~spilling~~ discharge, leaking, pumping, pouring, emitting, or dumping of wastes or materials that, when spilled, become wastes.

"Start-up" or "cold start-up" means the beginning of a combustion operation from a condition where the combustor unit is not operating and less than 140º F. in all areas.

"Storage" means the holding, including during transportation, of more than ~~64~~ 200 gallons of waste, at the end of which the regulated medical waste is treated, ~~disposed,~~ or stored elsewhere. ~~Storage also means the transfer of a load of regulated medical waste from one vehicle to another during transportation, or the parking of a vehicle containing regulated medical waste during transport for 24 hours or more.~~

"Training" means formal instruction, supplementing an employee's existing job knowledge, designed to protect human health and the environment via attendance and successful completion of a course of instruction in regulated medical waste management procedures, including contingency plan implementation, relevant to those operations connected with the employee's position at the facility.

"Transfer facility" means any transportation-related facility including loading docks, parking areas, storage areas, and other similar areas where shipments of regulated medical waste are held during the normal course of transportation.

"Transportation or transport" means the movement of regulated medical waste by air, rail, highway, or water.

"Transport vehicle" means any vehicle used for the transportation of cargo.

"Vector" means a living animal, insect or other arthropod that may transmit an infectious disease from one organism to another.

"VRGTHM" means Virginia Regulations Governing the Transportation of Hazardous Materials promulgated by the Virginia Waste Management Board as authorized by §§ 10.1-1450 through 10.1-1454 of the Code of Virginia.

~~"Waste generation" means the act or process of producing a regulated medical waste~~.

"Waste management facility" means all contiguous land and structures, other appurtenances, and improvements on them used for treating, storing, ~~and~~ or disposing of waste.

"Waste management unit" means any unit at a treatment~~, storage or disposal~~ or storage facility that ~~is seeking or~~ possesses a permit, or that has received regulated medical waste (as defined in this chapter) at any time, including units that are not currently active.

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PART II.

Legislative Authority and General Information.

9 VAC 20-120-20. Authority for regulations.

These regulations are issued pursuant to the Virginia Waste Management Act, Chapter 14 (§ ~~10.1-1400 et seq.~~ 10.1-1402(11) of Title 10.1 of the Code of Virginia (hereinafter Code) which authorizes the Virginia Waste Management Board to promulgate and enforce such regulations as may be necessary to carry out its ~~duties and powers~~ powers and duties and the intent of that chapter, the Virginia Waste Management Act and the federal acts.

9 VAC 20-120-30. Purpose of regulations.

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The purpose of these regulations is to establish standards and procedures pertaining to regulated medical waste management in this Commonwealth in order to protect the public health and public safety, and to enhance the environment and natural resources.

9 VAC 20-120-40. Administration of regulations.

A. The Virginia Waste Management Board promulgates and enforces regulations that it deems necessary to protect the public health and safety, the environment, and natural resources.

B. ~~The director is authorized to issue orders to require any person to comply with this chapter or to require such steps as he deems necessary to bring about compliance. Orders shall be issued in writing through certified mail and shall be issued in accordance with provisions of applicable law. Nothing contained in this chapter shall be considered to prevent or curtail the director in the exercise of any power granted to that office by statute, executive order, or separate action of the board.~~

The Virginia Waste Management Board and/or the director may enforce the provisions of this chapter utilizing all applicable procedures under the law.

9 VAC 20-120-50. Applicability of regulations.

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A. This chapter applies to all persons who manage regulated medical waste, own or operate regulated medical waste management facilities or allow regulated medical waste management facilities to be operated on their property in this Commonwealth, to those who seek approval to engage in these activities and to all persons who manage regulated medical wastes, except those specifically exempted or excluded elsewhere in this chapter.

B. All existing regulated medical waste management facilities~~, including those under a permit on June 29, 1994,~~ must comply with this chapter~~, except as provided in this section. Any regulated medical waste management facility that is in operation on July 1, 1994, may delay until July 1, 1995, compliance with any requirement contained in this chapter that was not a requirement of "Regulated Medical Waste Management Regulations" (emergency regulations effective June 30, 1993)~~.

C. Within 180 days of the effective date of these regulations, all permitted regulated medical waste management facilities will place in their operating record, updated design and operation information in accordance with the requirements of 9 VAC 20-120-730.

D. All existing regulated medical waste management facilities in possession of a permit issued by the director are now deemed to be operating under the provisions of permit by rule. Any modification, transfer, violation or termination of the permit will be accordance with the procedures specified for permit by rule.

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9 VAC 20-120-60. Severability.

A. The board intends that these regulations be severable, so that if any provision or part of these regulations is held invalid, unconstitutional or inapplicable to any person or circumstances, such invalidity, unconstitutionality or inapplicability shall not affect or impair the remaining provisions of these regulations and their application.

B. This chapter supersedes and replaces all previous regulations of the Waste Management Board to the extent that those prior regulations conflict with the regulations presented here. Where there does not exist a conflict between the prior regulations and those presented here, no replacement shall be deemed to occur and the prior regulations shall remain. This chapter supersedes and replaces in their entirety the following previous rules of the board: "Infectious Waste Management Regulations, effective May 2, 1990, ~~and~~ "Regulated Medical Waste Management Regulations" effective June 30, 1993 and "Regulated Medical Waste Management Regulations effective June 29, 1994.

C. This chapter shall remain in effect ~~until the Virginia Waste Management Board shall amend, rescind or otherwise alter them~~ unless amended, rescinded, or otherwise altered by the Virginia Waste Management Board. Where there appears to be a conflict between this chapter and other regulations adopted at a future date, and such future regulations do not specifically clarify this chapter, this chapter shall be controlling.

D. These regulations are completely separate from all federal or local governmental regulations.

9 VAC 20-120-70. Relationship to other bodies of regulation.

A. The Solid Waste Management ~~regulations~~ Regulations, 9 VAC 20-80-10 *et seq,* address ~~special needs~~ other requirements for regulated medical waste management. Any regulated medical waste management facility must also conform to any applicable sections of the solid waste management regulations issued by the board and any special solid waste management regulations such as those defining financial assurance requirements. If there is a conflict between the details of regulations here and the others, this chapter is controlling.

B. ~~Any regulated~~ Regulatedmedical waste management facility must also comply with any applicable sections of the Hazardous Waste Management ~~regulations~~ Regulations, 9 VAC 20-60-10 *et seq,* issued by the department. If there is a conflict between the details of regulations here and the hazardous waste management regulations, the latter regulations are controlling.

C. Intrastate shipment of hazardous materials ~~are~~ is subject to the ~~Hazardous Materials Transportation regulations~~ Regulations Governing the Transportation of Hazardous Materials, 9 VAC 20-110-10 *et seq* of

the department. If there is a conflict between the details of regulations here and the hazardous materials transportation regulations, the latter are controlling.

D. Generators of regulated medical waste and regulated medical waste management facilities may be subject to the general industry standard for occupational exposure to bloodborne pathogens in 16 VAC 25-90-1910.1030 (29 CFR1910.1030).

E. Persons transporting regulated medical waste are subject to the federal hazardous material transportation requirements in 49 CFR 171 through 178.

~~D~~ F. If there is a conflict between the regulations here and adopted regulations of another agency of the Commonwealth, the provisions of these regulations are set aside to the extent necessary to allow compliance with the regulations of the other agency. If neither regulation controls, the more stringent standard applies.

~~E~~ G. Nothing here either precludes or enables a local governing body to adopt ordinances. Compliance with one body of regulation does not insure compliance with the other, and, normally, both bodies of regulation must be complied with fully.

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PART III.

Identification and Listing of Regulated Medical Wastes.

ARTICLE 1.

General.

9 VAC 20-120-80. Purpose and scope.

A. This part contains general provisions in 9 VAC 20-120-80 and 9 VAC 20-120-90, provisions for recycling of regulated medical wastes in 9 VAC 20-120-100, provisions for conditional exemption from regulation in 9 VAC 20-120-110, a description of persons exempt in all or in part from the regulations in 9 VAC 20-120-120, a description of waste and materials excluded from consideration in these regulations in 9 VAC 20-120-130, and the definition of regulated medical waste in 9 VAC 20-120-140 and 9 VAC 20-120-150.

~~B. The intent of 9 VAC 20-120-80 and 9 VAC 20-120-90 is to establish the part as defining regulated medical waste and to establish rules for wastes that were once regulated medical waste, but are no longer defined to be regulated medical waste because of treatment, recycling, reuse, or other reasons.~~

~~C~~ B. Wastes identified in Part III are regulated medical wastes, ~~which~~ and are subject to the Virginia Regulated Medical Waste Management Regulations.

~~D~~ C. The basic definition of solid waste appears in Part I along with other pertinent definitions and shall be referred to for the exact meaning of the terms used. Additional detailed descriptions of regulated medical wastes, exclusions and listings required to arrive at the proper classification of wastes are the subject of this part.

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9 VAC 20-120-90. Materials rendered nonregulated.

Wastes that were once regulated and ~~were~~ managed in accord with this chapter, and that are no longer regulated medical waste, shall be managed in accordance with such other regulations of the board that apply.

~~1.~~ A. Packaging. Treated waste that was once regulated, but is no longer regulated medical waste, shall not be packaged as regulated medical waste. Solid waste packaged as regulated medical waste is regulated medical waste.

~~2.~~ B. Recordkeeping. If the solid waste is no longer regulated medical waste because of treatment, the generator ~~or~~ and the permitted facility shall maintain a record of the treatment for three years after~~ward~~ treatment to include the date and type of treatment, type and amount of regulated medical waste treated, and the individual operating the treatment unit. Records for on-site treatment and shipping papers from commercial carriers for off-site treatment shall be maintained by the generator. Records for off-site treatment and shipping papers for off-site treatment shall be maintained by all permitted facilities. Generators or permitted facilities with more than one unit may maintain a centralized system of recordkeeping. All records shall be available for review by the department upon request.

9 VAC 20-120-100. Recycled materials.

A. Untreated regulated medical wastes shall not be used, reused, or reclaimed~~; however, wastes that have been sterilized, treated or incinerated in accord with these regulations and are no longer regulated medical waste may be used, reused, or reclaimed~~.

B. Wastes that have been treated in accord with these regulations are no longer regulated medical waste, and may be used, reused, or reclaimed in accordance with the provisions of the Virginia Solid Waste Management Regulations, 9 VAC 20-80-10 et seq.

~~B~~ C. Bed linen, instruments, medical care equipment and other materials that are routinely reused for their original purpose are not subject to these ~~regulation~~ regulations until they are discarded and are a solid waste. These items do not include reusable carts or other devices used in the management of regulated medical waste (See 9 VAC 20-120-~~380~~260).

9 VAC 20-120-110. Documentation of claims that materials are not solid wastes or are conditionally exempt from regulation.

Respondents in actions to enforce this chapter who raise a claim that a certain material is not a solid waste, or is conditionally exempt from regulation, shall demonstrate that they meet the terms of the exclusion

or exemption. In doing so, they shall provide appropriate documentation to demonstrate that the material is not a waste, or is exempt from regulation.

ARTICLE 2.

Exemptions and Exclusions.

9 VAC 20-120-120. Exemptions to the regulations.

9 VAC 20-120-130. Exclusions.

9 VAC 20-120-120. Exemptions to the regulations.

Exemptions to this chapter include:

~~1.~~ A. Composting of sewage sludge at the sewage treatment plant of generation and not involving other solid wastes.

~~2.~~ B. Land application of wastes regulated by the State Board of Health, the State Water Control Board, the Virginia Department of Agriculture and Consumer Services, or any other state agency with such authority.

~~3.~~ C. Wastewater treatment or pretreatment facilities permitted by the State Water Control Board by a NPDES permit.

~~4.~~ D. Management of hazardous waste as defined and controlled by the Virginia Hazardous Waste Management Regulations to the extent that any requirement of those regulations is in conflict with regulations here.

~~5. Persons who qualify under the rules of subdivision 5 of 9 VAC 20-120-120 are partially exempt from the regulations to the extent contained in subdivision 6 of 9 VAC 20-120-120. Health care professionals or microbiological laboratory managers who generate regulated medical waste in the provision of health care services in their own office, in the private home of a patient, or in a limited small clinic are exempt from those parts of the regulations listed in subdivision 6 of 9 VAC 20-120-120 provided the regulated medical waste is disposed of as authorized below:~~

~~a. With respect to regulated medical waste other than sharps, the office, clinic or the patient's home does not accumulate sufficient regulated medical waste to create a storage facility as regulated by Part V, the regulated medical waste is packaged and labeled in accord with Part IV, and the regulated medical waste is delivered to a permitted regulated medical waste treatment or storage facility in accordance with Part VI, except as exempted by subdivision 6 of 9 VAC 20-120-120.~~

~~b. With respect to sharps, the sharps are packaged in rigid, highly leak resistant and highly puncture resistant containers and labeled in accord with Part IV, and before filled to capacity, such containers are delivered to a permitted regulated medical waste treatment or storage facility.~~

~~c. The health care professional or microbiological laboratory manager transports or arranges for the transportation of the regulated medical waste:~~

~~(1) Himself or herself, or by his or her employee who is also a health care professional or microbiological laboratory manager, or~~

~~(2) By a transporter registered as such with the Department of Environmental Quality.~~

~~d. Notwithstanding any provisions to the contrary in these regulations, regulated medical waste transported pursuant to subdivision 5 c (1) of this section shall be exempt from subdivision 4 of 9 VAC 20-120-210,of these regulations~~

~~e. The regulated medical waste is not held in the office, the limited small clinic, or the patient's home for more than seven days after it is generated.~~

~~6. Persons qualifying under subdivision 5 of 9 VAC 20-120-120 shall be exempt from 9 VAC 20-120-270, 9 VAC 20-120-280, 9 VAC 20-120-290, 9 VAC 20-120-310 A, and 9 VAC 20-120-400 through 9 VAC 20-120-480 unless otherwise limited by subdivision 5 of 9 VAC 20-120-120.~~

9 VAC 20-120-130. Exclusions.

A. Materials described in this section may be partially or totally excluded from these regulations because they are not solid waste, not regulated medical waste or are regulated medical waste the board excludes from this chapter.

B. The following materials are not solid wastes for the purposes of this part:

1. Domestic sewage, including wastes that are not stored and are disposed of in a sanitary sewer system (with or without grinding);

2. Any mixture of domestic sewage and other wastes that pass through a sewer system to a wastewater treatment works permitted by the State Water Control Board or the State Department of Health;

3. Human remains under the control of a licensed physician or dentist, when the remains are being used or examined for medical purposes and are not solid wastes; ~~and~~

4. Human remains properly interred in a cemetery or in preparation by a licensed funeral director or embalmer for such interment or cremation~~.~~ ; and

5. Dead or diseased animals subject to regulation by the Virginia Department of Agriculture and Consumer Services.

C. The following solid wastes are not regulated medical wastes:

1. Meat or other food items being discarded because of spoilage or contamination, and not included in 9 VAC 20-120-150.

2. Garbage, trash, and sanitary waste from septic tanks and sewage holding tanks, which has been generated at any of the following locations: single or multiple residences, hotels, motels, bunkhouses, ranger stations, crew quarters, campground, picnic grounds and day-use recreation areas, except for regulated medical waste ~~generated by~~ resulting from the provision of professional health care services on the premises, provided that all medical sharps ~~shall be~~ discarded at those locations are placed in ~~a~~ an opaque container with a high degree of puncture resistance and labeled "do not recycle, medical sharps"

or otherwise managed in accordance with a local "safe sharps" program before being mixed with other wastes or disposed.

3. Used products for personal hygiene, such as diapers, facial tissues and sanitary napkins, underpads and adult incontinence products, unless a health care professional has determined these items to be regulated medical wastes in accordance with 9 VAC 20-120-140.

4. The following discarded items, when they are empty: urine collection bags and tubing, suction canisters and tubing, IV solution bags and tubing, colostomy bags, ileostomy bags, urostomy bags, plastic fluid containers, enteral feeding containers and tubing, hemovacs, and urine specimen cups.

5. The following discarded items: urinary catheters, suction catheters, plastic cannula, IV spikes, nasogastic tubes, oxygen tubing and cannula, ventilator tubing, enema bags and tubing, enema bottles, thermometer probe covers, irrigating feeding syringes, and bedpans/urinals.

6. Items such as bandages, gauze, or cotton swabs or other similar absorbent materials unless at any time following use they are saturated or would release human blood or human body fluids in a liquid or semi liquid state if compressed. Items that contain dried human blood or human body fluids and are capable of releasing these materials during handling are regulated medical waste. An item would be considered caked if it could release flakes or particles when handled.

~~D. The following regulated medical wastes are not subject to the requirements of this chapter when dispersed among other wastes and not accumulated separately:~~

~~1. Used products for personal hygiene, such as diapers, facial tissues and sanitary napkins.~~

~~2. Material, not including sharps, containing small amounts of blood or body fluids, but containing no free flowing or unabsorbed liquid.~~

ARTICLE 3.

Characteristics.

9 VAC 20-120-140. Characteristics of regulated medical waste.

9 VAC 20-120-140. Characteristics of regulated medical waste.

A solid waste is a regulated medical waste if it meets either of the two criteria of this section:

~~1.~~ A. Any solid waste, as defined in this chapter is a regulated medical waste if it is suspected by the health care professional in charge of being capable of producing an infectious disease in humans. A solid waste shall be considered to be capable of producing an infectious disease if it has been or is likely to have been contaminated by an organism likely to be pathogenic to healthy humans, such organism is not routinely and freely available in the community, and if such organism has a significant probability of being present in sufficient quantities and with sufficient virulence to transmit disease. If the exact cause of a patient's illness is unknown, but the health care professional in charge suspects a contagious disease is the cause, the likelihood of pathogen transmission shall be assessed based on the pathogen suspected of being the cause of the illness.

~~2.~~ B. Any solid waste that is not excluded from regulation is a regulated medical waste if it is listed in 9 VAC 20-120-150.

ARTICLE 4.

Controlled Regulated Medical Wastes.

9 VAC 20-120-150. Lists of controlled regulated medical wastes.

9 VAC 20-120-150. Lists of controlled regulated medical wastes.

In addition to wastes described by the characteristics set forth in 9 VAC 20-120-140, each solid waste or solid waste stream on the following lists is subject to this chapter, unless exempted in 9 VAC 20-120-120 or excluded in 9 VAC 20-120-130.

~~1.~~ A. Cultures and stock of microorganisms and biologicals. Discarded cultures, stocks, specimens, vaccines and associated items likely to have been contaminated by them are regulated medical wastes if they are likely to contain organisms likely to be pathogenic to healthy humans. Discarded etiologic agents are regulated medical waste. Wastes from the production of biologicals and antibiotics likely to have been contaminated by organisms likely to be pathogenic to healthy humans are regulated medical wastes.

~~2.~~ B. ~~Blood and blood products~~ Human blood and human body fluids. Wastes consisting of human blood~~, human blood products (includes serum, plasma, etc.) and items contaminated by human blood are regulated medical waste.~~ or human body fluids or items contaminated with human blood or human body fluids.

~~3.~~ C. Tissues and other anatomical wastes. All human anatomical wastes and all wastes that are human tissues, organs, ~~body parts, or body fluids~~ or body parts are regulated medical waste.

~~4.~~ D. Sharps. Sharps likely to be contaminated with organisms that are pathogenic to healthy humans, and all ~~sharps~~ needles, syringes with attached needles, suture needles, and scalpels ~~used in patient care or veterinary practice~~ are regulated medical wastes.

~~5.~~ E. Animal carcasses, body parts, bedding and related wastes. When animals are intentionally infected with organisms likely to be pathogenic to healthy humans for the purposes of research, in vivo testing, production of biological materials or any other reason; the animal carcasses, body parts, bedding material and all other wastes likely to have been contaminated are regulated medical wastes when discarded, disposed of or placed in accumulated storage.

~~6.~~ F. Any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill of any regulated medical waste.

~~7.~~ G. Any solid waste contaminated by or mixed with regulated medical waste.

Regulated Medical Waste Management Regulations

PART IV.

General Requirements.

ARTICLE 1.

Permits and On-site Permits by Rule.

9 VAC 20-120-160. Permit required.

No person who is subject to this chapter shall treat, store, or dispose of regulated medical waste without a permit from the department to engage in those activities. Any person required to have a permit for the management of regulated medical waste shall submit an application for a permit in accord with Part X of this chapter, with the exception that certain facilities deemed to have an on-site permit by rule in accord with 9 VAC 20-120-180.

9 VAC 20-120-170. ~~Persons required to have a permit~~. Exemptions from permitting.

~~Any person required to have a permit for facilities for the management of regulated medical waste shall make an application for a permit in accord with Part X of this chapter, with the exception that certain facilities may be deemed to have an on-site permit by rule in accord with 9 VAC 20-120-180.~~ A. The ~~accumulation~~ holding of regulated medical waste ~~in bulk transport containers or~~ on loading docks or areas designated for loading shall not require ~~the operator to hold either~~ an on-site permit by rule or a permit under Part X of this chapter if:

1. The regulated medical wastes are packaged, marked, and labeled for transport in accordance with applicable requirements of ~~49 CFR Part 171through 178~~ 9 VAC 20-120-210 D.

~~1~~2. ~~Those facilities merely facilitate~~ The facility merely facilitates transportation and ~~do~~ does not involve holding of regulated medical waste for more than ~~seven days~~ twenty-four (24) hours.

~~2~~3.. No more than 25% of the regulated medical waste ~~received~~ at the loading dock is generated off-site~~. or the site is exclusively a collection point for nonstationary health care providers and is not owned or operated by a vendor of waste management services~~.

4. While regulated medical waste is present, the area is secure from unauthorized access, and means are provided to prevent damage to the packaging by the elements or other factors.

~~This exemption of permitting requirements does not include or imply any exemption from the design and operation standards contained in Part V or elsewhere in this chapter.~~

B. Facilities generating 100 gallons per week or more of regulated medical waste shall not be required to hold an on-site permit by rule for storage or a permit for storage under Part X of this chapter if:

1. A designated storage area is provided for all areas of the facility accumulating in excess of 200 gallons of regulated medical waste. Designated storage areas shall meet the special requirements for storage facilities in Part V.

2. All regulated medical waste stored in a designated storage area is properly packaged in accordance with the provisions of 9 VAC 20-120-210 and labeled in accordance with the provisions of 9 VAC 20-120-220.

3. While regulated medical waste is in storage the first date the RMW is placed in storage is affixed to the outer packaging.

~~3.~~ 4. No more than 25% of the regulated medical waste received at the facility is generated off-site.

5. Regulated medical waste is not treated on-site.

C. Facilities generating less than 100 gallons per week of regulated medical waste shall not be required to hold an on-site permit by rule for storage or a permit for storage under part X of this chapter, or maintain records as required under 9 VAC 20-120-310 if:

1. Regulated medical waste is not held on-site in quantities greater than 200 gallons.

2. Regulated medical waste is accumulated and held in a safe and secure manner ensuring the waste cannot spill, or contact workers or the general public.

3. When regulated medical waste is ready to be discarded the generator complies with the provisions for loading docks or areas designated for loading in 9 VAC 20-120-170A.

4. Regulated medical waste is not treated on-site.

D. If a facility does not meet the above requirements for the storage of regulated medical waste, that facility is required to obtain an on-site permit by rule for on-site storage in accordance with the provisions of 9 VAC 20-120-180.

9 VAC 20-120-180. Persons qualifying for an on-site permit by rule.

Qualifying facilities are deemed to operate under a permit for regulated medical waste management activities and their owners or operators are not required to comply with the permit issuance procedures of Part X of this chapter. While persons who own or operate qualifying facilities are not subject to Part X or required to have a written permit from the department for those qualifying facilities, they are subject to this chapter and all other parts thereof. If a person owns or operates a regulated medical waste management unit that does not qualify for an on-site permit by rule, that person must comply with Part X and all other parts of this chapter for those units, without regard to the presence of any other units on the site that are

operated under a permit by rule. Only those units that are in complete compliance with all the following conditions are qualified and considered to be under an on-site permit by rule for their operation, and no on-site permit by rule shall exist for a facility failing to fulfill any of the following conditions:

~~1.~~ A. The facility and all regulated medical waste activities are in compliance with all parts of these regulations except Part X.

~~2.~~ B. More than 75% (by weight, in a calendar year) of all regulated medical waste that is stored, treated or disposed of by the facility is generated on-site ~~or the site is exclusively a collection point for nonstationary health care providers and is not owned or operated by a vendor of waste management services~~.

~~3.~~ C. No regulated medical waste is transported from or received by the facility without being properly packaged and labeled in accordance with this chapter. Facilities storing regulated medical waste will indicate the first date that the waste was placed in storage date on the outer packaging of the regulated medical waste.

~~4.~~ D. The activities at the facility do not involve the placing of regulated medical waste directly into or on the land.

~~5.~~ E. The owner or operator of the facility has notified the director in writing that the facility is operating under an on-site permit by rule. The notice shall give the name of the facility; the mailing address of the facility; the location address of the facility; the type of business the facility serves; the type of facilities (treatment, storage, transportation, disposal) involving regulated medical waste; and the name, address and telephone number of the ~~principal corporate officer~~ responsible party indicated on the disclosure statement as required below.

~~6.~~ F. The owner or operator of the facility has submitted to the director a certification from the local governing body (city, county, or town in which the facility is to be located) stating; without qualifications, conditions, or reservations; that the location and operation of the facility are consistent with all applicable ordinances.

~~7.~~ G. The owner or operator of the facility has submitted to the director appropriate Key Personnel Disclosure Statements.

H. The facility will be operated by an individual certified by the Board of Waste Management Facility Operators.

ARTICLE 2.

Financial Assurance.

9 VAC 20-120-190. Financial assurance requirements.

9 VAC 20-120-190. Financial assurance requirements.

The department has adopted and will maintain separate regulation, the Financial Assurance Regulations for Solid Waste Facilities, which shall be applicable in all parts to regulated medical waste management facilities. Nothing in this chapter governing regulated medical waste management shall be considered to delete or alter any requirements of the department as set out in Financial Assurance Regulations for Solid Waste Facilities.

ARTICLE 3.

Packaging and Labeling Requirements for Regulated Medical Waste.

Regulated Medical Waste Management Regulations

9 VAC 20-120-200. Responsibility for packaging and labeling.

A. The generator of regulated medical waste is responsible for the packaging and labeling of regulated medical wastes. As a bag or container becomes full, it must be sealed~~, packaged~~, labeled and managed as described in this chapter. Contractors or other agents may provide services to the generator, including packaging and labeling of regulated medical waste, however, no contract or other relationship shall relieve the generator of the responsibility for packaging and labeling the regulated medical waste as required by this chapter.

B. No person shall receive for transportation, storage~~, treatment or disposal~~ or treatment any regulated medical waste that is not packaged and labeled in accord with this chapter. Contractors or other agents may package or repackage regulated medical wastes to comply with this chapter, if the packaging or repackaging is performed on-site where the regulated medical waste was generated and no transportation, storage, treatment or disposal occurs prior to the packaging or repackaging. Nothing in this section shall prevent the proper repackaging and further transportation of regulated medical waste that has spilled during transportation.

9 VAC 20-120-210. Packaging prior to storage, treatment~~, transport or disposal.~~ or transport

All regulated medical waste shall be packaged as follows ~~before it is stored, treated~~ or ~~transported or disposed of~~:

~~1. Regulated medical wastes shall be contained in two highly leak resistant, plastic bags each capable of passing the ASTM 125 pound Standard Test Method for Drop Test of Loaded Containers by Free Fall, D5276-92, and each sealed separately, or one highly leak resistant, plastic bag inside a rigid container. Free liquids shall be contained in sturdy highly leak resistant containers that resist breaking; heavy materials must be supported in boxes. Sharps shall be collected at the point of generation in highly puncture resistant containers, and those containers closed and placed inside a plastic bag prior to storage or transport.~~A. When regulated medical wastes are discarded they shall be placed in containers meeting the requirements of the standards for occupational exposure to bloodborne pathogens in the general industry standard in 16 VAC 25-90-1910.1030. The general industry standard requires the packaging to be closable, constructed to prevent leakage, labeled with the biohazard symbol, and closed to prevent spillage during handling. Upon being placed in storage, red bags shall be used for the packaging of all regulated medical waste except as provided in 9 VAC 20-120-210.2 below. Packaging shall be labeled as provided for in 9 VAC 20-120-220.

Regulated Medical Waste Management Regulations

B. Contaminated sharps shall be placed directly in containers as required by the general industry standards in 16 VAC 25-90-1910.1030. The containers shall be labeled as provided for in 9 VAC 20-120-220.

~~2. All bags containing regulated medical waste shall be red in color. Waste contained in red bags shall be considered regulated medical waste and managed as regulated medical waste.~~

~~3. Bags~~ C. As bags and containers become full, they shall be sealed ~~by lapping the gathered open end and binding with tape or closing device~~ such that no ~~liquid~~ waste materials can leak.

~~4. In addition to the plastic bag containers described in this section, all regulated medical wastes must be enclosed in a rigid container before it is transported off-site or in a vehicle on a street or highway. The box or container must meet the performance standards of 49 CFR 171 through 178.~~ D. Prior to transporting regulated medical waste, waste will be packaged for transportation in accordance with the standards of 49 CFR 173 or packaged in accordance with an exemption approved by the United States Department of Transportation.~~196 or 49 CFR 173.197 as applicable. 49 CFR 173.196 contains the packaging standards for etiologic agents, and 49 CFR 173.197 contains the packaging requirements for regulated medical waste.~~

9 VAC 20-120-220. Labeling requirements.

~~All regulated medical waste shall be labeled immediately after packaging.~~ Waste packaged under the provisions of 9 VAC 20-120-210 A or 9 VAC 20-120-210 B shall be labeled. The label shall be securely attached to or printed on ~~the outer layer of~~ packaging ~~and be clearly legible~~. The label may be a tag securely affixed to the package. Indelible ink shall be used to complete the information on the label , ~~and the~~. The label ~~shall be at least three inches by five inches in size~~ and the information provided on the label must be clearly legible. The following information shall be included:

~~1.~~ A. The name, address and business telephone number of the generator. ~~and the date on which the bag of regulated medical waste was discarded.~~

~~2.~~ B. "Regulated Medical Waste" in large print.

~~3. The name, address and business telephone number of all transporters or other persons to whose control the regulated medical waste is transferred.~~

~~4.~~ C. The Biological Hazard Symbol. The Biological Hazard Symbol can be found in the Virginia Administrative Code print product.

9 VAC 20-120-230. Etiological agents.

All etiological agents, as defined in 49 CFR 171 through 178, that are transported must be packaged and labeled as described in 49 CFR 171 through 178 ~~and labeled as described in 49 CFR 171 through 178, even when that transport is wholly within the boundaries of the Commonwealth~~.

9 VAC 20-120-240. Sharps.

Sharps must be placed directly into ~~rigid and highly~~ puncture resistant containers as required by the general industry standards in 16 VAC 25-90-1910.1030(d)(4)(iii)(A).

Regulated Medical Waste Management Regulations

9 VAC 20-120-250. Protection of packagers.

Persons packaging regulated medical waste shall wear ~~heavy gloves of neoprene or equivalent materials and other~~ appropriate items of personal ~~protection~~ protective equipment.

9 VAC 20-120-260. Special requirements for reusable containers.

Regulated medical waste may be conveyed in reusable carts or containers under the following conditions:

~~1.~~ A. The waste in the cart or container ~~is~~ packaged and labeled fully in accordance with 9 VAC 20-120-210 through 9 VAC 20-120-240. ~~Discrete packages of waste and the cart or container shall each be properly labeled in accordance with 9 VAC 20-120-220.~~

~~2.~~ B. Immediately following each time a reusable cart or container is emptied and prior to being reused it is ~~thoroughly cleaned, rinsed and effectively disinfected with a hospital grade disinfectant effective against mycobacteria. The area where carts or containers are cleaned, rinsed or disinfected is a storage area and regulated under Part V of this chapter.~~ thoroughly cleaned with detergent or general purpose disinfectant.

~~3. Unloading of reusable carts or containers that contain regulated medical waste should be accomplished by mechanical means and not require handling of bags or packages by humans. Mechanical means can consist of tipping floors, chutes, snares and other simple mechanisms.~~

~~4~~ C. When reusable carts or containers containing regulated medical waste are used for off-site transport, all aspects of the cart or container management shall comply with ~~9 VAC 20-120-500~~ Federal Department of Transportation Hazardous Material Regulations 49 CFR 171 to 178 as applicable.

ARTICLE 4.

Management of Spills of Regulated Medical Waste.

9 VAC 20-120-270. Spill containment and cleanup kit.

9 VAC 20-120-280. Containment and cleanup procedures.

9 VAC 20-120-270. Spill containment and cleanup kit.

Regulated Medical Waste Management Regulations

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

~~1.~~ A. Material designed to absorb spilled liquids. The amount of absorbent material shall be that having a capacity, as rated by the manufacturer, of one gallon of liquid for every cubic foot of regulated medical waste that is normally managed in the area for which the kit is provided or 10 gallons, whichever is less.

~~2.~~ B. One gallon of disinfectant in a sprayer capable of dispersing its charge in a mist and in a stream at a distance. The disinfectant shall be hospital grade and effective against mycobacteria.

~~3.~~ C. Enough red plastic bags to ~~double~~ enclose 150% of the maximum load accumulated or transported (up to a maximum of 500 bags), that meet ~~the ASTM 125 pound Drop Test For Filled Bags (D959) and are accompanied by sealing tape (or devices) and labels (or tags).~~ the applicable requirements of 49 CFR 173 or an exemption approved by the United States Department of Transportation. These bags shall be large enough to overpack any box or other container normally used for regulated medical waste management by that facility.

~~4.~~ D. ~~Two new sets of liquid impermeable and disposable overalls, gloves, boots, caps and protective breathing devices. Overalls, boots and caps shall be oversized or fitted to regulated medical waste workers. Boots may be of thick rubber and gloves shall be of heavy neoprene or equivalent (Boots, gloves, and breathing devices; may be reused if fully disinfected between uses). Protective breathing devices shall be approved for filtering particulates and mists; usually, disposable surgical masks will suffice. Tape for sealing openings at wrists and ankles shall also be in the kit.~~ Appropriate personal protective equipment.

~~5.~~ E. ~~A~~ For vehicles only, include a first aid kit, fire extinguisher, boundary marking tape, lights and other appropriate safety equipment.

9 VAC 20-120-280. Containment and cleanup procedures.

~~A.~~ Following a spill of regulated medical waste or its discovery, the following procedures shall be implemented:

~~1. Leave the area until the aerosol settles (no more than a few minutes delay).~~

~~2. The clean up crew will don the cleanup outfits described in subdivision 4 of 9 VAC 20-120-270 and secure the spill area.~~

~~3. Spray the broken containers of regulated medical waste with disinfectant.~~

~~4. Place broken containers and spillage inside overpack bags in the kit, minimizing exposure.~~

~~5. Disinfect the area and take other cleanup steps deemed appropriate.~~

~~6. Clean and disinfect nondisposable items.~~

~~7. Clean and disinfect cleanup outfits before removing.~~

~~8. Remove cleanup outfits and place disposable items in cleanup bag.~~

A. Take appropriate precautions to ensure personnel do not come into contact with any contaminants by wearing appropriate personal protective equipment.

B. Repackage spilled waste in accordance with the packaging requirements in 9 VAC 20-120-210.

C. Transportation of any regulated medical waste must be by a transporter registered in accordance with the provisions of 9 VAC 20-120-480, Registration of Transporters.

D. Clean and disinfect any areas having been contacted by regulated medical wastes. Materials used to decontaminate the area will be disinfectants effective against mycobacteria.

~~9.~~ E. Take necessary steps to replenish containment and cleanup kit ~~with items used~~.

~~B. When a spill involves only a single container of regulated medical waste whose volume is less than 32 gallons and spilled liquid whose volume is less than one quart, the individual responsible for the cleanup may elect to use alternate appropriate dress and procedures than those described in 9 VAC 20-120-270 and 9 VAC 20-120-280. Such alternate dress or procedures shall provide for the protection of the health of workers and the public equivalent to that described above.~~

ARTICLE 5.

Closure Requirements.

9 VAC 20-120-290. Closure requirements.

9 VAC 20-120-290. Closure requirements.

When a unit that has been used for regulated medical waste management is to cease operations involving regulated medical wastes, it shall be thoroughly cleaned and disinfected. All regulated medical waste shall be disposed of in accord with this chapter, and items of equipment shall be ~~disinfected~~ decontaminated.

ARTICLE 6.

Treatment and Disposal.

9 VAC 20-120-300. Methods of treatment and disposal.

9 VAC 20-120-300. Methods of treatment and disposal.

A. All regulated medical waste must be incinerated, sterilized by steam, or treated by a method as described in Part VII, VIII, or IX of this chapter.

B. No regulated medical waste shall be disposed of in a solid waste landfill or other solid waste management facility. Upon authorized treatment and management in accord with this chapter, the solid waste or its ash is not regulated medical waste and may be disposed of at any landfill or other solid waste management facility permitted to receive ~~putrescible~~ municipal solid waste or garbage, provided the disposal

is in accordance with the Solid Waste Management Regulations, 9 VAC 20-80-10 et seq., and other applicable regulations and standards.

C. Regulated medical waste in closed bags or containers shall not be compacted or subjected to violent mechanical stress; however, after it is fully treated and it is no longer regulated medical waste, it may be compacted in a closed container. Nothing in this section shall prevent the puncturing of containers or packaging immediately prior to permitted treatment in which grinding, shredding, or puncturing is integral to the process units; however, all grinding, shredding and puncturing shall be done with safe and sanitary methods. ~~Devices that grind, shred, compact or reduce the volume of regulated medical waste~~ Nothing in this section shall prevent the use of devices that grind shred or compact to reduce volume at the point of generation. Devices will be constructed in a manner that prevents employee exposure to the waste, contains any aerosol or mist which may be caused by the process, and treats or filters any air evacuated from the chamber during processing. These devices may be employed at the point of generation and prior to enclosing the regulated medical waste in plastic bags and other required packaging; however, the waste remains regulated medical waste. Appropriate means must be employed to appropriately protect workers and contain the waste when unloading regulated medical wastes from such a device.

ARTICLE 7.

Recordkeeping.

9 VAC 20-120-310. Recordkeeping requirements.

9 VAC 20-120-310. Recordkeeping requirements.

A. ~~All~~ Unless a generator is exempt from this requirement under the provisions of 9 VAC 20-120-170 C, generators and regulated medical waste management facilities that manage regulated medical waste shall maintain the following records and assure that they are accurate and current:

1. A list of the members of any committee for the management of infection control for the facility, their address, their phone numbers and the period of their membership.

2. The date, persons involved and short description of events in each spill of ~~regulated medical wastes involving~~ more than 32 gallons of regulated medical waste or one quart of regulated medical waste consisting of free liquid.

3. A notebook or file containing the adopted policies and procedures of the facility for dealing with regulated medical wastes.

4. A log of all special training received by persons involved in regulated medical waste management.

5. A log of regulated medical waste received from off-site, the generator, the amount and its ~~generation~~ storage and receipt dates. Records shall be maintained for a period of three years and be available for review.

B. All regulated medical waste management facilities shall maintain the following records and assure that they are accurate and current:

1. A signed certificate for each load received in which the generator affirms that the load does not contain hazardous waste (including cytotoxic medications) or radioactive materials, except as provided in 9 VAC 20-120-320; or

2. A signed and effective contract, inclusive of all loads received from a generator, in which the generator affirms that all loads will not contain hazardous waste (including cytotoxic medications) or radioactive materials, except as provided in 9 VAC 20-120-320.

ARTICLE 8.

Radioactive Materials.

Regulated Medical Waste Management Regulations

9 VAC 20-120-320. Management of radioactive materials.

9 VAC 20-120-320. Management of radioactive materials.

The United States Nuclear Regulatory Commission (USNRC) has established regulations under Title 10 of the Code of Federal Regulations for the management of radioactive materials. The Virginia Department of Health has established other requirements in accordance with Title 32.1 of the Code of Virginia. No regulated medical waste containing radioactive materials, regardless of amount or origin, shall be treated unless its management and treatment are in full compliance with these two bodies of regulations and are deemed by both regulations not to represent a threat to public health and the environment.

Regulated Medical Waste Management Regulations

PART V.

Special Requirements for Storage Facilities.

9 VAC 20-120-330. Application.

The requirements of this part apply only to areas of storage where more than ~~64~~ 200 gallons of regulated medical waste are accumulated, including storage of regulated medical waste during transportation and at incinerator, steam sterilization and other treatment and disposal facilities. This part applies to areas used to transfer a load of regulated medical waste from one vehicle to another during transportation, or park a vehicle containing regulated medical waste during transportation for 24 hours or more. This part also applies to areas that are exempt from permitting requirements as specified in 9 VAC 20-120-170B which

includes designated on-site storage areas. Regulated medical waste holding areas exempt from the requirements of this part are discussed in 9 VAC 20-120-170A and 9 VAC 20-120-170C

9 VAC 20-120-340. Sanitation.

All areas used to store regulated medical waste must be clean and impermeable to liquids. Carpets and floor coverings with ~~seams~~ cracks or gaps shall not be used in storage area. Where tile floors are used and seams are present in the tile, the floor must be sealed with wax or other floor coatings in order to meet this requirement. Vectors shall be controlled.

9 VAC 20-120-350. Access.

All areas used to store regulated medical waste must have access control that limits access to those persons specifically designated to manage regulated medical waste.

9 VAC 20-120-360. Temperature control and storage period.

Any regulated medical waste ~~that is more than seven days past its date of generation and is stored~~ stored for more than seven days must be refrigerated, stored in an ambient temperature between 35º and 45ºF (2º and 7ºC). If the material is stored away from the site of generation and the time in storage is

unknown, the regulated medical waste must be refrigerated. No regulated medical waste shall be stored for more than ~~30~~ 15 days at the site of generation. Procedures shall be provided to ensure that the above storage timeframes are met. The date that the waste is first placed in storage will be provided on any outer packaging while the waste is in storage.

9 VAC 20-120-370. Drainage and ventilation.

All floor drains shall discharge directly to an approved sanitary sewer system. All ventilation shall discharge so as to minimize human exposure to the effluent. Storage, transport and transfer to, from, and between vehicles shall be under a cover that protects the waste containers from rainfall and over a floor or bermed pavement that will contain leaks and spills of liquid from the waste. No requirement for cover, floor, or pavement shall be construed if the activity is transient in nature, such as in the case of spill cleanup or weekly collection of waste packages from professional offices for transport.

9 VAC 20-120-380. Facilities for management of reusable carts or containers.

Waste managed in reusable carts or containers shall meet ~~the following requirements:~~

~~1. The regulated medical waste in the cart or container shall be packaged fully in accordance with 9 VAC 20-120-210 through 9 VAC 20-120-240. Discrete units of regulated medical waste and the cart or container must be properly labeled.~~

~~2. Immediately following each time a reusable cart or container is emptied and prior to being reused it shall be thoroughly cleaned, rinsed and effectively disinfected with a hospital grade disinfectant. The disinfectant must be in used in accord with manufacturer's direction and effective against mycobacteria.~~

~~3. Unloading of reusable carts or containers that contain regulated medical waste not contained in non-reusable rigid containers should be accomplished by mechanical means and not require handling of packages by humans. Mechanical means can consist of tipping floors, chutes, snares and other simple mechanisms.~~

~~4. The area where cleaning, rinsing, and disinfecting occurs is a storage area and shall comply with all other sections of Part V.~~

the special requirements for reusable containers in 9 VAC 20-120-260.

9 VAC 20-120-390. Container management.

Regulated Medical Waste Management Regulations

Persons loading, unloading, or handling containers of regulated medical waste shall wear ~~clean, heavy neoprene (or equivalent) gloves and clean uniforms~~ appropriate personal protective equipment.

Regulated Medical Waste Management Regulations

PART VI.

Special Requirements for Transportation.

9 VAC 20-120-400. Application.

The requirements of this part apply to all transportation of regulated medical waste.

9 VAC 20-120-410. Sanitation.

Surfaces of equipment used to transport regulated medical waste must be clean and impermeable to liquids, if those areas are involved with the management of the waste. Carpets and floor coverings with ~~seams~~ cracks or gaps shall not be used. Vectors shall be controlled. All trucks and equipment used to transport regulated medical waste must be thoroughly cleaned ~~and disinfected~~ with detergent or hospital grade disinfectant before being used for any other purpose~~, at the end of each business day or 24-hour period of use,~~ and prior to any transfer of ownership. Any areas of trucks or equipment that are visibly contaminated, or that become contaminated as a result of a spill will be immediately decontaminated in accordance with 9 VAC 20-120-280.A.4.

9 VAC 20-120-420. Access.

All vehicles~~, equipment and service or parking area~~s and equipment used in the transportation of regulated medical waste must have access control that limits access to those persons specifically designated to manage regulated medical waste.

9 VAC 20-120-430. Temperature control and storage period.

Regulated Medical Waste Management Regulations

Any regulated medical waste that is stored for more than seven days ~~past its date of generation and is transported~~ must be refrigerated, maintained in an ambient temperature between 35º and 45ºF (2ºand 5ºC)~~, during transport and during any storage following transport~~. ~~No regulated medical waste shall be stored for more than 30 days. Time in transport shall be accounted as time in storage.~~ Any vehicle parked 24 hours or more during transport will be considered a storage facility subject to the requirements of Part V. No storage during transport will be allowed without a permit issued in accordance with the procedures in Part X.

9 VAC 20-120-440. Drainage.

~~All drainage shall discharge directly or through a holding tank to an approved sanitary sewer system.~~ Storage, transport and transfer to, from, and between vehicles shall be under a cover that protects the waste containers from rainfall and over a floor or bermed pavement that will contain leaks and spills of liquid from the waste. All drainage shall discharge directly to or through a holding tank to an approved sanitary sewer system. No requirement for cover, floor, or pavement shall be construed if the activity is transient in nature, such as in the case of spill cleanup or weekly collection of waste packages from professional offices for transport.

9 VAC 20-120-450. Packaging, labeling and ~~placards~~ signage.

Regulated Medical Waste Management Regulations

A. No person shall transport or receive for transport any regulated medical waste that is not packaged and labeled in accord with Part IV of this chapter.

B. The access doors to any area holding regulated medical waste in transport shall have a warning sign in bold ~~and large~~ 1inch letters that indicates the cargo is regulated medical waste.

9 VAC 20-120-460. Management of spills of regulated medical waste.

A. All vehicles transporting regulated medical wastes are required to carry a spill containment and cleanup kit in the vehicle as specified in 9 VAC 20-120-270, whenever regulated medical wastes are conveyed. ~~The kit shall consist of at least the following items:~~

~~1. Material designed to absorb spilled liquids. The amount of absorbent material shall be rated by the manufacture as having a capacity to absorb 10 gallons.~~

~~2. One gallon of disinfectant in a sprayer capable of dispersing its charge in a mist and in a stream at a distance. The disinfectant shall be hospital grade and effective against mycobacteria.~~

~~3. Enough red plastic bags to double enclose 150% of the maximum load accumulated or transported (up to a maximum of 500 bags) that meet the ASTM 125 pound Drop Test For Filled Bags (D959)~~

~~and are accompanied by seals and labels. These bags shall be large enough to overpack any box or other container normally used for regulated medical waste management.~~

~~4. Two new sets of disposable overalls, gloves, boots, caps and breathing protective devices. Overalls, boots and caps shall be oversized or fitted to regulated medical waste workers and be made of materials impermeable to liquids. Boots may be of thick rubber and gloves shall be of heavy neoprene or equivalent (boots, gloves and breathing devices, may be reused if fully disinfected between uses). Protective breathing devices shall be approved for filtering particulates and mists; disposable surgical masks will suffice. Tape for sealing openings at wrists and ankles shall also be in the kit.~~

~~5. A first aid kit, fire extinguisher, boundary marking tape, lights and other appropriate safety equipment.~~

B. Following a spill of regulated medical waste or its discovery, the ~~following~~ procedures specified in 9 VAC 20-120-280 shall be implemented~~:~~

~~1. Leave the area until the aerosol settles (no more than a few minutes delay).~~

~~2. The clean up crew will don the clean up outfits described in subdivision A 4 of this section and secure the spill area.~~

~~3. Spray the broken containers of regulated medical waste with disinfectant.~~

~~4. Place broken containers and spillage inside the overpack bags in the kit, minimizing exposure.~~

~~5. Disinfect the area and take other clean up steps deemed appropriate.~~

~~6. Clean and disinfect clean up outfits before removing.~~

~~7. Clean and disinfect nondisposable items.~~

~~8. Remove clean up outfits and place disposal items in clean up bag.~~

~~9. Take necessary steps to replenish containment and clean up kit with items used.~~

~~C. When a spill involves only a single container of regulated medical waste whose volume is less than 32 gallons and spilled liquid whose volume is less than one quart, the individual responsible for the clean up may elect to use alternate appropriate dress and procedures. Such alternate dress or procedures shall provide protection of the health of workers and the public equivalent to that described above.~~

9 VAC 20-120-470. Loading and unloading.

Persons loading and unloading transportation vehicles with regulated medical waste shall wear ~~clean, heavy neoprene (or equivalent) gloves and clean uniforms~~ appropriate personal protective equipment.

9 VAC 20-120-480. Registration of transporters.

A. ~~At least 30 days prior~~ Prior to transporting any regulated medical waste within the Commonwealth, all transporters must register with the Department of Environmental Quality. Registration shall consist of filing the data specified in subsection B of this section, in written form, and the department will issue a registration number to the transporter. No regulated medical waste shall be transported until the registration number is issued. Transporter shall notify the generator of the waste of his registration number when he collects the waste.

B. Data to be submitted by persons wishing to register as a transporter of regulated medical waste shall be as follows:

1. Name of the person or firm.

2. Business address and telephone number of person or firm. Include headquarters and local office.

3. Make, model and license number of each vehicle to be used to transport regulated medical waste within the Commonwealth.

4. Name, business address and telephone number of each driver who will operate in the Commonwealth.

5. Areas (counties and cities) of the Commonwealth in which the transporter will operate.

6. a. Any person or firm other than reported in subdivision 1 of this subsection that is associated with the registering firm or any other name under which that person or firm does business.

b. Any other person or firm using any of the same vehicles and operators.

7. The name and phone number of a person who may be contacted in the event of an accident or release.

8. A copy of the signed certification statement as follows:

I, (Full Name of Chief Executive), am chief executive officer of (Legal Name Of Firm) and do hereby affirm that all the information provided in this application is correct to the best of

my knowledge; and I further affirm that neither this firm, any antecedent firm to this firm, or any of the officers of this or antecedent firms has been convicted of a felony in any state.

C. Within 30 calendar days following the change of any data in subsection B of this section, the transporter shall notify the department of that change. Failure to notify the department nullifies the registration and invalidates the registration number. When the transporter changes legal name, corporate ownership, or the chief executive officer, he shall notify the department within 30 days of such a change. Upon receiving such a notification, the department will revoke the old registration, and reissue a new registration based on the new information.

D. Use of a false or invalid registration number is prohibited.

Note: All filings of data and requests for registration number and issuance of a registration number shall be in writing.

9 VAC 20-120-490. Transport by mail.

Transport of regulated medical waste by the United States Postal Services that fully complies with 39 CFR 111 shall be considered to be transportation by a registered transporter and in compliance with this chapter if:

~~1.~~ A. The generator maintains a complete and legible copy of the manifest or mail disposal service shipping record for a period of three years (Note: disposer's certification and other tracking items must be completed and shown on the copy);

~~2.~~ B. The addressee is a facility permitted by all the appropriate agencies of the Commonwealth of Virginia or the host state; and

~~3.~~ C. No package may be more than 35 pounds by weight.

9 VAC 20-120-500. Transport using reusable carts or containers.

A. No reusable carts or containers that have been used to manage regulated medical waste may be transported unless they ~~have been cleaned, rinsed and disinfected in a storage facility permitted under this chapter and in compliance with Part V of this chapter.~~ meet the provisions of 9 VAC 20-120-260 which requires cleaning of the cart.

B. Reusable carts or containers used to transport regulated medical waste must be sealed, highly puncture resistant, and highly leak resistant. They shall conform in all respects to 49 CFR 172 through 178 for containers and transport of "regulated medical waste."

Regulated Medical Waste Management Regulations

9 VAC 20-120-510. [Reserved Section].

Regulated Medical Waste Management Regulations

PART VII.

Special Requirements for Incineration.

9 VAC 20-120-520. Application.

The requirements of this part apply to all facilities that incinerate regulated medical waste.

9 VAC 20-120-530. Performance standards.

A. All incinerators for regulated medical waste shall maintain the following level of operational performance at all times:

1. Operational temperature and retention time. Whenever regulated medical wastes are incinerated, all the regulated medical waste shall be subjected to a burn temperature of not less than 1400ºF (760ºC) for a period not less than one hour. For all incinerators, gases generated by the combustion shall be subjected to a temperature of not less than 1800ºF (982ºC) for a period of one second or more. For certain incinerators, gases generated by the combustion shall be subjected to a temperature of not less than 2000ºF (1094ºC) for a period of two seconds or more under separate requirements of the State Air Pollution Control Board. Except at start-up, interlocks or other process control devices shall prevent feeding of the incinerator unless ~~these~~ the required conditions are achieved.

2. Loading and operating controls. The incinerator shall have interlocks or other process control devices to prevent feeding of the incinerator until the conditions in subdivision A 1 of this section are achieved. Such devices may have an override for cold start-up. In the event low temperatures occur, facilities shall have automatic auxiliary burners that are capable~~, excluding the heat content of the wastes, of independently~~ of maintaining the secondary chamber temperature at the minimum of 1800ºF.

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

4. Waste destruction efficiency. All combustible regulated medical waste shall be converted by the incineration process into ash that is not recognizable as to its former character.

B. The incinerator shall be permitted under regulations of the State Air Pollution Control Board and be in compliance with the regulations of that body.

9 VAC 20-120-540. Analysis and management of the ash product; procedure; results and records; disposition of ash; ash storage.

A. Once every eight hours of operation of a continuously fed incinerator and once every batch or 24 hours of operation of a batch fed incinerator, a representative sample of 250 milliliters of the bottom ash shall be collected from the ash discharge or the ash discharge conveyer. Samples collected during 1000 hours of operation or quarterly, whichever is more often, shall be thoroughly mixed and seven random portions of equal volume shall be composited into one sample for laboratory analysis. This sample shall be tested in accord with the methods established by the Virginia Hazardous Waste Management Regulations for determining if a solid waste is a hazardous waste. Also, the sample shall be tested for total organic carbon content.

At incinerators equipped with air pollution control devices that remove and collect incinerator emissions control ash or dust, this ash shall be held separately and not mixed with bottom ash. Once every eight hours

of operation of a continuously fed incinerator and once every batch or 24 hours of operation of a batch fed incinerator, a representative sample of 250 milliliters of the air pollution control ash or dust shall be collected from the pollution control ash discharge. Air pollution control ash or dust samples collected during 1000 hours of operation or quarterly, whichever is more often, shall be thoroughly mixed and seven random portions of equal volume shall be composited into one sample for laboratory analysis. This sample shall be tested in accord with the methods established by the Virginia Hazardous Waste Management Regulations for determining if a waste is a hazardous waste.

B. A log shall document the ash sampling, to include the date and time of each sample collected; the date, time and identification number of each composite sample; and the results of the analyses, including laboratory identification. Results of analyses must be returned from the laboratory and recorded within four weeks following collection of the composite sample. The results and records described in this part shall be maintained for a period of three years, and shall be available for review.

C. If a waste ash is found to be hazardous waste (based on a sample and a confirmation sample) the waste ash shall be disposed of as a hazardous waste in accord with the Virginia Hazardous Waste Management Regulations. If ash is found not to be hazardous waste by analysis, it may be disposed of in a solid waste landfill that is permitted to receive garbage, ~~putrescible~~ municipal solid waste or incinerator ash, provided the disposal is in accordance with the Solid Waste Management Regulations, 9 VAC 20-80-10 et seq. If the ash is found to be hazardous waste, the operator shall notify the Director of the Department of

Environmental Quality within 24 hours. No later than 15 calendar days following, the permittee shall submit a plan for treating and disposing of the waste on hand at the facility and all unsatisfactorily treated waste that has left the facility. The permittee may include with the plan a description of the corrective actions to be taken to prevent further unsatisfactory performance. No ash subsequently generated from the incinerator waste stream that was found to be hazardous waste shall be sent to a nonhazardous solid waste management facility in the Commonwealth without the express written approval of the director.

D. Air pollution control ash and bottom ash shall be held separately and not mixed ; however, once both are determined not to be hazardous waste, they may be combined and disposed of as other solid waste. Throughout the storage of the untested material it shall be kept in covered highly leak resistant containers. It should be held until the generator determines whether the ash waste is hazardous waste. Areas where untested material containers are placed must be constructed with a berm to prevent runoff from that area.

E. Regulated medical waste treated in compliance with Part VII, Part VIII or Part IX shall be deemed to be treated in accordance with this chapter. Regulated medical waste not treated in accordance with this chapter shall not be transported, received for transport or disposal, or disposed of in any solid waste management facility.

9 VAC 20-120-550. Compliance with other parts of this chapter.

In general, incinerator facilities shall comply with all other parts of this chapter. The site of the incinerator facility is a storage facility and must comply with Part V of this chapter. Management of spills or the opening in an emergency of any regulated medical waste package, shall comply with 9 VAC 20-120-270 and 9 VAC 20-120-280. Regulated medical wastes that are or will be incinerated in accordance with this chapter are not required to be shredded or ground.

9 VAC 20-120-560. Unloading operations.

Persons loading and unloading transportation vehicles with regulated medical waste shall wear ~~clean, heavy neoprene gloves (or equivalent) and clean overalls~~ appropriate personal protective equipment.

9 VAC 20-120-570. [Reserved Section].

PART VIII.

Special Requirements for Steam Sterilization.

9 VAC 20-120-580. Application.

The requirements of this part apply to all steam sterilizers (autoclaves) that sterilize regulated medical waste.

9 VAC 20-120-590. Performance standards.

All sterilizers for regulated medical waste shall maintain the following level of operational performance at all times:

~~1.~~ A. Operational temperature and detention. Whenever regulated medical wastes are treated in a steam sterilizer, all the regulated medical waste shall be subjected to the following operational standards (at 100% steam conditions and all air evacuated):

~~a.~~ 1. Temperature of not less than 250ºF for 90 minutes at 15 pounds per square inch of gauge pressure,

~~b.~~ 2. Temperatures of not less than 272ºF for 45 minutes at 27 pounds per square inch of gauge pressure, or

~~c.~~ 3. Temperatures of not less than 320ºF for 16 minutes at 80 pounds per square inch of gauge pressure.

Equivalent combinations of operational temperatures, pressure and time may be approved by the director if the installed equipment has been proved to achieve a reliable and complete kill of all microorganisms in regulated medical waste at design capacity. Written requests for approval of an equivalent standard shall be submitted to the director. Complete and thorough testing shall be fully documented, including tests of the capacity to kill B. stearothermophilus. Longer steam sterilization times are required when a load contains a large quantity of liquid.

~~2.~~ B. Operational controls and records.

~~a.~~ 1. Steam sterilization units shall be evaluated under full loading for effectiveness with spores of B. stearothermophilus no less than once per month.

~~b.~~ 2. A log shall be kept at each steam sterilization unit that is complete for the preceding three-year period. The log shall record the date, time and operator of each usage; the type and approximate amount of regulated medical waste treated; the dates and results of calibration; and the results of effective testing described in subdivision 2 a of this section. Where multiple steam sterilization units are used, a working log can be maintained at each unit and such logs periodically consolidated at a central location. The consolidated logs shall be retained for three years and be available for review.

~~c.~~ 3. Except as described in subdivision ~~2 b~~ B4 of this section, regulated medical waste shall not be compacted or subjected to violent mechanical stress before steam sterilization; however, after it is fully sterilized it may be compacted in a closed container.

~~d.~~ 4. Except as provided in 9 VAC 20-120-550, 9 VAC 20-120-600 E or 9 VAC 20-120-650 D, regulated medical waste shall be ground or shredded into particles that are no larger than an approximate size of 0.75 inches in any dimension. Grinding or shredding shall occur in a closed unit immediately preceding or following the treatment unit. Transfer from a grinder or shredder to or

from a treatment unit shall be under forced draft ventilation that removes fumes from the operations area to a safe discharge.

~~e.~~ 5. All process units for the preparation or treatment of regulated medical waste shall be in closed vessels under a negative pressure atmospheric control that filters all vents, discharges, and fugitive emissions of air from the process units through a high efficiency particulate air (HEPA) filter with an efficiency of 99.97% of 0.3 microns. Air and gases which have themselves been sterilized by the process are not required to pass through a filter.

9 VAC 20-120-600. Disposal of treated wastes.

A. Solid waste that has been steam sterilized and managed in compliance with these regulations is no longer regulated medical waste and is solid waste. Steam sterilized solid waste may be compacted.

B. All shredded or ground solid waste that has been steam sterilized shall be placed in opaque plastic bags and sealed. The bags may not be red in color. Where bulk sterilization is used and the solid waste is compacted or immediately placed in closed bulk solid waste management containers, which are more than 64 gallons in volume, the repackaging of the solid waste in bags is not required.

C. Regulated medical waste that has been treated must also be ground or shredded in accordance with 9 VAC 20-120-590 ~~2~~ B or packaged and labeled in accordance with subsection E of this section.

D. Regulated medical waste treated in compliance with Part VII, Part VIII or Part IX shall be deemed to be treated in accordance with this chapter. Regulated medical waste not treated in accordance with this chapter shall not be transported, received for transport or disposal, or disposed of in any solid waste management facility.

E. Steam sterilization facilities in operation on July 1, 1994, and small scale processes providing treatment in accordance with this part of no more than 100 pounds of regulated medical waste per day (monthly average) are not required to shred or grind the waste. Facilities that do not grind or shred the waste must seal the treated waste in an orange plastic bag and securely attach a tag or label with the following message in indelible ink and legible print of a 21-point or greater typeface:

"The generator certifies that this waste has been treated in accordance with the Virginia Regulated Medical Waste Management Regulations and is no longer regulated medical waste.

Treated: (include date treatment performed)

Generator: (include name, address and telephone number of generator)."

9 VAC 20-120-610. Compliance with other parts of this chapter.

In general, sterilizer facilities shall comply with all other parts of this chapter. The site of the sterilizer facility is a storage facility and must comply with Part V of this chapter. Management of spills or the opening in an emergency of any regulated medical waste package, shall comply with 9 VAC 20-120-270 and 9 VAC 20-120-280.

9 VAC 20-120-620. [Reserved Section].

Regulated Medical Waste Management Regulations

PART IX.

Special Requirements for Alternative Treatment.

9 VAC 20-120-630. Application.

The requirements of this part apply to all alternative treatment methods that treat regulated medical waste.

9 VAC 20-120-640. Performance standards.

All alternative treatment facilities for regulated medical waste shall maintain the following level of operational performance at all times:

Regulated Medical Waste Management Regulations

~~1.~~ A. Operational controls and records. The following requirements apply to all alternative treatment facilities.

~~a.~~ 1. Except as provided in 9 VAC 20-120-550, 9 VAC 20-120-600 E or 9 VAC 20-120-650 D, regulated medical waste shall be ground or shredded into particles that are no larger than an approximate size of 0.75 inches in any dimension. Grinding or shredding shall occur in a closed unit immediately preceding or following the treatment unit. Transfer from a grinder or shredder to or from a treatment unit shall be under forced draft ventilation that removes fumes from the operations area to a safe discharge.

~~b.~~ 2. Alternative treatment units shall be evaluated under full loading for effectiveness with spores of B. stearothermophilus or B. subtilis no less than once per month (See 9 VAC 20-120-910 B).

~~c.~~ 3. A log shall be kept at each alternative treatment unit that is complete for the preceding three year period. The log shall record the date, time and operator; the type and approximate amount of solid waste treated; and the dates and results of calibration and testing. Where multiple alternative 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 and all performance parameter recordings shall be retained for three years and be available for review.

~~d.~~ 4. Except as described in 9 VAC 20-120-300 C and subdivision~~s 1 a and 1 e~~ A1 of this section, regulated medical waste shall not be compacted or subjected to violent mechanical stress before treatment. After it is fully treated it may be compacted in a closed container in a safe and sanitary manner.

~~e.~~ 5. All process units for the preparation or treatment of regulated medical waste shall be in closed vessels under a negative pressure atmospheric control that filters all vents, discharges, and fugitive emissions of air from the process units through a high efficiency particulate air (HEPA) filter with efficiency of 99.97% for 0.3 microns.

~~2.~~ B. Special requirements by type of treatment. Facilities shall comply with the following treatment requirements for the specific technology employed. Each treatment unit shall be preceded by grinding or shredding in accordance with subdivision ~~1 a~~ A1 of this section.

~~a.~~ 1. Dry heat treatment.

~~(1)~~ a. Any treatment unit employing dry heat as the main treatment process shall subject all the regulated medical waste to:

~~(a)~~ (1) A temperature of no less than 480ºF for no less than 30 minutes,

~~(b)~~ (2) A temperature of no less than 390ºF for no less than 38 minutes, or

~~(c)~~ (3) A temperature of no less than 355ºF for no less than 60 minutes.

~~(2)~~ b. No treatment unit employing dry heat as the main treatment process shall have a treatment chamber capacity greater than 1.0 cubic feet in volume.

~~(3)~~ c. Each treatment unit shall be equipped to sense, display and continuously record the temperature of the treatment chamber.

~~b.~~ 2. Microwave treatment.

~~(1)~~ a. Microwaving treatment shall incorporate pretreatment by shredding and steam injection or induction.

~~(2)~~ b. Any treatment unit employing microwave radiation as the main treatment process shall subject all the solid waste to a temperature of no less than 203ºF for no less than 25 minutes.

~~(3)~~ c. Microwave radiation power of the treatment process shall be at least six units each having a power of 1,200 watts or the equivalent power output.

~~(4)~~ d. Each microwave treatment unit shall be equipped to sense, display and continuously record the temperature at the start, middle and end of the treatment chamber.

~~(5)~~ e. Process temperatures at the exposure chamber entry and exit and the waste flow rate shall be continuously monitored, displayed, and recorded.

~~c.~~ 3. Chlorination.

~~(1)~~ a. Any treatment unit employing chlorination as the main treatment process shall subject all the solid waste to a solution whose initial free residual chlorine concentration is not less than 3,000 milligrams per liter for no less than 25 minutes.

~~(2)~~ b. The free chlorine residual of the solid waste slurry after treatment shall be maintained at 200 milligrams per liter. The treated solid waste stream shall be equipped to continuously analyze, display, and record free chlorine residual concentration. Interval sampling every two minutes or less may be substituted for continuous analysis.

~~d.~~ 4. Other alternative treatment technologies. All alternative treatment technologies approved by the director shall conform to the requirements of this part and any additional requirements the director shall impose at the time of approval.

~~(1)~~ a. Any person who desires to use a treatment technology other than those described in subdivisions ~~2 a, 2 b, and 2 c~~ B1, B2, and B3 of this section, Part VII or Part VIII shall petition the director for a review under 9 VAC 20-120-860 and 9 VAC 20-120-870.

~~(2)~~ b. If the director finds that the technology and application is in accord with Article 3 (9 VAC 20-120-900 et seq.) of Part XI, he may consider the facility for permitting ~~under Part X of these regulations~~.

~~(3)~~ c. The director may issue a public notice that an applicant has demonstrated compliance of a process with 9 VAC 20-120-910 through 9 VAC 20-120-950 and consider 9 VAC 20-120-960 in a separate review.

9 VAC 20-120-650. Disposal of treated wastes.

Regulated Medical Waste Management Regulations

A. Regulated medical waste that has been treated by an alternate treatment technique and managed in compliance with this chapter is no longer regulated medical waste and is solid waste. Treated solid waste may be compacted.

B. All regulated medical waste that has been treated shall be placed in opaque plastic bags and sealed. The bags may not be red in color. Where bulk treatment is used and the solid waste is compacted and immediately placed in closed bulk solid waste management containers, which are more than 64 gallons in volume, the repackaging of the treated solid waste in bags is not required.

C. Regulated medical waste treated in compliance with Part VII, Part VIII or Part IX shall be deemed to be treated in accordance with this chapter. Regulated medical waste not treated in accordance with this chapter shall not be transported, received for transport or disposal, or disposed of in any solid waste management facility.

D. Small scale processes providing treatment of no more than five pounds per day (monthly average) of regulated medical waste in accordance with this part are not required to shred or grind the waste. Small scale facilities that do not grind or shred the waste must seal the treated waste in an orange plastic bag and securely attach a tag or label with the following message in indelible ink and legible print of a 21-point or greater typeface:

"The generator certifies that this waste has been treated in accordance with the Virginia Regulated Medical Waste Management Regulations and is no longer regulated medical waste.

Treated: (include date treatment performed)

Generator: (include name, address and telephone number of generator)."

9 VAC 20-120-660. Compliance with other parts of this chapter.

In general, alternative treatment facilities shall comply with all other parts of this chapter. The site of the treatment facility is a storage facility and must comply with Part V of this chapter. Management of spills or the opening in an emergency of any regulated medical waste package, shall comply with 9 VAC 20-120-270 and 9 VAC 20-120-280 of this chapter.

9 VAC 20-120-670. [Reserved Section].

Regulated Medical Waste Management Regulations

PART X.

Permit Application and Issuance Procedures.

Regulated Medical Waste Management Regulations

9 VAC 20-120-820. Duration of permits.

9 VAC 20-120-830. Existing facilities qualifications.

9 VAC 20-120-680. Scope.

This part of the chapter describes procedures for obtaining a permit for the transfer, treatment or storage of regulated medical waste, unless specifically excluded by these regulations or under a permit by rule as defined in 9 VAC 20-120-160, 9 VAC 20-120-170, and 9 VAC 20-120-180. Owners and operators of regulated medical waste management units shall have permits during the active life (including the closure periods) of the unit. ~~The director may issue or deny a permit~~ An applicant may be considered to have a permit or a permit may be terminated for one or more units at a facility without simultaneously ~~issuing or denying a permit to~~ affecting all of the units at the facility.

9 VAC 20-120-690. Applicability; exemptions from permit requirements; off-site permits by rule; experimental facility permits; variances.

A. Except for on-site permit by rule facilities described in Part IV, no person shall construct, operate or modify a regulated medical waste management facility in this Commonwealth without a permit issued by the director in accordance with this part. Notwithstanding the above, the management of materials excluded under Part III or conditionally exempt under Part III of this chapter shall not require a permit.

B. Each regulated medical waste management facility permit shall be limited to one site and shall be nontransferable between sites.

C. ~~Issuance of a~~ A new permit is required when there is:

1. Any new regulated medical waste management facility; or

2. Any change in design or process of a regulated medical waste management facility that will, in the opinion of the director, result in a substantially different type of facility.

D. ~~Unless the~~ The owner or operator of the following facilities ~~chooses to apply for and receive a full permit, he~~ shall be deemed to have a regulated medical waste management facility permit notwithstanding any other provisions of Part X, if all the conditions listed are met:

1. The owner or operator of a storage facility or transfer station:

a. Notifies the director of his intent to operate such a facility and provides to the department documentation required under 9 VAC 20-120-710 B of this chapter;

b. Provides the director with a certification that the facility meets the standards of Part V;

c. Furnishes to the director a certificate signed by a registered professional engineer that the facility has been designed and constructed in accordance with the standards of Part V;

d. Submits to the director an operational plan describing how the standards of Part V will be met, and provides the operational information required in 9 VAC 20-120-730;

e. Submits to the director a closure plan describing how the standards of 9 VAC 20-120-290 will be met;

f. Submits to the director the proof of financial responsibility if required by the Financial Assurance Regulations for Solid Waste Facilities (9 VAC 20-70-10 et seq.); and

g. Submits to the director the results of the public participation effort conducted in accordance with the requirements contained in 9 VAC 20-120-690 D 4.

2. The owner or operator of an incineration or other treatment facility:

a. Notifies the director of his intent to operate such a facility and provides to the department documentation required under 9 VAC 20-120-710 B of these regulations;

b. Provides the director with a certification that the facility meets the standards of Part VII, VIII, or IX;

c. Furnishes to the director a certificate signed by a registered professional engineer that the facility has been designed and constructed in accordance with the standards of Part VII, VIII, or IX;

d. Submits to the director an operational plan describing how the standards of Part VII, VIII, or IX will be met, and provides the operational information required in 9 VAC 20-120-730;

e. Submits to the director a closure plan describing how the standards of 9 VAC 20-120-290 will be met;

f. Submits to the director the proof of financial responsibility if required by the Financial Assurance Regulations for Solid Waste Facilities (9 VAC 20-70-10 et seq.); and

g. Furnishes to the director a copy of the facility permit issued for air pollution control of any regulated point source discharges at the facility.

3. Use of materials in a manner constituting disposal. (Reserved)

4. Public participation.

a. Before the initiation of any construction at the facility under 9 VAC 20-120-690 D 1 or 9 VAC 20-120-690 D 2, the owner or operator shall publish a notice in a major local newspaper of general circulation informing the public that he intends to construct and operate a facility eligible for an off-site permit by rule. The notice shall include:

(1) A brief description of the proposed facility;

(2) A statement that the purpose of the public participation is to acquaint the public with the technical aspects of the facility and how the standards and the requirements of this chapter will be met;

(3) Announcement of a 30-day comment period, in accordance with 9 VAC 20-120-690 D 4 d, and the name and address of the owner's or operator's representative where comments shall be sent;

(4) Announcement of the date, time, and place for a public meeting held in accordance with 9 VAC 20-120-690 D 4 c; and

(5) Location where copies of the documentation to be submitted to the department in support of the off-site permit by rule notification and any supporting documents can be viewed and copied.

b. The owner or operator shall place a copy of the documentation and support documents in a location accessible to the public in the vicinity of the proposed facility.

c. The owner or operator shall hold a public meeting not earlier than 15 days after the publication of the notice required in 9 VAC 20-120-690 D 4 a and no later than seven days before the close of the 30-day comment period. The meeting shall be held to the extent practicable in the vicinity of the proposed facility.

d. The public shall be provided 30 days to comment on the technical and the regulatory aspects of the proposal. The comment period will begin on the date the owner or operator publishes the notice in the local newspaper.

5. Upon receiving the certifications and other required documents and after conducting a completeness review, the director will acknowledge their receipt and inform the owner or operator of the status of the submittal. If the applicant's submission is administratively incomplete, the letter will state that the facility will not be considered to have an off-site permit by rule until the missing certifications or other required documentation is submitted. At the time of the initial receipt or at a later date, the director may require changes in the documents designed to assure compliance with the standards of Parts V, VI, VII, VIII and IX, if applicable. Should such changes not be accomplished by the facility owner or operator, ~~the director may require the operator to submit the full permit application and to obtain a regular regulated medical waste management facility permit in accordance with the standards of Part X~~ the facility will not be deemed to have a regulated medical waste management facility permit.

6. An off-site permit by rule may not be transferred by the permittee to a new owner or operator. However, when the property transfer takes place without proper closure, the new owner shall notify the department of the sale and fulfill all the requirements contained in 9 VAC 20-120-690 D 1 through 9 VAC 20-120-690 D 3 with the exception of those dealing with the financial assurance. Upon presentation of the financial assurance proof required by 9 VAC 20-70-10 et seq. by the new owner, the department will release the old owner from his closure and financial responsibilities and acknowledge existence of the new off-site permit by rule in the name of the new owner.

7. The owner or operator of a facility operating under an off-site permit by rule may modify its design and operation by furnishing the department a new certificate prepared by the professional engineer and a new operational plan. Whenever modifications in the design or operation of the facility affect the provisions of the approved closure plan, the owner or operator shall also submit an amended closure plan. Should there be an increase in the closure costs, the owner or operator shall submit a new proof of financial responsibility as required by the Financial Assurance Regulations for Solid Waste Facilities (9 VAC 20-70-10 et seq.).

8. In the event that a facility operating under an off-site permit by rule violates any applicable siting, design and construction, or closure provisions of Part V, VII, VIII, or IX, the owner or operator of the facility will be considered to be operating an unpermitted facility and shall be required to ~~either obtain a new permit in accordance with the procedures in 9 VAC 20-120-690 or~~ close under 9 VAC 20-120-290, 9 VAC 20-120-710 and 9 VAC 20-120-750.

9. The director shall terminate off-site permit by rule and shall require closure of the facility whenever he finds that:

a. As a result of changes in key personnel, the requirements necessary for an off-site permit by rule are no longer satisfied;

b. The applicant has knowingly or willfully misrepresented or failed to disclose a material fact in his disclosure statement, or any other report or certification required under this chapter, or has knowingly or willfully failed to notify the director of any material change to the information in the disclosure statement; or

c. Any key personnel has been convicted of any of the crimes listed in § 10.1-1409 of the Code of Virginia, punishable as felonies under the laws of the Commonwealth or the equivalent of them under the laws of any other jurisdiction; or has been adjudged by an administrative agency or a court of competent jurisdiction to have violated the environmental protection laws of the United States, the Commonwealth or any other state and the director determines that such conviction or adjudication is sufficiently probative of the permittee's inability or unwillingness to operate the facility in a lawful manner.

d. The operation of the facility is inconsistent with the facility's operations manual and the operational requirements of the regulations.

E. The director may issue an experimental facility permit for any regulated medical waste treatment facility that proposes to utilize an innovative and experimental regulated medical waste treatment technology or process for which permit standards for such experimental activity have not been promulgated under Part

VII, Part VIII or Part IX. Any such permit shall include such terms and conditions as will assure protection of human health and the environment. Such permits shall:

1. Provide for the construction of such facilities based on the standards shown in Part V, Part VII, Part VIII, or Part IX, as necessary;

2. Provide for operation of the facility for no longer than one calendar year unless renewed as provided elsewhere in this chapter;

3. Provide for the receipt and treatment by the facility of only those types and quantities of regulated medical waste that the director deems necessary for purposes of determining the efficiency and performance capabilities of the technology or process and the effects of such technology or process on human health and the environment, and

4. Include such requirements as the director deems necessary to protect human health and the environment (including, but not limited to, requirements regarding monitoring, operation, closure and remedial action), and such requirements as the director deems necessary regarding testing and providing of information to the director with respect to the operation of the facility.

For the purpose of expediting review and issuance of permits under this subsection, the director may, consistent with the protection of human health and the environment, modify or waive permit application and permit issuance requirements in Parts V, VII, VIII or IX, except that there may be no modification or waiver of regulations regarding local certification, disclosure statement requirements, financial responsibility ~~(including insurance)~~ or of procedures regarding public participation.

No experimental permit may be renewed more than three times. Each such renewal shall be for a period of not more than one calendar year.

F. The director may grant a variance, in accordance with the procedures in Part XI, from any regulation contained in this part to a permittee provided the requirements of Part X are met.

9 VAC 20-120-700. Permit conditions.

~~When issuing a permit, the~~ The director may include conditions in any permit that he finds necessary to protect public health or the environment or to ensure compliance with this chapter.

9 VAC 20-120-710. ~~Permit application procedures; notice~~ Notice of intent; ~~Part A application; Part B application; permit issuance.~~

Regulated Medical Waste Management Regulations

A. Any person who proposes to establish a new regulated medical waste management facility, or modify an existing regulated medical waste management facility, shall submit a permit application to the department, using the procedures set forth in 9 VAC 20-120-690 and other pertinent sections of this part.

B. To initiate the permit application process, any person who proposes to establish a new regulated medical waste management facility ("regulated medical waste management"), or modify an existing regulated medical waste management facility, or to amend an existing permit shall file a notice of intent with the director stating the desired permit or permit amendment, the precise location of the proposed facility, and the intended use of the facility. The notice shall be in letter form and be accompanied by ~~area and site location maps~~ the information described in 9 VAC 20-120-720.

No application shall be deemed complete unless it is accompanied by a disclosure statement as shown in APPENDIX 10.1 for all key personnel.

No application for a permit for a regulated medical waste management facility shall be considered complete unless the notice of intent is accompanied by a certification from the governing body of the county, city, or town in which the facility is to be located stating that the location and operation of the facility are consistent with all applicable ordinances. No certification shall be required for the application for an amendment or modification of an existing permit. For the convenience of the regulated community, a certification form is shown in APPENDIX 10.2.

If the location and operation of the facility is stated by the local governing body to be consistent with all its ordinances, without qualifications, conditions, or reservations, the applicant ~~will be notified that he~~ may submit his application for a permit. ~~This application shall be submitted in two parts, identified as Part A and Part B.~~

~~C. Part A application provides the information essential for assessment of the site suitability for the proposed facility. It contains information on the proposed facility to be able to determine site suitability for intended uses. It provides information on all siting criteria applicable to the proposed facility.~~

~~1. The applicant shall complete, sign and submit three copies of the Part A application containing required information and attachments as specified in 9 VAC 20-120-720 to the director.~~

~~2. The Part A application will be reviewed for completeness. The applicant will be notified within 15 calendar days whether the application is administratively complete or incomplete. If complete information is not provided within 30 calendar days after the applicant is notified, the application will be returned to the applicant without further review.~~

~~3. Upon receipt of a complete Part A application, the department shall conduct a technical review of the submittal. Additional information may be required or the site may be visited before the review is completed.~~

~~The director shall notify the applicant in writing of approval or disapproval of the Part A application or provide conditions to be made a part of the approval.~~

~~4. In case of the approval or conditional approval, the applicant may submit the Part B application providing the required conditions are addressed in the Part B application.~~

~~D. The Part B application involves the submission of the detailed engineering design and operating plans for the proposed facility.~~

~~1. The applicant, after receiving Part A approval, may submit to the director a Part B application to include the required documentation for the specific regulated medical waste management facility as provided for in 9 VAC 20-120-710, 9 VAC 20-120-720, or 9 VAC 20-120-730. The Part B application and supporting documentation shall be submitted in three copies. The Part B application must include the required financial assurance documentation. Until the closure plans are approved and a draft permit is being prepared, the applicant must provide evidence of commitment to provide the required financial assurance from a financial institution or insurance company. If financial assurance is not provided within 30 calendar days of notice by the director, the permit shall be denied.~~

~~2. The Part B application shall be reviewed for administrative completeness before technical evaluation is initiated. The applicant shall be advised in writing within 30 calendar days whether the application is~~

~~complete or what additional documentation is required. The Part B application will not be evaluated until a administratively complete application is received.~~

~~3. The administratively complete application will be coordinated with other state agencies according to the nature of the facility. The comments received shall be considered in the permit review by the department. The application will be evaluated for technical adequacy and regulatory compliance. In the course of this evaluation, the department may require the applicant to provide additional information. At the end of the evaluation, the department will notify the applicant that the application is technically and regulatorily adequate or that the department intends to deny the application.~~

~~4. The procedures addressing the denial are contained in 9 VAC 20-120-770.~~

~~E. If the application is found to be technically adequate and in full compliance with this chapter, a draft permit shall be developed by the department.~~

~~A notice of the availability of the proposed draft permit shall be made in a newspaper with general circulation in the area where the facility is to be located. An informational proceeding will be scheduled and the notice shall be published at least 30 calendar days in advance of the informational proceeding on the draft permit. Copies of the proposed draft permit will be available for viewing at the applicant's place of business or at the regional office of the department upon request in advance of the informational proceeding.~~

~~The department shall hold the announced informational proceeding 30 calendar days or more after the notice is published in the local newspaper. The informational proceeding shall be conducted by the department within the local government jurisdiction where the facility is to be located. A comment period shall extend for a 10-day period after the conclusion of the informational proceeding.~~

~~A final decision to permit, to deny a permit or to amend the draft permit will be rendered by the director within 30 calendar days of the close of the public comment period.~~

~~The permit applicant and the persons who commented during the public participation period shall be notified in writing of the decision on the draft permit. That decision may include denial of the permit (see also 9 VAC 20-120-770), issuance of the permit as drafted, or amendment of the draft permit and issuance.~~

9 VAC 20-120-720. ~~Part A permit application requirements~~. Submission requirements

A. The information provided in this section shall be included in ~~Part A of the permit application for all regulated medical waste management facilities~~ the submission of a notice of intent as required in 9 VAC 20-120-710 unless otherwise specified in this section.

B. ~~The Part A permit application consists of a~~ A letter will be provided stating the type of ~~the~~ facility for which the permit application is made and the certification required in subsection F of this section, ~~the Part A application form shown in APPENDIX 10.3 with~~ and all pertinent information and attachments required by this section.

C. A key map ~~of the Part A permit application,~~ delineating the general location of the proposed facility, shall be prepared and attached as part of the application. The key map shall be plotted on a seven and one-half minute United States Geological Survey topographical quadrangle. The quadrangle shall be the most recent revision available, shall include the name of the quadrangle and shall delineate a minimum of one mile from the perimeter of the proposed facility boundaries. One or more maps may be utilized where necessary to insure clarity of the information submitted.

D. A near-vicinity map shall be prepared and attached as part of the application. The vicinity map shall have a minimum scale of one inch equals 200 feet (1inch~~1;~~ = 200'). The vicinity map shall delineate an area of 500 feet from the perimeter of the property line of the proposed facility. The vicinity maps may be an enlargement of a United States Geological Survey topographical quadrangle or a recent aerial photograph. The vicinity map shall depict the following:

1. All homes, buildings or structures including the layout of the buildings that will comprise the proposed facility;

2. The boundaries of the proposed facility;

3. The limits of the actual ~~disposal operations~~ waste management areas within the boundaries of the proposed facility, if applicable;

4. Lots and blocks taken from the tax map for the site of the proposed facility and all contiguous properties;

5. The base flood plain, where it passes through the map area; or, otherwise, a note indicating the expected flood occurrence period for the area;

6. Existing land uses and zoning classification;

7. All water supply wells, springs or intakes, both public and private;

8. All utility lines, pipelines or land based facilities (including mines and wells); and

9. All parks, recreation areas, dams, historic areas, wetlands areas, monument areas, cemeteries, wildlife refuges, unique natural areas or similar features.

E. A copy of the lease or deed (showing page and book location) or certification of ownership of the site. The department will not consider an application for a permit from any person who does not demonstrate legal control over the site for the period of the permit life. ~~A documentation of an option to purchase will be considered as a temporary substitute for a deed; however, the true deed must be provided to the department before construction at the site begins.~~

F. A ~~signed~~ statement signed by the applicant indicating that he has sent written notice to all adjacent property owners or occupants that he intends to develop a regulated medical waste management facility on the site~~., a~~. A copy of the notice and the names and addresses of those to whom the notices were sent will also be provided.

9 VAC 20-120-730. ~~Part B permit application requirements~~Operational Information.

~~A. Owners or operators of all regulated medical waste management facilities will use the application procedures of this section. The information provided in this section is required in a Part B permit application.~~

~~B. Design plans shall be prepared by a person or firm registered to practice professional engineering in the Commonwealth. The plans shall demonstrate compliance with Parts V, VII, VIII, and IX and include at least the following:~~

~~1. Existing site conditions plans sheet indicating site conditions prior to development.~~

~~2. Engineering modification plan sheet indicating the appearance of the site after installation of engineering modifications. More than one plan sheet may be required for complicated sites.~~

~~3. Phasing plan sheets showing the progression of site development through time. At a minimum, a separate plan shall be provided for initial site preparations and for each subsequent major phase or new area where substantial site preparation must be performed. Each such plan shall include a list of construction items and quantities necessary to prepare the phase indicated.~~

~~4. Design drawings of the regulated medical waste management facility to include:~~

~~a. Profile and plan views of all structures and enclosures showing dimensions. Plan views showing building setbacks, side and rear distances between the proposed structure and other existing or proposed structures, roadways, parking areas and site boundaries;~~

~~b. Interior floor plans showing the layout, profile view and dimensions of the processing lines, interior unloading, sorting, storage and loading areas as well as other functional areas;~~

~~c. A plan identifying, locating and describing utilities that will service the facility including, but not limited to, the storm water drainage system, sanitary sewer system, water supply system and energy system; interface of the proposed facility with the existing utility systems.~~

~~5. When applicable, the following information shall be presented on plan sheets:~~

~~a. All information on existing site conditions map unless including this information leads to confusion with the data intended for display.~~

~~b. A survey grid with base lines and monuments to be used for field control.~~

~~c. All drainage patterns and surface water drainage control structures both within the area and at the site perimeter to include berms, ditches, sedimentation basins, pumps, sumps, culverts, pipes, inlets, velocity breaks, sodding, erosion matting, or other methods of erosion control.~~

~~d. Access roads and traffic flow patterns to and within the storage and transfer areas.~~

~~e. All temporary and permanent fencing.~~

~~f. The methods of screening such as berms, vegetation or special fencing.~~

~~g. Wastewater collection, control and treatment systems that may include pipes, manholes, trenches, berms, collection sumps or basins, pumps, and risers.~~

~~h. Special waste handling areas.~~

~~i. Construction notes and references to details.~~

~~j. Other appropriate site features.~~

~~6. Detailed drawings and typical sections for, as appropriate, drainage control structures, access roads, fencing, buildings, signs, and other construction details.~~

~~C~~ A. ~~A design report for the facility is required and will provide the technical details and specifications necessary to support the design plans consisting of, at least, the following information~~ A narrative will be provided outlining the details of the design/operational capacities of the facility, emergency contingency information and daily operation of the facility as follows:

Regulated Medical Waste Management Regulations

1. The ~~introduction to the design report~~ narrative shall identify the project title; engineering consultants; site owner, licensee and operator; site life and capacity; municipalities, industries and collection and transportation agencies served; and waste types to be disposed. It shall also identify any exemptions desired by the applicant.

2. The ~~design capacity specifications~~ narrative shall include~~, at a minimum~~, the following information:

a. The rated capacity of the facility, in both tons per day and tons per hour;

b. The expected short-term and projected future long-term daily loadings;

c. The designation of normal loading, unloading and storage areas, including capacities in cubic yards and tons. Description of the time such areas can be practically used, based on expected short-term daily loadings;

d. The designation of emergency loading, unloading, storage or other ~~disposal capabilities to be used~~ actions to be taken when facility system down time exceeds 24 hours;

e. The designation of alternate ~~disposal~~ treatment areas or plans for transfer of stored waste in the event facility system down time exceeds 72 hours;

3. The ~~design specifications for~~ narrative will discuss the generation of process residues to include the following:

a. The expected daily quantity of waste residue generated;

b. The proposed ultimate disposal location for all facility-generated waste residues including, but not limited to, treated waste, ash residues and by-pass material, residues resulting from air pollution control devices, and the proposed alternate treatment or disposal locations for any unauthorized waste types, which may have been unknowingly accepted. The schedule for securing contracts for the treatment or disposal of these waste types at the designated locations shall be provided;

c. A descriptive statement of any materials use, reuse, or reclamation activities to be operated in conjunction with the facility, either on the incoming regulated medical waste or the outgoing residue;

4. A ~~descriptive statement and detailed specification~~ discussion of the proposed onsite and off-site transportation system intended to service vehicles hauling waste to the facility for processing, and vehicles removing reclaimed materials and or process residues from the facility. Onsite parking, access and exit points, and the mechanisms or features that will be employed to provide for an even flow of traffic into, out of, and within the site, shall be identified;

5. A detailed analysis shall be made of the financial responsibility for the time of site closing; ~~and~~

~~6. An appendix to the design plan shall be submitted and shall include any additional data not previously presented, calculations, material specifications, operating agreements, wastewater treatment agreements, documents related to long-term care funding and other appropriate information.~~

~~D. The results of a waste supply analysis program characterizing the quantity and composition of the regulated medical waste in the service area shall be submitted. The waste characterization shall be performed by utilizing a statistically relevant plan that justifies the population sample. The sampling program shall provide for seasonal fluctuations in the quantity and composition of the waste types to be handled at the facility. Anticipated changes in regulated medical waste quantity and composition for each of the waste types to be serviced by the proposed facility shall be projected for that term reflecting anticipated facility life. Within this framework, the effect of existing or future source separation programs on the supply of regulated medical waste within the service area shall be described and quantified. Quantity and compositions analyses shall be carried out simultaneously where possible and provide information relating to anticipated maximum, minimum and average daily loading.~~ Reserved

~~E~~ B. The operations manual shall provide the detailed procedures ~~by which the operator will implement the design plans and specifications~~ describing actions taken by facility personnel from the time of waste

delivery, through waste storage, processing and final transportation and disposal. As a minimum, the operations manual shall include:

1. Daily operations including ~~a~~ : A discussion of the timetable for development; waste types accepted or excluded; typical waste handling techniques; hours of operation; traffic routing; drainage and erosion control; windy, wet and cold weather operations; fire protection equipment; manpower; methods for handling of any unusual waste types; methods for vector, dust and odor control; daily cleanup; salvaging; record keeping; parking for visitors and employees; monitoring; backup equipment with names and telephone numbers where equipment may be obtained; and other special design features. This information may be developed as a removable section to improve accessibility for the site operator.

2. The procedures that will be used to label individual waste containers, bulk containers or trailers with the date that the waste materials were received from off-site, and the procedures that will be used to demonstrate that the waste is treated within 15 days of receipt.

~~2.~~ 3.Site closing information consisting of a discussion of the anticipated sequence of events for site closing and discussion of those actions necessary to prepare the site for ~~long-term care and final use~~ any anticipated post-closure use.

~~3. Long-term care information including a discussion of the procedures to be utilized for the inspection and maintenance of run-off control structures, erosion damage, wastewater control, and other long-term care needs as required by the specific facility design.~~

~~F~~ C. An emergency contingency plan that delineates procedures for responding to fire, explosions or any unplanned sudden or non-sudden releases of harmful constituents to the air, soil, or surface or ground water shall be submitted to the department as part of the Part B application. Before submission to the department it will be coordinated with the local police and fire departments, and the appropriate health care facility. The contingency plan shall contain:

1. A description of the actions facility personnel shall take in the event of various emergency situations;

2. A description of arrangements made with the local police and fire department that allow for immediate entry into the facility by their authorized representatives should the need arise, such as in the case of response personnel responding to an emergency situation; and

3. A list of names, addresses and phone numbers (office and home) of all persons qualified to act as an emergency coordinator for the facility. Where more than one person is listed, one shall be named as primary emergency coordinator and the other shall be listed in the order in which they will assume responsibility as alternates.

~~G~~ D. The applicant shall prepare and submit a detailed plan for closing any regulated medical waste management unit. Such a plan shall be prepared to reflect the actions required at any point in the life of the facility and at the time of closing the facility. The plan should reflect all steps necessary to isolate the facility from the environment or to remove ~~and dispose of~~ all regulated medical waste and residue in the facility for proper treatment and to decontaminate the facility. The closure plan should reflect all actions necessary for facility abandonment or uses other than for regulated medical waste management.

9 VAC 20-120-740. Effect of the permit.

~~A. A completed permit for a regulated medical waste management facility permit shall be prepared in detail to establish the construction requirements, monitoring requirements, operating limitations or guides, waste limitations if any, and any other details essential to the operation and maintenance of the facility and its closure of the facility. Before receipt of waste by the facility, the applicant must:~~

~~1. Notify the department, in writing, that construction has been completed; and submit to the department a letter from a professional engineer licensed to practice in the Commonwealth certifying that the facilities have been completed in accordance with the approved plans and specifications and is ready to begin operation.~~

~~2. Arrange for a department representative to inspect the site and confirm that the site is ready for operation.~~

~~B.~~ A. Each facility permitted to accept regulated medical waste requires periodic inspection and review of records and reports. Such requirements shall be set forth in the final permit issued by the department. The permit applicant, by accepting the permit, agrees to the specified periodic inspections.

~~C.~~ Compliance with a valid permit and this chapter during its term constitutes compliance for purposes of enforcement, with the Virginia Waste Management Act. However, a permit may be ~~amended, revoked and reissued, or revoked for cause as set forth in 9 VAC 20-120-790 and 9 VAC 20-120-810~~modified, considered invalid, or terminated for cause as set forth in 9 VAC 20-120-690D7, 9 VAC 20-120-690D8, and 9 VAC 20-120-690D9.

~~D. The issuance of a~~ A permit does not convey any property rights of any sort, or any exclusive privilege.

~~E. The issuance of a~~ A permit does not authorize any injury to persons or property or invasion of other private rights, or any infringement of federal, Commonwealth or local law or regulations.

~~F.~~ A permit may be transferred ~~by the permittee to a new owner or operator only if the permit has been revoked and reissued, or a minor amendment made to identify the new permittee and incorporate such other requirements as may be necessary~~in accordance with the procedures in 9 VAC 20-120-690D6.

~~G.~~ The permit may, ~~when appropriate~~consistent with 9 VAC 20-120-700, specify a schedule of compliance leading to compliance with this chapter.

1. Any schedules of compliance under subsections G or H of this section shall require compliance as soon as possible.

2. Except as otherwise provided, if a permit establishes a schedule of compliance that exceeds one year from the date of permit issuance, the schedule shall set forth, interim requirements and the dates for their achievement.

a. The time between interim dates shall not exceed one year;

b. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages of completion, the permit shall specify interim dates for the submission of

reports of progress toward completion of the interim requirements and indicate a projected completion date.

3. The permit shall be written to require that no later than 14 calendar days following each interim date and the final date of compliance, a permittee shall notify the director, in writing, of his compliance or noncompliance with the interim or final requirements.

~~H.~~ A permit applicant or permittee may cease conducting regulated activities (by receiving a terminal volume of regulated medical waste and, in case of treatment or storage facilities, closing pursuant to applicable requirements, or, in case of disposal facilities, closing and conducting post-closure care pursuant to applicable requirements) rather than continue to operate and meet permit requirements as follows:

1. If the permittee decides to cease conducting regulated activities at a specified time for a permit that has already been issued:

a. The permit may be ~~amended~~ modified to contain a new or additional schedule leading to timely cessation of activities; or

b. The permittee shall cease conducting permitted activities before noncompliance with any interim or final compliance schedule requirement already specified in the permit.

2. If the decision to cease conducting regulated activities is made before the issuance of a permit whose terms will include the termination date, the permit shall contain a schedule leading to termination that will ensure timely compliance with applicable requirements.

3. If the permittee is undecided whether to cease conducting regulated activities, the director may issue or amend a permit to continue two schedules as follows:

a. Both schedules shall contain an identical interim deadline requiring a final decision on whether to cease conducting regulated activities no later than a date that ensures sufficient time to comply with applicable requirements in a timely manner if the decision is to continue conducting regulated activities;

b. One schedule shall lead to timely compliance with applicable requirements;

c. The second schedule shall lead to cessation of regulated activities by a date that will ensure timely compliance with applicable requirements.

d. Each permit containing two schedules shall include a requirement that, after the permittee has made a final decision, he shall follow the schedule leading to compliance if the decision is to

continue conducting regulated activities, and follow the schedule leading to termination if the decision is to cease conducting regulated activities.

4. The applicant's decisions to cease conducting regulated activities shall be evidenced by a firm public commitment satisfactory to the director, such as a resolution of the board of directors of a corporation.

9 VAC 20-120-750. Closure care.

A. An owner, operator or permittee intending to close a regulated medical waste management facility shall notify the department of the intention to do so as least 180 calendar days prior to the anticipated date of closing.

B. Closure shall occur in accord with an approved closure plan, which shall be submitted with the permit application documents and approved ~~with the permit issuance~~ when the director acknowledges that the facility is considered to have a permit. The holder of the permit shall submit a proposed modified closure plan to the department for review and approval as such modifications become necessary during the life of the facility.

C. The department shall inspect all regulated medical waste management facilities that have been closed to determine if the closing is complete and adequate. It shall notify the owner of a closed facility, in writing,

if the closure is satisfactory, and shall order necessary construction or such other steps as may be necessary to bring unsatisfactory sites into compliance with this chapter. Notification by the department that the closure is satisfactory does not relieve the operator of responsibility for corrective action to prevent or abate problems caused by the facility.

9 VAC 20-120-760. Recording and reporting required of a permittee.

A. A permit may specify:

1. Required monitoring, including type, intervals and frequency, sufficient to yield data that are representative of the monitored activity;

2. Requirements concerning the proper use, maintenance, and installation of monitoring equipment or methods, including biological monitoring methods when appropriate; and

3. Applicable reporting requirements based upon the impact of the regulated activity and as specified in this chapter.

B. A permittee shall be subject to the following whenever monitoring is required by the permit:

Regulated Medical Waste Management Regulations

1. The permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation for at least three years from the sample or measurement date. The director may request that this period be extended.

2. Records of monitoring information shall include:

a. The date, exact place and time of sampling or measurements;

b. The individuals who performed the sampling or measurements;

c. The dates analyses were performed;

d. The individuals who performed the analyses;

e. The analytical techniques or methods used; and

f. The results of such analyses.

3. Monitoring results shall be maintained on file for inspection by the department.

C. A permittee shall be subject to the following reporting requirements:

1. Written notice of any planned physical alterations to the permitted facility, unless such items were included in the plans and specifications or operating plan approved by the department, shall be given to the director and approved before such alterations are to occur.

2. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of the permit, shall be submitted no later than 14 calendar days following each schedule date.

3. The permittee shall report to the department any noncompliance or unusual condition that may endanger health or environment. Any information shall be provided orally within 24 hours from the time the permittee becomes aware of the circumstances. A written submission shall also be provided within five calendar days of the time the permittee becomes aware of the circumstances. The written submission shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and, if the noncompliance has not been corrected, the anticipated time it is expected to continue. It shall also contain steps taken or planned to reduce, eliminate and prevent reoccurrence of the noncompliance.

~~4. The permittee shall submit groundwater monitoring reports if required by Part V of this chapter.~~

D. Copies of all reports required by the permit, and records of all data used to complete the permit application must be retained by the permittee for at least three years from the date of the report or application. The director may request that this period be extended.

E. When the permittee becomes aware that he failed to submit any relevant facts or submitted incorrect information in a permit application or in any report to the director, he shall promptly submit such omitted facts or the correct information with an explanation.

9 VAC 20-120-770. [Reserved] ~~Permit denial.~~

~~A. A permit shall be denied if:~~

~~1. The applicant fails to provide complete information required for an application;~~

~~2. The facility does not conform with the siting standards set forth for the facility in Part V or Part VI of this chapter unless an exemption or variance from the specific siting criteria has been granted;~~

~~3. The facility design and construction plans or operating plans or both fail to comply with requirements specified for the proposed type of facility unless an exemption or variance from the specific requirement has been granted;~~

~~4. The department finds that there is an adverse impact on the public health or the environment by the design, construction or operation will result; or~~

~~5. The applicant is not able to fulfill the financial responsibility requirements specified in the Virginia Waste Management Board financial assurance regulations.~~

~~B. Reasons for the denial of any permit shall be provided to the applicant in writing by the director.~~

9 VAC 20-120-780. [Reserved] ~~permit denial.~~

~~A. If the department denies a permit to an applicant, the applicant shall be informed in writing of the decision and the reasons supporting the denial decision. The department shall mail the decision to the applicant by certified mail. Within 30 calendar days of the notification date of denial of the permit, the applicant may make a written request of the director for an informational proceeding or hearing to contest the director's decision. The proceeding or hearing shall be conducted in accordance with the Administrative Process Act § 9-6.14:1 et seq. of the Code of Virginia.~~

~~B. The director shall render a decision affirming or modifying the previous denial, and shall notify the applicant of his decision in writing. If the director's decision is adverse to the applicant, the applicant may appeal in accordance with the Administrative Process Act § 9-6.14:1 et seq. of the Code of Virginia.~~

9 VAC 20-120-790. [Reserved]~~Revocation or suspension of permits.~~

~~A. Any permit issued by the director may be revoked when any of the following conditions exist:~~

~~1. The permit holder violates any regulation or order of the board or any condition of a permit where such violation poses a threat of release of harmful substances into the environment or presents a hazard to human health;~~

~~2. The regulated medical waste management facility is maintained or operated in such a manner as to constitute an open dump or pose a substantial present or potential hazard to human health or the environment, or the violation is representative of a pattern of serious or repeated violations which, in the opinion of the director, demonstrate the permittee's disregard for or inability to comply with applicable laws, regulations or requirements;~~

~~3. The regulated medical waste management facility because of its location, construction or lack of protective construction or measures to prevent pollution, constitutes an open dump or poses a substantial present or potential hazard to human health or the environment;~~

~~4. Leachate or residues from the regulated medical waste management facility used for disposal storage or treatment of regulated medical waste pose a threat of contamination or pollution of the air, surface waters or groundwater;~~

~~5. The person to whom the permit was issued abandons, sells, leases or ceases to operate the facility permitted;~~

~~6. The owner or operator fails to maintain financial assurance mechanism if required to do so by the Financial Assurance Regulations for Solid Waste Facilities (9 VAC 20-70-10 et seq.);~~

~~7. As a result of changes in key personnel, the director finds that the requirements necessary for issuance of a permit are no longer satisfied;~~

~~8. The applicant has knowingly or willfully misrepresented or failed to disclose a material fact in applying for a permit or in his disclosure statement, or any other report or certification required under this law or~~

~~under the regulations of the board, or has knowingly or willfully failed to notify the director of any material change to the information in the disclosure statement; or~~

~~9. Any key personnel has been convicted of any following crimes punishable as felonies under the laws of the Commonwealth or the equivalent of them under the laws of any other jurisdiction: murder; kidnapping; gambling; robbery; bribery; extortion; criminal usury; arson; burglary; theft and related crimes; forgery and fraudulent practices; fraud in the offering, sale, or purchase of securities; alteration of motor vehicle identification numbers; unlawful manufacture, purchase, use or transfer of firearms; unlawful possession or use of destructive devices or explosives; violation of the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia; racketeering; or violation of antitrust laws; or has been adjudged by an administrative agency or a court of competent jurisdiction to have violated the environmental protection laws of the United States, the Commonwealth or any other state and the director determines that such conviction or adjudication is sufficiently probative of the applicant's inability or unwillingness to operate the facility in a lawful manner, as to warrant denial, revocation, amendment or suspension of the permit. In making such determination, the director shall consider:~~

~~a. The nature and details of the acts attributed to key personnel;~~

~~b. The degree of culpability of the applicant, if any;~~

~~c. The applicant's policy or history of discipline of key personnel for such activities;~~

~~d. Whether the applicant has substantially complied with all rules, regulations, permits, orders and statutes applicable to the applicant's activities in Virginia;~~

~~e. Whether the applicant has implemented formal management controls to minimize and prevent the occurrence of such violations; and~~

~~f. Mitigation based upon demonstration of good behavior by the applicant including, without limitation, prompt payment of damages, cooperation with investigations, termination of employment or other relationship with key personnel or other persons responsible for violations or other demonstrations of good behavior by the applicant that the director finds relevant to its decision.~~

~~B. If the director finds that regulated medical wastes are no longer being stored,~~ or ~~treated or disposed at a facility in accordance with department regulations, the director may revoke the permit issued for such facility and reissue it with a condition requiring the person to whom the permit was issued to provide closure and post-closure care of~~ close ~~the facility.~~

~~If the director is notified by the permittee that the ownership of the facility will be transferred to a new owner or that the operation will be conducted by a new operator, the director will upon receipt of financial assurance documents required by Financial Assurance Regulations of Solid Waste Facilities (9 VAC 20-70-10 et seq.), revoke the original permit and reissue it to the new owner or operator.~~

~~C. Except in an emergency, a facility posing a substantial threat to public health or the environment, the director may revoke a permit only after a hearing, or a waiver of a hearing, in accordance with § 9-6.14:1 et seq. of the Code of Virginia.~~

~~D. If the director summarily suspends a permit pursuant to an emergency based on subdivision 18 of § 10.1-1402 of the Virginia Waste Management Act, the director shall hold a conference pursuant to § 9-6.14:11 of the Virginia Administrative Process Act, within 48 hours to consider whether to continue the suspension pending a hearing to amend or revoke the permit, or to issue any other appropriate order. Notice of the hearing shall be delivered at the conference or sent at the time the permit is suspended. Any person whose permit is suspended by the director shall cease activity for which the permit was issued until the permit is reinstated by the director or by a court.~~

9 VAC 20-120-800.[Reserved] ~~Appeal of a revocation of a permit.~~

~~If the director suspends, revokes or revokes and reissues a permit, the permittee may appeal in accordance with § 9-6.14:1 et seq. of the Code of Virginia.~~

9 VAC 20-120-810.[Reserved] ~~Amendment of permits.~~

~~A. Permits may be amended at the request of any interested person or upon the director's initiative. However, permits may only be amended for the reasons specified in subsections E and F of this section. All requests shall be in writing and shall contain facts or reasons supporting the request.~~

~~B. If the director decides the request is not justified, he shall send the requester a brief response giving a reason for the decision.~~

~~C. If the director tentatively decides to amend he shall prepare a draft permit incorporating the proposed changes. The director may request additional information and may require the submission of an updated permit application. In a permit amendment under subsection E of this section, only those conditions to be amended shall be reopened when a new draft permit is prepared. All other aspects of the existing permit shall remain in effect. During any amendment proceeding the permittee shall comply with all conditions of the existing permit until the amended permit is issued.~~

~~D. When the director receives any information, he may determine whether or not one or more of the causes listed for amendment exist. If cause exists, the director may amend the permit on his own initiative subject to the limitations of subsection E of this section and may request an updated application if necessary. If a permit amendment satisfies the criteria in subsection F of this section for minor amendments, the permit may be amended without a draft permit or public review. Otherwise, a draft permit shall be prepared and other appropriate procedures followed.~~

~~E. The director may amend a permit upon his own initiative or at the request of a third party. The director may amend a permit when there is a significant change in the manner and scope of operation which may require new or additional permit conditions or safeguards to protect the public health and environment; there is found to be a possibility of pollution causing significant adverse effects on the air, land, surface water or groundwater; investigation has shown the need for additional equipment, construction, procedures and testing to ensure the protection of the public health and the environment from significant adverse effects; or the amendment is necessary to meet changes in applicable regulatory requirements. Circumstances that may necessitate an amendment include, but are not limited to, the following:~~

~~1. When there are material and substantial alterations or additions to the permitted facility or activity that occurred after permit issuance that justify the application of permit conditions that are different or absent in the existing permit;~~

~~2. When there is found to be a possibility of pollution causing significant adverse effects on the air, land, surface water or groundwater;~~

~~3. When an investigation has shown the need for additional equipment, construction, procedures and testing to ensure the protection of the public health and the environment from adverse effects;~~

~~4. If the director has received information pertaining to circumstances or conditions existing at the time the permit was issued that was not included in the administrative record and would have justified the application of different permit conditions, the permit may be amended accordingly if in the judgment of the director such amendment is necessary to prevent significant adverse effects on public health or the environment;~~

~~5. When the standards or regulations on which the permit was based have been changed by promulgation of amended standards or regulations or by judicial decision after the permit was issued;~~

~~6. When the director determines good cause exists for amendment of a compliance schedule, such as an act of God, strike, flood, or material shortage or other events over which the permittee has little or no control and for which there is no reasonably available remedy;~~

~~7. When an amendment of a closure plan is required and the permittee has failed to submit a permit amendment request within the specified period;~~

~~8. When the permittee has filed a request under 9 VAC 20-70-130 G of the Financial Assurance Regulations of Solid Waste Facilities for a variance to the level of financial responsibility or when the director demonstrates under 9 VAC 20-70-130 E that an upward adjustment of the level of financial responsibility is required; and~~

~~9. When cause exists for revocation under 9 VAC 20-120-790 and the director determines that an amendment is more appropriate.~~

~~F. This subsection provides for permit modification or amendment at the request of the permittee.~~

~~1. Minor modifications and permit amendments.~~

~~a. Except as provided in subdivisions 1 b and 1 c of this subsection, the permittee may put into effect minor modifications listed in APPENDIX 10.4 under the following conditions:~~

~~(1) The permittee shall notify the director concerning the modification by certified mail or other means that establish proof of delivery at least 14 calendar days before the change is put into~~

~~effect. This notice shall specify the changes being made to permit conditions or supporting documents referenced by the permit and shall explain why they are necessary. Along with the notice, the permittee shall provide the applicable information required by 9 VAC 20-120-700 and 9 VAC 20-120-710, 9 VAC 20-120-720, or 9 VAC 20-120-730.~~

~~(2) The permittee shall send a notice of the modification to the governing body of the county, city or town in which the facility is located. This notification shall be made within 90 calendar days after the change is put into effect. For the minor modifications that require prior director approval, the notification shall be made within 90 calendar days after the director approves the request.~~

~~b. Minor permit modifications identified in APPENDIX 10.4 by an asterisk may be made only with the prior written approval of the director.~~

~~c. In addition to permit modifications listed in APPENDIX 10.4, the permittee may request the director to approve a modification that will result in a facility that is more protective of the health and environment than this chapter requires. The request for such a minor permit modification will be accompanied by a description of the desired change and an explanation of the manner in which the health and environment will be protected in a greater degree than the chapter provides for.~~

~~d. For a minor permit modification, the permittee may elect to follow the procedures in subdivision 2 of this subsection for substantive amendments instead of the minor permit modification procedures. The permittee shall inform the director of this decision in the notice required in subdivision 2 of this subsection.~~

~~2. Substantive amendments.~~

~~a. For substantive modifications, listed in APPENDIX 10.4, the permittee shall submit an amendment request to the director that:~~

~~(1) Describes the exact change to be made to the permit conditions and supporting documents referenced by the permit;~~

~~(2) Identifies that the modification is a substantive amendment;~~

~~(3) Explains why the amendment is needed;~~

~~(4) Provides the applicable information required by 9 VAC 20-120-700 and 9 VAC 20-120-710, 9 VAC 20-120-720, or 9 VAC 20-120-730; and~~

~~(5) Provides the proposed facility mailing list containing the names and addresses of persons, organizations, and agencies of local government that might be affected by the proposed amendment. The director may inform the permittee of additional entries he may require.~~

~~b. The permittee shall send a notice of the amendment request to all persons on the facility mailing list and shall publish this notice in a major local newspaper of general circulation. This notice shall be mailed and published within 14 calendar days after the date of submission of the amendment request, and the permittee shall provide to the director evidence of the mailing and publication. The notice shall include:~~

~~(1) Announcement of a 60-day comment period, in accordance with subdivision 2 e of this subsection, and the name and address of this department where comments shall be sent;~~

~~(2) Announcement of the date, time, and place for a public meeting held in accordance with subdivision 2 d of this subsection;~~

~~(3) Name and telephone number of the permittee's contact person;~~

~~(4) Name and telephone number of a contact person at the department;~~

~~(5) Location where copies of the amendment request and any supporting documents can be viewed and copied; and~~

~~(6) The following statement: "The permittee's compliance history during the life of the permit being modified is available from the Department of Environmental Quality."~~

~~c. The permittee shall place a copy of the permit amendment request and support documents in a location accessible to the public in the vicinity of the permitted facility.~~

~~d. The permittee shall hold a public meeting not earlier than 30 calendar days after the publication of the notice required in subdivision F 2 b of this subsection and no later than 15 calendar days before the close of the 60-day comment period. The meeting shall be held to the extent practicable in the vicinity of the permitted facility.~~

~~e. The public shall be provided 60 calendar days to comment on the amendment request. The comment period will begin on the date the permittee publishes the notice in the local newspaper. Comments should be submitted to the department.~~

~~f. Administrative procedure.~~

~~(1) No later than 90 calendar days after receipt of the notification request, the director will determine whether the information submitted under subdivision 2 a (4) of this subsection is adequate to formulate a decision. If found to be inadequate, the permittee will be requested to furnish additional information within 30 calendar days of the request by the director to complete the amendment request record. The 30-day period may be extended at the request of the applicant.~~

~~(2) After the completion of the record, the director will:~~

~~(a) Approve the amendment request, with or without changes, and modify the permit accordingly;~~

~~(b) Deny the request;~~

~~(c) Determine that the amendment request shall follow the procedures in subdivision 3 of this subsection for major amendments if (i) the complex nature of the change requires the more extensive procedures for major amendments; or (ii) the department receives notice by the local governing body that the proposed modification requires a determination by that body of consistency with its ordinances; or~~

~~(d) Approve the request, with or without changes, as a temporary authorization having a term of up to 180 calendar days in accordance with subdivision 5 of this subsection.~~

~~(3) In making a decision to approve or deny a amendment request, including a decision to issue a temporary authorization or to reclassify a amendment as a major, the director will consider all written comments submitted to the department during the public comment period and will respond in writing to all significant comments in his decision.~~

~~g. The director may deny or change the terms of a substantive permit amendment request under subdivision 2 f (2) of this subsection for the following reasons:~~

~~(1) The amendment request is incomplete;~~

~~(2) The requested amendment does not comply with the appropriate requirements of Part V, Part VI, or other applicable requirements; or~~

~~(3) The conditions of the amendment fail to protect human health and the environment.~~

~~3. Major amendments.~~

~~a. For major modifications listed in APPENDIX 10.4, the permittee shall submit an amendment request to the director that:~~

~~(1) Describes the exact change to be made to the permit conditions and supporting documents referenced by the permit;~~

~~(2) Identifies that the modification is a major amendment;~~

~~(3) Explains why the amendment is needed;~~

~~(4) Provides the applicable information required by 9 VAC 20-120-700 and 9 VAC 20-120-710, 9 VAC 20-120-720, or 9 VAC 20-120-730; and~~

~~(5) Provides the proposed facility mailing list containing the names and addresses of persons, organizations, and agencies of local government. The director may inform the permittee of additional entries he may require.~~

~~b. The permittee shall send a notice of the amendment request to all persons on the facility mailing list and shall publish this notice in a major local newspaper of general circulation. This notice shall be mailed and published within 14 calendar days after the date of submission of the amendment~~

~~request, and the permittee shall provide to the director evidence of the mailing and publication. The notice shall include:~~

~~(1) Announcement of a 60-day comment period, in accordance with subdivision F 2 e of this section, and the name and address of this department where comments shall be sent;~~

~~(2) Announcement of the date, time, and place for a public meeting held in accordance with subdivision F 2 d of this section;~~

~~(3) Name and telephone number of the permittee's contact person;~~

~~(4) Name and telephone number of a contact person at the department;~~

~~(5) Location where copies of the amendment request and any supporting documents can be viewed and copied; and~~

~~(6) The following statement: "The permittee's compliance history during the life of the permit being modified is available from the Department of Environmental Quality."~~

~~c. The permittee shall place a copy of the permit amendment request and support documents in a location accessible to the public in the vicinity of the permitted facility.~~

~~d. The permittee shall hold a public meeting not earlier than 30 calendar days after the publication of the notice required in subdivision F 2 b of this section and no later than 15 calendar days before the close of the 60-day comment period. The meeting shall be held to the extent practicable in the vicinity of the permitted facility.~~

~~e. The public shall be provided 60 calendar days to comment on the amendment request. The comment period will begin on the date the permittee publishes the notice in the local newspaper. Comments should be submitted to the department.~~

~~f. The director shall grant or deny the permit amendment request according to the permit amendment procedures of this section, and other pertinent sections of Part VII.~~

~~4. Other amendments.~~

~~a. In the case of modifications not explicitly listed in APPENDIX 10.4, the permittee may submit a major amendment request, or he may request a determination by the director that the modification should be reviewed and approved as a minor or substantive amendment. If the permittee requests~~

~~that the modification be classified as a minor or a substantive amendment, he shall provide the department with the necessary information to support the requested classification.~~

~~b. The director will make the determination described in subdivision F 4 a of this section as promptly as practicable. In determining the appropriate classification for a specific modification, the director will consider the similarity of the modification to other modifications in APPENDIX 10.4 and the following criteria:~~

~~(1) Minor modifications apply to minor changes that keep the permit current with routine changes to the facility or its operation. These changes do not substantially alter the permit conditions or reduce the capacity of the facility to protect human health or the environment. In the case of minor modifications, the director may require prior approval.~~

~~(2) Substantive amendments apply to changes that are necessary to enable a permittee to respond, in a timely manner, to:~~

~~(a) Common variations in the types and quantities of the wastes managed under the facility permit,~~

~~(b) Technological advancements, and~~

~~(c) Changes necessary to comply with new regulations, where these changes can be implemented without substantially changing design specifications or management practices in the permit.~~

~~(3) Major amendments substantially alter the facility or its operation.~~

5. Temporary authorizations.

a. Upon request of the permittee, the director may, without prior public notice and comment, grant the permittee a temporary authorization in accordance with the requirements of subdivision F 5 of this section. Temporary authorizations shall have a term of not more than 180 calendar days.

b. (1) The permittee may request a temporary authorization for:

(a) Any substantive amendment meeting the criteria in subdivision F 5 c (2) (a) of this section, and

(b) Any major amendment that meets the criteria in subdivision F 5 c (2) (a) or F 5 c (2) (b) of this section; or that meets the criteria in subdivisions F 5 c (2) (c) and F 5 c (2) (d) of

this section and provides improved management or treatment of a regulated medical waste already listed in the facility permit.

(2) The temporary authorization request shall include:

(a) A description of the activities to be conducted under the temporary authorization;

(b) An explanation of why the temporary authorization is necessary; and

(c) Sufficient information to ensure compliance with Part V or Part VI standards.

(3) The permittee shall send a notice about the temporary authorization request to all persons on the facility mailing list. This notification shall be made within seven calendar days of submission of the authorization request.

c. The director shall approve or deny the temporary authorization as quickly as is practical. To issue a temporary authorization, the director shall find:

(1) The authorized activities are in compliance with the standards of Part V, VII, VIII or IX.

(2) The temporary authorization is necessary to achieve one of the following objectives before action is likely to be taken on a amendment request:

(a) To facilitate timely implementation of closure or corrective action activities;

(b) To prevent disruption of ongoing waste management activities;

(c) To enable the permittee to respond to sudden changes in the types or quantities of the wastes managed under the facility permit; or

(d) To facilitate other changes to protect human health and the environment.

d. A temporary authorization may be reissued for one additional term of up to 180 calendar days provided that the permittee has requested a substantive or a major permit amendment for the activity covered in the temporary authorization, and (i) the reissued temporary authorization constitutes the director's decision on a substantive permit amendment in accordance with subdivisions F 2 f (2) (d) or F 2 f (3) (d) of this section, or (ii) the director determines that the reissued temporary authorization involving a major permit amendment request is warranted to allow the authorized activities to continue while the amendment procedures of subdivision F 3 of this section are conducted.

~~6. Appeals of permit amendment decisions. The director's decision to grant or deny a permit amendment request under subsection F of this section may be appealed under the case decision provisions of the Virginia Administrative Process Act~~.

7. Newly defined or identified wastes. The permittee is authorized to continue to manage wastes defined or identified as regulated medical waste under Part III if he:

a. Was in existence as a regulated medical waste management facility with respect to the newly defined or identified regulated medical waste on the effective date of the final rule defining or identifying the waste; and

b. Is in compliance with the standards of Part V, VII, VIII or IX, as applicable, with respect to the new waste, submits a minor modification request on or before the date on which the waste becomes subject to the new requirements; or

c. Is not in compliance with the standards of Part V or VI, as applicable, with respect to the new waste, but submits a complete permit amendment request within 180 calendar days after the effective date of the definition or identifying the waste.

G. The suitability of the facility location will not be considered at the time of permit amendment unless new information or standards indicate that an endangerment to human health or the environment exists that was unknown at the time of permit issuance.

9 VAC 20-120-820. Duration of permits.

Any permit for the management of regulated medical waste shall expire after 10 years of operation. Permits shall not be extended beyond the 10 year permit by permit transfer or modifications. At any time more than 180 calendar days prior to the expiration of the permit and no more than 480 calendar days prior to the expiration of the permit, the holder of a valid permit may request that the director renew the permit and submit all information known to permit holder that is changed or new since the original permit application and that has not been previously submitted to the director. A permit may be renewed for a period of 10 years of operation. Processing of the request will be in accordance with the following:

~~1.~~ A. If the holder of a valid permit for a regulated medical waste management facility files with the director a request to renew the permit at least 180 calendar days prior to the expiration of that permit, the director will cause an audit to be conducted of the facility's past operation, its current condition and the records held by the department concerning the facility. Within 60 calendar days of receipt of a proper request, the director will report to the applicant the findings of the audit and those items of correction or information required before renewal will be considered. The director shall review the

environmental compliance history of the permittee, material changes in key personnel, and technical limitations, standards, or regulations on which the original permit was based. If the director finds repeated material or substantial violations of the permittee or material changes in the permittee's key personnel would make continued operation of the facility not in the best interest of human health or the environment, the director shall deny the request for renewal of the permit. If the director finds the facilities to be insufficient to comply with regulations in effect at the time of the proposed renewal, the director shall deny the request for renewal. The director shall request any information from the permittee that is necessary to conduct the audit, and that is reasonably available to the permittee and substantive to the proposed renewal.

~~2.~~ B. If the applicant files for renewal less than 180 calendar days prior to the expiration of the original permit or files an improper application the director shall deny the application for renewal. If an application for renewal has been denied for a facility, any further applications and submittals shall be identical to those for a new facility.

9 VAC 20-120-830. Existing facilities qualifications.

Owners and operators of existing and permitted infectious waste management facilities are not required to submit an application for a new permit at the time these amended regulations become effective. Existing permits will remain valid, except that conditions or waivers in existing permits that conflict with these

amended regulations are void on the date six months from the effective date of these amended regulations. Operators of existing facilities are required to comply with these amended regulations within six months following their effective date and may comply at any time with any item contained in this chapter in lieu of a conflicting condition contained in an existing permit.

APPENDIX 10.1

DISCLOSURE FORM

Under § 7(b) of the Privacy Act of 1974, 5 U.S.C. § 552a (note), any government agency that requests an individual to disclose his Social Security Account Number (SSAN) must inform that individual whether the disclosure is mandatory or voluntary, by what statutory or other authority such number is solicited, and what uses will be made of it.

The department is directed to request SSANs by § 10.1-1400 of the Code of Virginia, as specified in the paragraph defining the disclosure statement. The SSAN is used as a secondary identifier by the director when he determines that a criminal records check of the key personnel will be obtained pursuant to subsection D of § 10.1-1405 of the Code of Virginia. The SSAN will then be used to ensure correct identification when information is solicited from outside sources to determine whether the individual named in the records and the individual under consideration are the same or different persons.

The listing of SSANs on the disclosure forms is voluntary. Under Section 7(a) of the Privacy Act, the department cannot deny or revoke a permit or impose any penalty because of an individual's refusal to

disclose SSAN. However, the absence of such number as a secondary identifier may delay processing of permit applications because of the additional investigative time that may be necessary to confirm identifications. In addition, there is the possibility that the absence of a SSAN may result in the initial identification of an individual as having a criminal record that actually is that of another person. That, again, may result in delay in the processing of the permit application.

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~~APPENDIX 10.4~~

~~CLASSIFICATION OF PERMIT AMENDMENTS~~

~~Modifications~~	~~Classification~~
~~A. General Permit Provision~~	
~~1. Administrative and informational changes~~	~~Minor~~
~~2. Correction of typographical errors~~	~~Minor~~
~~3. Equipment replacement or upgrading with functionally equivalent components~~	~~Minor~~
~~4. Changes in the frequency of or procedures for monitoring, reporting, or sampling by the permittee:~~	

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~~a. To provide for more frequent monitoring, reporting, or sampling, Minor~~

~~b. Other changes Substantive~~

~~5. Schedule of compliance:~~

~~a. Changes in interim compliance dates, with prior approval of the Director Minor~~

~~b. Extension of the final compliance date Major~~

~~6. Changes in ownership or operational control of a facility *Minor~~

~~B. General Facility Standards~~

~~1. Changes in procedures in the operating plan~~

~~a. That do not affect environmental protection afforded Minor~~

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~~b. Other changes Major~~

~~2. Changes in frequency or content of inspection schedule Substantive~~

~~3. Changes in the training plan:~~

~~a. That do not affect the type or decrease the amount of training given to employees Minor~~

~~b. Other changes Substantive~~

~~3. Contingency plan:~~

~~a. Changes in emergency procedures (i.e., spill or release response procedures) Substantive~~

~~b. Replacement with functionally equivalent equipment, upgrade, or relocate emergency equipment listed Minor~~

~~c. Removal of equipment from emergency equipment list Substantive~~

~~d. Changes in name, address, or phone number of coordinators or other persons or agencies identified in the plan Minor~~

~~D. Closure~~

~~1. Changes to the closure plan:~~

~~a. Changes in estimate of maximum extent of operations or maximum inventory of waste on-site at any time during the active life of the facility, with prior approval of the Director *Minor~~

~~b. Changes in the closure schedule for any unit, changes in the final closure schedule for the facility, or extension of the closure period, with prior approval of the Director *Minor~~

~~c. Changes in the expected year of final closure, where other permit conditions are not changed, with prior approval of the Director~~ ~~*Minor~~

~~d. Changes in procedures for decontamination of facility equipment or structures, with prior approval of the Director~~ ~~*Minor~~

~~e. Changes in approved closure plan resulting from unexpected events occurring during partial or final closure, unless otherwise specified in this appendix~~ ~~Substantive~~

~~2. Addition of the new storage or treatment units to be used temporarily for closure activities~~ ~~Major~~

~~E. Post-Closure~~

~~1. Changes in name, address, or phone number of contact in post-closure plan~~ ~~Minor~~

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~~2. Extension of post-closure care period Substantive~~

~~3. Reduction in the post-closure care period Major~~

~~4.~~ 3. ~~Changes to the expected year of final closure, where other permit conditions are not changed~~ ~~Minor~~

~~5. Changes in post-closure plan necessitated by events occurring during active life of the facility, including partial and final closure~~ ~~Substantive~~

~~I. Incinerators and Energy Recovery Facilities~~

~~1. Changes to increase by more than 25% of the waste feed rate limit authorized in the permit~~ ~~Major~~

~~2. Changes to increase by up to 25% any of the waste feed rate limit authorized in the permit~~ ~~Substantive~~

~~3. Modification of the facility in a manner that would~~ ~~Substantive~~

~~not likely affect the capability of the unit to meet~~

~~the regulatory performance standards but which would~~

~~change the operating conditions or monitoring~~

~~requirements specified in the permit~~

~~4. Modification of any inspection or recordkeeping Substantive~~

~~requirement specified in the permit~~

~~5. Incineration of different wastes:~~

~~a. If the waste contains wastes regulated under Major~~

~~Part III not authorized by the permit or if~~

~~incineration of the waste requires compliance~~

~~with different regulatory performance standards~~

~~than specified in the permit.~~

~~b. If the waste does not contain wastes regulated under Minor~~

~~Part VIII and if incineration of the waste does not~~

~~require compliance with different regulatory performance~~

~~standards than specified in the permit~~

~~J. All Other Facilities~~

~~1. Changes to increase by more than 25% of the waste handling capacity authorized in the permit~~	~~Major~~
~~2. Changes to increase by up to 25% of the waste handling capacity authorized in the permit~~	~~Substantive~~
~~3. Modification of the facility in a manner that would not likely affect the capability of the unit to meet the regulatory performance standards but which would change the operating conditions, or monitoring requirements specified in the permit~~	~~Substantive~~
~~4. Modification of any inspection or recordkeeping requirement specified in the permit~~	~~Minor~~
~~5. Management of different wastes:~~	

~~a. If the waste contains wastes regulated under Part III not authorized by the permit or if handling of the waste requires compliance with different regulatory performance standards than specified in the permit.~~ ~~Major~~

~~b. If the waste does not contain wastes regulated under Part VIII and if handling of the waste does not require compliance with different regulatory performance standards than specified in the permit~~ ~~Minor~~

~~K. Changes in operation of a facility permitted prior to June 30, 1994, when changes reflect compliance with items in this chapter in substitution of similar items or conditions of the existing permit.~~ ~~Minor~~

Regulated Medical Waste Management Regulations

PART XI.

Variances and Other Procedures.

ARTICLE 1.

Petition for Variance.

9 VAC 20-120-840. General.

Any person directly affected by this chapter may petition the director to grant a variance from any requirement of this chapter, subject to the provisions of this part. Any petition submitted to the director is also subject to the provisions of the Virginia Administrative Process Act (§ 9-6.14:1 et seq. of the Code of Virginia).

The director will not accept any petition relating to:

~~1.~~ A. Equivalent testing or analytical methods contained in EPA Publication SW-846;

~~2.~~ B. Definitions of regulated medical waste contained in Part III of this chapter; and

~~3.~~ C. A change in the regulatory requirements that the petitioner is currently violating until such time as the violation has been resolved through the enforcement process.

ARTICLE 2.

Variances to Requirements.

9 VAC 20-120-850. Application and conditions.

9 VAC 20-120-860. Effects of the decisions.

9 VAC 20-120-870. Submission of petition.

9 VAC 20-120-880. Petition processing.

9 VAC 20-120-890. Petition resolution.

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9 VAC 20-120-850. Application and conditions.

The director may grant a variance from any regulation contained in Parts IV through X to a petitioner if the petitioner demonstrates to the satisfaction of the director that:

~~1. a.~~ A. Strict application of the regulation to the facility will result in undue hardship that is caused by the petitioner's particular situation, or

~~b.~~ B. Technical conditions exist that make a strict application of the regulation difficult to achieve, and

~~c.~~ C. The alternate design or operation will result in a facility that is equally protective of the human health and the environment as that provided for in the regulations; and

~~2.~~ D. Granting the variance will not result in an unreasonable risk to the public health or the environment.

VAC 20-120-860. Effects of the decisions.

A. When the director renders a decision under this section in accordance with the procedures contained here, he may:

1. Deny the petition;

2. Grant the variance as requested; or

3. Grant a modified or partial variance.

B. When a modified variance is granted, the director may:

1. Specify the termination date of the variance;

2. Include a schedule for:

a. Compliance, including increments of progress, by the facility with each requirement of the variance; and

b. Implementation by the facility of such control measures as the director finds necessary in order that the variance may be granted.

Regulated Medical Waste Management Regulations

9 VAC 20-120-870. Submission of petition.

A. All petitions submitted to the director shall include:

1. The petitioner's name and address;

2. A statement of petitioner's interest in the proposed action;

3. A description of desired action and a citation to the regulation from which a variance is requested;

4. A description of need and justification for the proposed action;

5. The duration of the variance, if applicable;

6. The potential impact of the variance on public health or the environment;

7. Other information believed by the petitioner to be pertinent; and

8. The following statements signed by the petitioner or his authorized representative:

"I certify that I have personally examined and am familiar with the information submitted in this petition and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

B. In addition to the general information required of all petitioners under this article:

1. To be successful the petitioner shall address the applicable standards and criteria.

2. The petitioner shall provide an explanation of the petitioner's particular situation that prevents the facility from achieving compliance with the cited regulation.

3. The petitioner shall provide other information as may be required by the department.

9 VAC 20-120-880. Petition processing.

A. After receiving a petition that includes the information required in 9 VAC 20-120-870, the director will determine whether the information received is sufficient to render the decision. If the information is

deemed to be insufficient, the director will specify additional information needed and request that it be furnished.

B. The petitioner may submit the additional information requested, or may attempt to show that no reasonable basis exists for the request for additional information. If the director agrees that no reasonable basis exists for the request for additional information, he will act in accordance with subsection C of this section. If the director continues to believe that a reasonable basis exists to require the submission of such information, he will proceed with the denial action in accordance with the Virginia Administrative Process Act (VAPA).

C. After the petition is deemed complete:

1. The director will make a tentative decision to grant or deny the petition;

2. In case that petition may be tentatively denied, the director will offer the petitioner the opportunity to withdraw the petition, submit additional information, or request the director to proceed with the evaluation;

3. Unless the petition is withdrawn, the director will issue a draft notice tentatively granting or denying the application. Notification of this tentative decision will be provided by newspaper advertisement in

the locality where the petitioner is located. The director will accept comment on the tentative decision for 30 calendar days.

4. Upon a written request of any interested person, the director may, at his discretion, hold an informal fact finding meeting described in Article 3 (§ 9-6.14:11 et seq.) of the Virginia Administrative Process Act. A person requesting a meeting shall state the issues to be raised and explain why written comments would not suffice to communicate the person's views. The director may in any case decide on his own motion to hold such a meeting.

5. After evaluating all public comments the director will, within 15 calendar days after the expiration of the comment period:

a. Notify the petitioner of the final decision; and

b. Notify all persons who commented on the tentative decision or publish it in a newspaper having circulation in the locality.

9 VAC 20-120-890. Petition resolution.

A. In the case of a denial, the petitioner has a right to request a formal hearing to challenge the rejection.

B. If the director grants a variance request, the notice to the petitioner shall provide that the variance may be terminated upon a finding by the director that the petitioner has failed to comply with any variance requirements.

ARTICLE 3.

Innovative Treatment Technology Review.

Regulated Medical Waste Management Regulations

9 VAC 20-120-900. General.

The requirements for alternate treatment methods contained in Part IX allow, at subdivision 2 d of 9 VAC 20-120-640, that new or innovative treatment technologies can be approved for permitting if the director reviews the process and determines that it provides treatment in keeping with this chapter and protects public health and the environment, and if the director establishes appropriate conditions for their siting, design, and operation. This article establishes the criteria, protocols, procedures, and processes to be used to petition the director for review and to demonstrate the suitability of the proposed process for the treatment of regulated medical waste.

9 VAC 20-120-910. Criteria for microbial inactivation.

A. Inactivation is required to be demonstrated of vegetative bacteria, fungi, all 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).

B. 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).

Regulated Medical Waste Management Regulations

9 VAC 20-120-920. Representative of biological indicators.

A. One or more representative microorganisms from each microbial group shall be used in treatment efficacy evaluation.

1. Vegetative Bacteria.

- Staphylococcus aureus (ATCC 6538)

- Pseudomonas aeruginosa (ATCC 15442)

2. Fungi.

- Candida albicans (ATCC 18804)

- Penicillium chrysogenum (ATCC 24791)

- Aspergillus niger

3. Viruses.

- Polio 2 or Polio 3

- MS-2 Bacteriophage (ATCC 15597-B1)

4. Parasites.

- Cryptosporidium spp. oocysts

- Giardia spp. cysts

5. Mycobacteria.

- Mycobacterium terrae

- Mycobacterium phlei

- Mycobacterium bovis (BCG) (ATCC 35743)

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

1. B. stearothermophilus (ATCC 7953)

2. B. subtilis (ATCC 19659)

9 VAC 20-120-930. Quantification of microbial inactivation.

A. Microbial inactivation ("kill") efficacy 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 equated as:

Log_{10} Kill = Log_{10} I(cfu/g) - Log_{10} R(cfu/g) 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.

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

B. 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 treatment efficacy. Quantification is evaluated by growth or no growth of the cultured biological indicator.

C. For those treatment mechanisms that cannot ensure or provide integrity of the biological indicator (i.e., chemical inactivation/grinding), quantitative measurement of treatment efficacy 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.

1. Step 1.

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

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

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

d. Plate recovered microorganism suspensions to quantify microbial recovery. (The numbe 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).

e. 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 9 VAC 20-120-910 (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 equation:

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

where: $Log_{10}RC$ is greater than or equal to 6 for vegetative microorganisms and is greater than or equal to 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 nontreated 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) that were not recovered after processing. $Log_{10}NR$ represents an accountability fad-or for microbial loss.

2. Step 2.

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

b. Add suspension to the standardized medical waste load that is to be processed under normal operating conditions with the addition of the microbial inactivation agent.

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

d. Plate recovered microorganism suspensions to quantify microbial recovery.

e. 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) that were not recovered after processing.

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

9 VAC 20-120-940. Efficacy testing protocols.

A. 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 Test Methods for Evaluating Solid Waste, Physical/Chemical Methods and Standard Methods for the Examination of Water and Waste Water.

B. The department 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.

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

1. Waste compositions that typify actual waste to be processed;

2. Waste types that provide a challenge to the treatment process;

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

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

5. Assurances of inoculum traceability, purity, viability and concentration;

6. Dilution and neutralization methods that do not affect microorganism viability;

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

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

9 VAC 20-120-950. Technology approval process.

A. To initiate the technology review process the petitioner shall complete and submit the "Petition For Evaluation and Approval of Regulated Medical Waste Treatment Technology Part A: General Information" to the department. The petitioner shall:

Regulated Medical Waste Management Regulations

1. 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;

2. 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 treatment efficacy, of user verification methodology, and of microbial culturing protocols that ensure traceability, purity and concentration;

3. Provide information on available parametric controls, verifying treatment efficacy and ensuring operator non-interference;

4. Provide documentation of applicable emission controls for suspected emissions;

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

6. Provide documentation providing occupational safety and health assurance; and

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

B. The petitioner shall demonstrate that all required surrogate pathogens and resistant bacterial endospores are inactivated to criteria specified in 9 VAC 20-120-910 and 9 VAC 20-120-930 under the representative challenge waste load compositions.

C. The petitioner shall develop and demonstrate that site approval and user verification testing protocols are workable and valid.

D. The petitioner shall demonstrate where technically practical, the treatment efficacy relationship between biological indicator data and data procured from real-time parametric treatment monitoring equipment.

E. The petitioner shall demonstrate evidence of U.S. EPA pesticide registration for those treatment processes that employ a chemical agent to inactivate microorganisms.

F. Upon completion of items contained in 9 VAC 20-120-910 through 9 VAC 20-120-950, the technology approval that results 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. Any significant revisions to these equipment and operating conditions, as warranted relevant to the department, will require reapplication for approval to the department.

9 VAC 20-120-960. Site approval process.

A. To fulfill treatment efficacy and information requirements for site approval, the equipment user shall:

1. Demonstrate that the equipment cited is the same equipment and process approved by the department as specified in 9 VAC 20-120-950.

2. Demonstrate that required resistant bacterial endospores are inactivated as specified in 9 VAC 20-120-910 B criteria under typical waste load and department specified challenge compositions;

3. Verify that user verification protocols adequately demonstrate treatment effectiveness; and

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

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

1. The names or positions of the equipment operators;

2. The waste types or categories to be treated;

3. Waste segregation procedures required;

4. Wastes types prohibited for treatment;

5. Equipment operation parameters;

6. Treatment efficacy monitoring procedures;

7. Personal protective equipment requirements;

8. Emergency response plans; and

9. Operator training requirements.

C. The site facility shall submit to the department for their review:

1. Equipment model number and serial number;

2. Equipment specification and operations manual;

3. A copy of the facility's written plan; and

4. Certification documentation of operator training.

D. As a condition of site approval, the department 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 plan.

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

9 VAC 20-120-970. User verification.

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

1. Demonstrate that required resistant bacterial endospores are inactivated to criteria as specified in 9 VAC 20-120-910 B under standard operating procedures using protocols that have previously been approved by the department as specified under 9 VAC 20-120-950 and 9 VAC 20-120-960;

2. Establish a frequency of biological monitoring; and

3. Document and record all biological indicator and parametric monitoring data.

B. To document treatment efficacy for steam sterilizers and autoclaves, the equipment operator shall:

1. Adopt standard written operating procedures that denote:

a. Sterilization cycle time, temperature, pressure

b. Types of waste acceptable

c. Types of containers and closures acceptable

d. Loading patterns or quantity limitations;

2. Document times/temperatures for each complete sterilization cycle;

3. Use time-temperature sensitive indicators to visually denote the waste has been decontaminated;

4. Use biological indicators placed in the waste load (or simulated load) periodically to verify conditions meet microbial inactivation requirements as specified in 9 VAC 20-120-910 B; and

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

9 VAC 20-120-980. Small medical waste treatment devices.

A. All small medical waste treatment devices shall fulfill the requirements necessary for technology approval and shall meet the treatment efficacy requirements as defined in 9 VAC 20-120-910.

B. Technology and siting approval are the responsibility of the petitioner. The petitioner shall provide to the department:

1. All information required for technology approval as defined in 9 VAC 20-120-950;

2. All information required of site approval for a typical site for which the equipment is designed as defined in 9 VAC 20-120-960; and

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

a. An operations and maintenance manual;

b. Information on proper use and potential misuse;

c. Treatment efficacy testing instructions;

d. Training/education manual; and

e. Available service agreements/programs.

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

1. An operations and maintenance manual;

2. Information on proper use and potential misuse;

3. Treatment efficacy testing instructions;

4. Training/education manual; and

5. Available service agreements/programs.

D. Upon the installation of the treatment device, the manufacturer shall compile a record of the buyer, the location, and the results of onsite challenge testing at time of purchase. This information shall be submitted annually to the department by the petitioner as the notification record of site registrations of equipment installed that previous year.

9 VAC 20-120-990. Waste residue disposal.

A. Information on the characteristics of all waste residues (liquids and solids), and the mechanisms and models of their disposal shall be provided by the petitioner on the "Evaluation of Medical Waste Treatment Technology: Information Request Form." This information will include:

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

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

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

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

B. Information on waste residue disposal shall be provided by the user facility as required under site approval (9 VAC 20-120-960). This information shall include:

1. All information requested in 9 VAC 20-120-1000 A;

2. The site of disposal (name and address);

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

4. The amounts of residues anticipated to be disposed (e.g., volume and weight per week).

C. If residues are to be recycled the following information shall be provided by the user facility as required under site approval (9 VAC 20-120-960). This information shall include:

1. The types of waste residue to be recycled;

2. The amounts of waste residue to be recycled;

3. The percentage of the total waste and waste residue to be recycled;

4. The recycling mechanism used; and

5. The name and location of the recycler.

D. 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 as untreated medical waste.

E. 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 surrogate pathogens can be disposed as general solid wastes after verification of treatment effectiveness.

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

9 VAC 20-120-1000. Operator training.

A. 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 that will include:

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

2. A description of system's operations including waste types acceptable, loading parameters, process monitors, treatment conditions, and disposal;

3. A description of all parametric controls, their appropriate settings as correlated with biological indicators, and calibration requirements;

4. 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);

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

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

B. The facility shall additionally develop a written treatment equipment operations plan that will include:

1. Responsibility delegation for safe and effective equipment operation to operating personnel;

2. A description of operating parameters that must be monitored to ensure effective treatment;

3. A description of all process monitoring instrumentation and established ranges for all operating parameters;

4. A description of the methods required to ensure process monitoring instrumentation is operating properly; and

5. A description of methods and schedules for periodic calibration of process monitoring instrumentation.

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

Regulated Medical Waste Management Regulations

DISCLOSURE FORM

NOTICE

Under § 7(b) of the Privacy Act of 1974, 5 U.S.C. § 552a (note), any government agency that requests an individual to disclose his Social Security Account Number (SSAN) must inform that individual whether the disclosure is mandatory or voluntary, by what statutory or other authority such number is solicited, and what uses will be made of it.

The Department is directed to request SSANs by § 10.1-1400, Chapter 14, Title 10.1, Code of Virginia (1950), as amended, as specified in the paragraph defining the disclosure statement. The SSAN is used as a secondary identifier by the Director when he determines that a criminal records check of the key personnel will be obtained pursuant § 10.1-1405.D. of the Code. The SSAN will then be used to ensure correct identification when information is solicited from outside sources to determine whether the individual named in the records and the individual under consideration are the same or different persons.

The listing of SSANs on the disclosure forms is voluntary. Under Section 7(a) of the Privacy Act, the Department cannot deny or revoke a permit or impose any penalty because of an

individual's refusal to disclose SSAN. However, the absence of such number as a secondary identifier may delay processing of permit applications because of the additional investigative time that may be necessary to confirm identifications. In addition, there is the possibility that the absence of a SSAN may result in the initial identification of an individual as having a criminal record that actually is that of another person. That, again, may result in delay in the processing of the permit application.

Regulated Medical Waste Management Regulations

WASTE MANAGEMENT FACILITY ERMIT APPLICANT'S

DISCLOSURE STATEMET
COVER SHEET

Applicant's Name:	Applicant's Interest
Company Name:	(Check All Applicable Boxes)
Address:	? Owner ? Operator

Enter Below the names of all key personnel and the starting page number showing more detail. A separate DEO form DISC-02 must be completed for each individual listed below.

	Page	Key Personnel	Page
1.		1.	
2.		2.	
3.		3.	
4.		4.	
5.		5.	
6.		6.	
7.		7.	
8.			
9.			
10.			
11.			
12.			

DEQ Form DISC-01

COVER SHEET

List all agencies outside the Commonwealth which have regulatory responsibility over the applicant or have issued any environmental permit or license to the applicant within the past ten years, in connection with the applicant's collection, transportation, treatment, storage or disposal of solid or hazardous

Agency Name and Permit or License Type	Expiration Date	State

COVER SHEET
List full name and business address of any member of the local governing body or planning commission in which the waste management facility is located or proposed to be licensed, who holds any equity interest in the facility

Full Name	Business Address

I certify under penalty of the law that the information contained in this disclosure statement and all attachments are, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

DEQ Form DISC-01

COVER SHEET

Continuation from previous pages:

WASTE MANAGEMENT FACILITY PERMIT APPLICANT'S

DISCLOSURE STATEMENT

KEY PERSONNELL
Name:
Social Security Name:
Business Address:
List full name and business address of any entity, other than natural persons, that collects, transports, treats, stores, or disposes of solid or hazardous waste in which the above named person holds an equity interest of five percent or more.

Company Name	Business Address

DEQ Form DISC-02

Key Personnel

Business Experience:

List all permits or licenses for collection, transportation, treatment, storage, or disposal issued to or held by the person named within the past ten years.

Full Name	Business Address

Key Personnel

List and explain any notices of violation, prosecution, administrative orders, license or permit suspensions or revocations, or enforcement actions of any sort by any state, federal, or local authority, within the past ten years, which are pending or have concluded with a finding of violation or entry of a consent agreement, regarding an allegation of civil or criminal violation of any law, regulation or requirement relating to the collection, transportation, treatment, storage or disposal of solid or hazardous waste by the person named. Furnish also an itemized list of all convictions with ten years

Key Personnel

Continuation Sheet

DEQ Form DISC-02

REQUEST FOR CERTIFICATION

APPLICANT:

APPLICANT'S MAILING ADDRESS:

DATE OF APPLICATION:

TELEPHONE:

TYPE OF THE FACILITY:

CONTACT PERSON:

The applicant is in the process of completing an application for a permit for a regulated medical waste management facility to be issued by the Virginia Department of Environmental Quality. In accordance with Section 10.1-1408.1, Title 10.1, Code of Virginia (1950), as amended, before such a permit application can be considered complete, the applicant has to obtain a certification from the governing body of the county, city or town in which the facility is to be located that the location and operation of the facility are consistent with all applicable ordinances. The undersigned requests that an authorized representative of the local governing body sign the certification below.

SIGNATURE OF THE APPLICANT:

NOTE: The applicant should enclose an appropriate map showing the location of the proposed facility.

The undersigned certifies that the proposed location and operation of the facility is consistent with all ordinances.

DEQ Form CERTIFICATE-01

SIGNATURE OF AUTHORIZED REPRESENTATIVE
COUNTY, CITY OR TOWN:

PART A APPLICATION COVER SHEET

NAME OF FACILITY:

TYPE OF FACILITY:

NAME OF APPLICANT:

MAILING ADDRESS:

SITE LOCATION: (Describe location and attach map showing exact location.)

	YES	NO
KEY MAP ATTACHED?		
NEAR-VICINITY MAP ATTACHED?		
COPY OF DEED or OWNERSHIP DOCUMENT ATTACHED?		

Written notice to adjacent owners or occupants that the undersigned applicant intends to develop a regulated medical waste management facility has been sent. The names and addresses of persons given this notice are shown as an attachment to the form.

Department of Environmental Quality

DEQ Form Part-1-01

SECTION II - SITING CRITERIA

	YES	NO
SUBJECT TO BASE FLOOD?		
SPRINGS, SEEPS, OR OTHER INTRUSIONS INTO THE SITE?		

TYPED NAME OF APPLICANT:
SIGNATURE OF APPLICANT:

PRESENCE OF OPEN DUMP, LANDFILL, LAGOON OR SIMILAR FACILITY?		
PRESENCE OF GAS, WATER, SEWAGE, ELECTRICAL OR OTHER TRANSMISSION LINES ON SITE?		

DISTANCE TO AIRPORT RUNWAY?	
DISTANCE TO REGULARLY FLOWING SURFACE WATER BODY OR RIVER?	
DISTANCE TO WELL, SPRING, OR OTHER GROUNDWATER?	
DISTANCE TO PUBLIC ROAD RIGHT-OF-WAY?	

OTHER CRITERIA APPLICABLE TO THE SITE

DISTANCE TO RESIDENCE, SCHOOL, OR RECREATIONAL AREA?	

PETITION FOR EVALUATION AND APPROVAL OF

REGULATED MEDICAL WASTE TREATMENT TECHNOLOGY

PART A: GENERAL INFORMATION

Name of Company

Name of Petitioner (Must be an individual(s) Name)			
Trade Name of Device		Model Number	
Petitioner Address			
City	State	ZIP Code	Petitioner Telephone Number

Department Use Only

Date Application and Questionnaire Received	Date Complete

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

EVALUATION OF MEDICAL WASTE TREATMENT TECHNOLOGY

INFORMATION REQUEST FORM

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

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

? **Onsite** ? **Commercial/Regional** ? **Both**

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

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

"Inactivation of vegetative bacteria, fungi, all viruses, parasites, and mycobacteria at a 6 Log_{10} reduction or greater, and *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 ? Plasma Arc

? Encapsulation ? Irradiation ? Radiowave

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

	Types 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.	Human anatomical waste, tissues and body fluids	?	?
D4.	Contaminated waste from animals	?	?

D. WASTE COMPATIBILITY WITH PROPOSED TREATMENT PROCESS

E. BY-PRODUCTS OF THE TREATMENT PROCESS

E1. Please indicate all by-products which may be generated as a result of this alternative treatment technology.

? Air Emissions	? Heat	? Slag	? Vapors or Fumes
? Ash	? Liquid	? Smoke	
? Dust	? Odor	? Steam	

? Other (Specify) _____

F. MICROBIAL TEST PROCEDURES

Any proposed treatment method shall be capable of inactivating vegetative bacteria, fungi or yeasts, parasites, 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 microbial group is required for testing.

F1. 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 data to support 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.

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)

F1. Were the results certified by an independent, public health or certified testing laboratory? ? No ? Yes - If so, indicate the name, address, telephone number of the certifying laboratory and attach test protocol and results.

G1. If the treatment involves the use of chemical inactivation:

a) What is the name of the active ingredients?_____

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.__

G2. What is the active life of the chemical agent after it has been exposed to air or contaminated medical waste?

_____

G3. Have studies been conducted relative to the long-term effectiveness of the chemical agent while in use?

? No ? Yes - If yes, please attach a copy of the study and test results.

G. CHEMICAL INACTIVATION TREATMENT PROCESSES

H. ENVIRONMENTAL EFFECTS ON THE TREATMENT PROCESS

H1. Can positive or negative effects on the environment be anticipated from the use and/or disposal of the treated waste from the treatment process?

? No ? Yes - If yes, specify _____

H2. What environmental, occupational, and/or public hazards would be associated with a malfunction of the treatment process? Specify _____

H3. If the treatment process includes the use of water, steam, or other liquids; how will this waste discharge be handled (i.e., sewer, recycle, etc.)?

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? ? No ? Yes

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

Specify _____

I6. Are these measures addressed in an emergency plan or in the operations protocol?

? No ? Yes - If yes, attach a copy

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

_____

I8. How long is a cycle? _____

I. CRITICAL FACTORS OF TREATMENT PROCESS

J1. How is the quality assurance of the treatment process addressed?

Specify _____

J2. What is the recommended frequency that a microbiological indicator should be used to confirm effectiveness of the system?

Specify _____

J3. Other than the biological indicators listed in Section F, 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.)

J4. 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

J. QUALITY ASSURANCE AND VERIFICATION OF ADEQUATE TREATMENT

K. POST TREATMENT RECYCLING

K1. Has a strategy been developed for the recycling of any part of the treated waste? ? No ? Yes

If yes, please include additional information regarding the strategy.

L. COMPLIANCE WITH MEDICAL WASTE REGULATIONS

L1. Does your treatment technology meet the requirements of the State's medical waste regulations for medical waste decontamination and disposal?

? No ? Yes

L2. Which of the following five categories of medical waste will be effectively treated by your system? (Check all that apply.)

NO YES

M1. Have you inquired from the State's medical waste permit coordinator as to whether any other permits are required? ? No ? Yes

If yes, please enclose the response and requirements with your application.

M. INTERAGENCY COORDINATION

N1. Has an energy analysis been conducted on the proposed technology?

? No ? Yes - If yes, specify and provide results of that analysis.

N2. Has an economic analysis been performed on the proposed technology?

? No ? Yes - If yes, specify and provide results of that analysis.

N. POTENTIAL ENVIRONMENTAL BENEFITS

O. OTHER RELEVANT INFORMATION AND COMMENTS

(Approvals received from other states, operator safety, competency or training requirements for the users/operators, etc.)

PETITION FOR EVALUATION AND APPROVAL OF

REGULATED MEDICAL WASTE TREATMENT TECHNOLOGY

PART B: ATTACHMENTS

The general information contained in Part A and this check sheet are a required part of the petition package. These assist the petitioner in submitting the petition and the Department in its review, and they are supplemental to the required documents listed below. The complete petition package consists of a completed Part A form, this Part B check sheet, all the documents listed below, and any other supportive data or information the petitioner wishes to be considered.

? Petitioner's submittal certification

? Quality Assurance and Quality Control Report

? Microbiological testing report

? Material Safety Data Sheets

? Environmental Protection Agency pesticide registration documents

? Maintenance manual

? Emergency operations manual

? Operations manual

? Design plans and specifications

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FORMS

Waste Management Facility Permit Applicant's Disclosure Statement DEQ Form DISC-01, DISC-02.

Request for Local Government Certification DEQ Form Cert.-01.

Part A - Application Cover Sheet DEQ Form PART-1-01, 1-02.

Treatment Process Petition.

Documents Incorporated by Reference

Pound Standard Test Method for Drop Test of Loaded Container by Free Fall (D5276-92), ASTM 125

Pound Drop Test for Filled Bags (D959), ASTM 125.