

Part 70

Regulated Medical Waste

(Statutory Authority: Public Health Law, Sections 1389-bb and 1389-ff,
as amended by Chapter 438 of the Laws of 1993)

SUBPART

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Subpart 70-1

Application and Definitions

Sec.

70-1.1 Application

70-1.2 Definitions

Section 70-1.1 Application. The requirements of this Part shall apply to hospitals, residential health care facilities, and diagnostic and treatment centers (see section 2801 of the Public Health Law) and clinical laboratories (see section 571 of the Public Health Law).

70-1.2 Definitions. Whenever used in this Part, unless the context of this Part clearly requires otherwise, the following terms shall have the following meanings:

(a) "Alternative regulated medical waste treatment system" shall mean a device, method, and/or technology approved by the Commissioner of Health pursuant to Subpart 70-5 of this Part for the treatment of regulated medical waste.

(b) "Autoclave" shall mean a device for decontaminating and/or sterilizing materials through exposure to steam under pressure for periods of time prescribed in Subpart 70-3 of this Part.

(c) "Biologicals" shall mean any preparations derived from a living organism and/or its products including, but not limited to, sera, nonviable vaccines, vaccines attenuated in a manner that prevents propagation, antigens, toxins and antitoxins, for use in diagnosis, immunization, or treatment of human beings or animals.

(d) "Certificate of treatment" shall mean a form prescribed by the Commissioner of Health to document treatment of regulated medical waste, signed by a person authorized by an on-site or

off-site treatment facility to attest to such treatment.

(e) "Challenge testing" shall mean monitoring testing or procedures periodically conducted at the installation site of a treatment system to demonstrate continued operation under conditions established by efficacy testing for an alternative regulated medical waste treatment system, or, for an autoclave, to verify continued effective treatment of regulated medical waste.

(f) "Clinical laboratory" shall have the same meaning as in Section 571 of the Public Health Law.

(g) "Cultures and stocks" shall mean materials and/or systems supporting in vitro growth or maintenance of infectious agents, including, but not limited to, the infectious agents themselves, nutrient agars, gels, broths, human and primate cell lines, impure animal cell lines, live vaccines, and attenuated vaccines capable of propagation.

(h) "Culture dishes and devices for transferring, inoculating and mixing cultures" shall mean any plates, flasks, tubes, beakers, vials, bottles, jars or inoculation loops of any material; manual or mechanical stirring or mixing devices; stoppers or plugs of any material; filtering devices of natural and artificial substances; and any other items or devices for growing and/or maintaining infectious agents in vitro.

(i) "Cycle" shall mean total operating time required for a device to treat regulated medical waste, and, for an autoclave, shall include warm-up, residence and cool down time.

(j) "Decontamination" shall mean reduction or inactivation of potentially infectious agents' bioload in waste, so that such waste, including any waste residual in or on a container, no longer constitutes a threat to public health and safety.

(k) "Destroyed" shall mean torn apart or mutilated through incineration, melting, shredding, grinding, tearing, breaking or other process; to render unusable and unrecognizable as the item that

underwent destruction. "Destroyed" shall not mean compacted or compacted following treatment. As used in this Part pertaining to sharps, unrecognizable shall mean that 100 percent of the sharps must be rendered not identifiable as intact sharps devices.

(l) "Efficacy testing" shall mean testing of an autoclave or alternative regulated medical waste treatment system, conducted by a laboratory independent of the system manufacturer that is generally recognized within the scientific community as having the capability for conducting, in conformance with generally recognized scientific principles, microbiologic examinations and/or other pertinent assessments of waste material to establish operating parameters for the system's effective treatment of regulated medical waste.

(m) "Hazardous waste" shall have the same meaning as in 6 NYCRR, section 360-1.2;

(n) "Toxic drug waste" shall mean waste contaminated by or mixed with a chemotherapeutic, cytotoxic and/or antineoplastic agent, and/or a biotechnological material (e.g., infectious nanoparticles), not otherwise regulated as hazardous waste under Part 371 of 6 NYCRR; and

(o) "Household medical waste" shall have the same meaning as in 6 NYCRR, section 360-1.2 and shall include residential sharps (i.e., lancets, hypodermic needles and syringes) generated in a household in the course of medical self-management.

(p) "Incinerator" shall mean an enclosed device using controlled flame combustion to effect thermal breakdown of solid waste, including refuse-derived fuel, to ash residue containing little or no combustible material, as defined in 6 NYCRR, section 200.1 and regulated under 6 NYCRR, Parts 200, 201, 211, 212, 219 and 257.

(q) "Infectious agent" shall mean any organism or agent that causes disease or an adverse health impact in humans, and shall include any agent listed in 10 NYCRR Part 2 and any agent

designated as requiring Biosafety Level 2, 3 or 4 processing in the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health publication, "Biosafety in Microbiological and Biomedical Laboratories," 4th ed., May, 1999 and any biological agents listed in 42 CFR Part 73 (Vol. 70, March 18, 2005): Possession, Use, and Transfer of Select Agents and Toxins. Federal regulations are published by the Office of the Federal Register, National Archives and Records Administration and may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402. Copies are available for inspection and copying in the New York State Department of Health, Bureau of Hospital and Primary Care Services, Hedley Park Place, 433 River Street, Troy, NY 12180.

(r) "Leakproof" shall mean designed and maintained to prevent the escape of contained liquids or other materials from sides or bottom, when appropriately closed regardless of container orientation (i.e., upright, tipped over).

(s) "Monitoring" shall mean periodic assessment and quality control of the operation of a regulated medical waste treatment system.

(t) "Operating parameters" shall mean the specific conditions of pressure, temperature, residence time, chemical concentration, and other physical or engineering condition established through efficacy testing of an alternative regulated medical waste treatment system, or verified through validation testing of an autoclave for effective treatment of regulated medical waste.

(u) "Operation plan" shall mean documented policies and procedures for a facility's operation of an on-site autoclave, incinerator or alternative regulated medical waste treatment system.

(v) "Parametric control" shall mean an electronic or other device designed to monitor
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accurately the performance of a regulated medical waste treatment system and /or regulate continuously the system's operation to achieve and maintain pre-set operating parameters.

(w) "Patient care area" shall mean a room or location at which a hospital, nursing home or clinical laboratory engages in medical services and/or specimen collection that results in the generation of regulated medical waste. For purposes of this Part, a patient service center (i.e., collection station) and a health fair operated by a clinical laboratory are patient care areas.

(x) "Primary container" shall mean the containment system in direct contact with, holding and securing regulated medical waste, i.e., a red bag or sharps container.

(y) "Radiological medical waste" shall mean regulated medical waste contaminated by or mixed with radioisotopes that are emitting ionizing radiation at a level distinguishable from natural background level.

(z) "Regulated medical waste" shall mean waste generated in diagnosis, treatment or immunization of humans or animals in research pertaining thereto, or in production and testing of biologicals; provided, however, that regulated medical waste shall not include hazardous waste and household medical waste except as prescribed in paragraph (4) below, and hazardous waste.

Regulated medical waste shall include:

(1) cultures and stocks; culture dishes and devices used to transfer, inoculate and mix cultures that have come into contact with cultures and stocks; and biologicals;

(2) human pathological waste, including: tissue; organs; body parts, excluding teeth and contiguous structures of bone and gum; body fluids removed during surgery, autopsy or other medical procedures; specimens of body fluids and their containers; and discarded materials saturated with body fluids other than urine. Human pathological waste shall not include urine or fecal material submitted for purposes other than diagnosis of infectious diseases;

(3) human blood and blood products, including their components (e.g., serum and plasma); containers with free-flowing blood; discarded blood products as defined in 10 NYCRR Subpart 58-2; and materials saturated with flowing blood (except feminine hygiene products);

(4) sharps whether used or unused including residential sharps accepted by a facility regulated under Article 28 of the Public Health Law pursuant to Section 1389-dd (4) of the Public Health Law;

(5) animal waste, including animal carcasses, body parts, body fluids, blood, and bedding originating from animals known to be contaminated with infectious agents (i.e., zoonotic organisms) or from animals inoculated with infectious agents for purposes including, but not limited to, research, production of biologicals, or drug testing; and

(6) any other waste materials containing infectious agents designated by the Commissioner of Health as regulated medical waste.

(aa) "Residence time" shall mean the time necessary for effective treatment of regulated medical waste at a specific temperature, pressure and/or chemical concentration, the duration of which:

(1) for an autoclave, begins when the autoclave's coldest area, as determined by the manufacturer, attains the temperature and pressure established by validation testing as effective for treatment of regulated medical waste, and continues for at least the minimum time established by validation testing as effective for treatment of such waste;

(2) for an incinerator, begins when the incinerator attains operating temperature in both the ignition and combustion (secondary) chambers, and continues for the time necessary to achieve a complete burn down as determined by inspection through a view port of the waste bed; and

(3) for an alternative regulated medical waste treatment system, begins when the

temperature, chemical concentration or other condition established through efficacy testing has been attained, and continues for the time established through such testing, as required for effective treatment of regulated medical waste.

(bb) "Secondary container" shall mean the containment system used to hold and secure a primary container. A secondary container (e.g., outer container) shall be a disposable or reusable rigid pail, carton, drum or portable bin that is, under normal conditions of use, leak-resistant; has leak-proof sides and bottom; has a tight-fitting cover or is otherwise closeable; and is in good repair.

(cc) "Sharp" shall mean an item capable of causing percutaneous injury, including, but not limited to, hypodermic, intravenous or other medical needles; hypodermic or intravenous syringes to which a needle or other sharp is attached; Pasteur pipettes; scalpel blades; blood vials; and broken and unbroken glass and plastic ware, including microscope slides and cover slips, in contact with infectious agents. Sharps shall not include those parts of syringes specifically designed to allow easy removal of a hypodermic, intravenous or other medical needle, and are intended for recycling or other disposal, provided the needle has been removed and such syringe has not been in contact with infectious agents.

(dd) "Solid waste" shall have the same meaning as in 6 NYCRR, section 360-1.2.

(ee) "Sterilize" shall mean to inactivate all microbial forms of life.

(ff) "Storage" shall mean temporary containment of regulated medical waste in such a manner as not to constitute disposal of such waste. "Storage area" shall mean a room, delineated area or designated space designed for storage of regulated medical waste in accordance with this Part, within a building, or on any permanent structure attached or unattached to a building, including a loading dock, situated on property owned by or under management of the facility

operator. "Storage area" shall not include a trailer, bulk container or other transportable container or vehicle not owned by the facility but situated on facility property.

(gg) "Transport" shall mean shipment or conveyance of regulated medical waste from the point of generation to any intermediate point, including a treatment facility, and finally to the point of ultimate disposal.

(hh) "Treatment" shall mean any method, technology or process designed to change the character or composition of any regulated medical waste so that it no longer constitutes a threat to public health and safety. Treatment shall not include compaction.

(ii) "Universal warning sign" shall mean a symbol design that conforms to the design shown by illustration at 29 CFR Section 1910.1030(g)(1)(i)(A) (Vol. 6, July 1, 2003). Federal regulations are published by the Office of the Federal Register, National Archives and Records Administration and may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402. Copies are available for inspection and copying in the New York State Department of Health, Bureau of Hospital and Primary Care Services, Hedley Park Place, 433 River Street, Troy, NY 12180.

(jj) "Validation testing" shall mean procedures conducted at the installation site of an alternative regulated medical waste treatment system, an incinerator, or an autoclave prior to initial operation for waste treatment, the purpose of which is to demonstrate, under pre-established operating parameters, the effective treatment of regulated medical waste at the installation site.

Subpart 70-2

Management of Regulated Medical Waste

Sec.

70-2.1 Waste management plan

70-2.2 Containment and storage

70-2.3 Treatment and disposal

70-2.4 Transfer of regulated medical waste for off-site treatment

70-2.5 Record keeping

Section 70-2.1 Waste management plan. Each facility shall develop, document and implement policies and procedures specific to the management of regulated medical waste generated on-site and/or treated at the facility. Such policies and procedures shall minimally include, but not be limited to: a description of the types, and method(s) for treatment and disposal, of regulated medical waste; procedures for safe handling and transport of the waste within the facility from the point of generation or intake to the point of storage and/or treatment; a description of storage areas, including, as applicable, patient care areas, which details the location, ventilation and capacity of each storage area, and the length of time waste is to be retained in each area; and the titles and contact information for persons responsible for monitoring compliance. Facilities that treat regulated medical waste on-site shall include in their regulated medical waste management plan an operation plan for each treatment system employed.

70-2.2 Containment and storage. (a) Regulated medical waste shall be separated from other waste as soon as practicable at the point of generation prior to storage, treatment or disposal. Containers

holding regulated medical waste containing or mixed with hazardous waste, radioisotopes and/or toxic drug waste shall be so labeled to identify waste types contained therein and so as to provide other information, including but not limited to isotope and level of radioactivity pertinent to determining whether specific procedures for management and/or disposal are applicable.

Radiological medical waste shall be stored until decayed to a background radiation level prior to transport off-site of the generating facility and/or treatment.

(b) Containment of regulated medical waste for handling, storage, and treatment shall be accomplished with a primary container for protection from the elements and limiting exposure to employees and the public. Each primary container holding regulated medical waste shall be:

(1) marked prominently with the universal warning sign or the word “biohazard”; and

(2) impervious to moisture, be secured and situated so as to prevent leakage or preclude loss of contents during handling, storage and/or transport.

(3) be located away from pedestrian traffic, be vermin and insect free, and shall be maintained in a sanitary condition.

(c) Whenever regulated medical waste is transported off-site for treatment elsewhere, the primary container shall have affixed a label or imprint indicating the name and address of the generation facility and shall comply with the transport requirements of subdivision (h) below.

(d) (1) In addition to the requirements of subdivisions (b) and (c) above, the primary container for regulated medical waste, with the exception of sharps, shall be a plastic bag; red in color; and of a strength sufficient to resist ripping, tearing, or bursting under normal conditions of use and handling.

(2) In addition to the requirements of subdivisions (b) and (c) above, the primary container for discarded sharps shall be rigid, leakproof, puncture-resistant and closable, and may serve as a

secondary container for purposes of transport, provided it meets the definition of a secondary container.

(e)(1) Under no circumstances shall a sharps container be filled beyond the fill line indicated on the container.

(2) Sharps containers shall be removed from patient care areas to a room or area designated for regulated medical waste storage, whenever the container has reached the fill line indicated on the container. Sharps containers shall be removed from patient care areas within thirty (30) days or upon the generation of odors or other evidence of putrefaction, whichever occurs first, without regard to fill level.

(f) Regulated medical waste, with the exception of sharps as provided in subdivision (e) above, may be held in patient care areas for a period not to exceed twenty-four (24) hours and at a clinical laboratory for a period not to exceed seventy-two (72) hours, at which time the waste shall be moved to a storage area.

(g)(1) Each storage area shall be adequate for the volume of regulated medical waste generated between scheduled waste pick-ups by a transporter, or, for facilities treating the waste on-site, the volume of waste that can be treated on-site within a twenty-four (24) hour period.

(2) Each storage area shall:

(a) display prominent signage indicating the space is used to store regulated medical waste;

(b) be designed or equipped to prevent unauthorized access;

(c) be designed or located to protect waste from the elements, and prevent access by vermin;

(d) hold the waste at a temperature that prevents rapid decomposition and resultant odor generation;

(e) be appropriately ventilated; and

(f) be of sufficient size to allow clear separation of regulated medical waste from any other waste, whenever waste other than regulated medical waste is stored in the same area.

(3) Regulated medical waste shall not be stored for a period exceeding thirty (30) days, except that a site generating under fifty (50) pounds of regulated medical waste per month and not accepting regulated medical waste for treatment from other facilities, may store waste for a period not exceeding sixty (60) days.

(g) Prior to transport off-site of the generating facility for treatment elsewhere:

(1) primary containers shall have affixed a label or imprint indicating the name and address of the generating facility; and

(2) primary containers, except as provided in (c)(2) above, shall be placed in a secondary container with an affixed label or imprint, indicating the name and address of the generating facility, and such container marked prominently with signage indicating that the contents are infectious or regulated medical waste; and, if applicable, with an affixed label indicating that the contents contain or are mixed with hazardous waste, and/or toxic drug waste.

(h) All internal surfaces of a reusable secondary container used to hold regulated medical waste shall be completely protected by a disposable liner, which may also function as the primary container provided it meets the criteria for a primary container provided in subdivisions (b) and (c) of this section. The liner shall be removed as a secured unit with the waste and treated as regulated medical waste. A reusable secondary container shall undergo washing and decontamination upon emptying whenever the liner is compromised; visual inspection yields evidence that the container's surface has come in contact with the contained waste prior to treatment; the contained waste includes cultures and/or stocks; or the contained waste has a highly infectious bioload.

(i) Under no circumstances shall regulated medical waste be transferred from one container to another (e.g., for consolidation or loading of a treatment system) in a manner that compromises health and safety of the persons handling the waste. Regulated medical waste being moved from one container to another, or one location to another within a facility shall as a minimum be secured in a primary container.

(j) Reusable sharps containers shall not be opened for consolidation or other purposes unless such procedure has been approved as part of the facility's treatment system operation plan.

(k) Disposable secondary containers for storing and handling regulated medical waste shall be treated as regulated medical waste.

(l) Transport of regulated medical waste within a facility from the point of generation to the point of storage or treatment shall be by covered cart or other appropriately covered conveyance system marked prominently with signage indicating that the contents are infectious or are regulated medical waste; provided, however, waste held in containers meeting the definition of secondary container may be transported within a facility from point of generation to the point of storage or treatment using an open conveyance system (e.g., laboratory cart or dolly) provided each container is labeled and appropriately closed. Regulated medical waste shall not be moved within a facility by gravity alone without control of impact, i.e., trash chutes or slides.

(m) Regulated medical waste shall not be compacted unless it has undergone treatment as provided in section 70-2.3 of this Subpart.

70-2.3 Treatment and disposal. (a) Except as provided in subdivisions (b) and (c) below, treatment of regulated medical waste shall be by:

(1) discharge into a sanitary sewerage system connected to a secondary treatment facility, if the waste is liquid or semi-liquid, except as specifically prohibited by the Commissioner of Health,

or by local law or ordinance;

(2) incineration in a regulated medical waste incineration facility under permit pursuant to Article 19 of the Environmental Conservation Law;

(3) decontamination by autoclaving in conformance with the requirements of Subpart 70-3 of this Part; or

(4) an alternative regulated medical waste treatment system approved by the Commissioner of Health.

(b) Restrictions on autoclave use. (1) no autoclave shall be used for treatment of regulated medical waste containing or mixed with hazardous waste and/or toxic drug waste;

(2) no autoclave shall be used for treatment of radiological medical waste;

(3) no autoclave shall be used for treatment of recognizable human body parts; and

(4) an autoclave may be used for the treatment of human tissue(s), human organs; animal carcasses or animal body parts provided the Department has expressly approved the autoclave model as an alternative treatment technology for such use pursuant to Subpart 70-5 of this Part.

(c) Cultures and stocks. (1) cultures and stocks containing select agents or toxins listed in 42 CFR Part 73 (Vol. 70, March 18, 2005) shall be treated on-site by incineration, autoclaving or use of alternative treatment system approved for such treatment provided, however, whenever a facility without a predictable need for on-site treatment generates such waste incidental to the delivery of medical care, the generating facility shall arrange for transportation of the select agents and toxins to a facility authorized to treat such material and shall comply with Federal regulations regarding possession, use and transfer of select agents and toxins. Such regulation shall include 42 CFR, Part 73 (Vol. 70, March 18, 2005). Federal regulations are published by the Office of the Federal Register, National Archives and Records Administration and may be purchased from the

Superintendent of Documents, Government Printing Office, Washington, DC 20402. Copies are available for inspection and copying in the New York State Department of Health, Bureau of Hospital and Primary Care Services, Hedley Park Place, 433 River Street, Troy, NY 12180.

(2) except where on-site treatment is required by local health code, cultures and stocks containing infectious agents other than those referenced in subdivision (c)(1) above may be transported off-site for treatment.

(d) Discarded sharps shall be destroyed prior to disposal. Sharps not coming in contact with infectious agents need not be treated in accordance with subdivision (a) above.

(e) Generators of regulated medical waste shall have in place a response plan to be followed in the event the facility is notified that regulated medical waste, known or suspected to be untreated, has been found commingled with solid waste. Such response plan and any corrective action taken shall be documented.

(f) Radiation detection. (1) each facility that treats regulated medical waste shall have a radiation detection system to screen waste for radiological medical waste and a contingency plan in the event radiation levels above background are detected in waste loads delivered for treatment. The radiation detection system shall be appropriate for effective screening of the type(s) and volume of waste, and shall be set to alarm whenever ionizing radiation above the local background ionizing radiation level is detected; and

(2) no facility shall treat radiological medical waste by autoclaving; and

(3) no facility shall treat radiological waste using an alternative regulated medical waste treatment system unless the system has been approved by the Department for such treatment pursuant to Section 70-5 of this Part.

(g) Treated regulated medical waste shall be disposed of as solid waste at an incinerator,

landfill or other disposal facility authorized by the Department of Environmental Conservation to accept regulated medical waste after treatment.

(h) No facility shall transfer or release treated regulated medical waste that is not accompanied by a Department of Health certificate of treatment.

70-2.4 Transfer of regulated medical waste for off-site treatment. (a) Generators of regulated medical waste shall transfer such waste for off-site treatment only to a regulated medical waste transporter permitted by the Department of Environmental Conservation; provided, however, that a generator of under fifty (50) pounds of regulated medical waste per month registered with the Department of Environmental Conservation pursuant to 6 NYCRR Part 364 may transport its own waste for off-site treatment.

(b) A facility that generates waste and arranges transport for off-site treatment or disposal, or otherwise participates in the transport of regulated medical waste shall ensure that a regulated medical waste tracking form prescribed by the Department of Environmental Conservation accompanies each load.

(c) All solid waste transported in a load containing regulated medical waste shall be treated as regulated medical waste, unless the regulated medical waste is separately contained in a secondary container meeting the requirements of section 70-2.2(h) of this Subpart or is otherwise kept separate from the solid waste by leak-proof barriers.

70-2.5 Record keeping. (a) A record of regulated medical waste by quantity and categories as defined in Public Health Law 1389-aa and for disposition of treated waste on-site shall be maintained and retained on-site by the generator for three (3) years from the date of disposition of the waste, and shall be available for inspection and copying by the Department. Documentation of

corrective action related to a commingling incident shall be retained three (3) years.

(b) A report of the regulated medical waste generated annually, by quantities and categories as defined in Public Health Law 1389-aa shall be submitted to the Commissioner of Environmental Conservation upon request.

Subpart 70-3

Requirements for Autoclaves Used to Treat Regulated Medical Waste

Sec.

70-3.1 Validation testing

70-3.2 Operational requirements

70-3.3 Generally accepted and alternative operating parameters

70-3.4 Record keeping

Section 70-3.1 Validation testing. (a) Prior to using an autoclave to treat regulated medical waste, a facility shall conduct validation testing under conditions, including, but not limited to load configuration, composition and volume, that simulate conditions anticipated during actual waste treatment. Validation testing protocols shall be included in the facility's autoclave operation plan submitted to the Department pursuant to section 70-3.2 of this Subpart.

(b)(1) Validation testing shall employ spores of *Geobacillus stearothermophilus* at a minimum concentration of 6 log₁₀ spores per indicator unit placed in the center of the load or otherwise coldest point in the autoclave chamber as identified by the manufacturer; provided, however, the Department may require alternative and/or supplemental indicators as necessary to demonstrate effectiveness of treatment;

(2) effective treatment of regulated medical waste shall be demonstrated by a 4 log₁₀ reduction in viable *Geobacillus stearothermophilus* spore concentration, or other measure of effectiveness for alternative and/or supplemental indicators as specified by the Department.

(c) No autoclave that fails to meet the criteria for effective treatment pursuant to subdivision (b) above upon validation testing at the site of installation shall be used to treat regulated medical

waste.

(d) A facility that seeks to operate an autoclave at other than the generally accepted operating parameters (i.e., time, temperature and pressure) provided in section 70-3.3(a) and (b) of this Subpart shall request and obtain Department approval for operation of the autoclave as an alternative treatment system pursuant to Subpart 70-5.

70-3.2 Operational requirements. (a) Each facility seeking to operate an autoclave shall develop an operation plan, and shall submit such plan to the Department for review and approval prior to using the autoclave to treat regulated medical waste. Any change in procedures related to the operation of the autoclave shall be reflected in a modified plan, which shall be dated with each revision.

(b) No autoclave shall be used to treat regulated medical waste without Department approval of the facility's operation plan and any modifications made to such plan on or after the effective date of this regulation.

(c) The operation plan shall be designed to promote safe and effective operation of the autoclave. The operation plan shall include, minimally, procedures to ensure:

(1) the autoclave meets Department criteria for effective treatment of regulated medical waste (i.e., the protocol for validation testing and a summary of the results);

(2) loads contain only those items or types of waste for which effective treatment has been demonstrated by validation testing; and exclude waste materials for which effective treatment by the system has not been demonstrated and/or is prohibited pursuant to section 70-2.3 of this Subpart, and, as applicable, materials expressly excluded in the Commissioner's notice of approval;

(3) each load is treated using residence time, temperature and pressure that have been validated as effective for the treatment of regulated medical waste, and conditions of treatment are

monitored and documented for each load;

(4) the effectiveness of treatment is maintained, by including, as applicable, procedures for and frequency of: calibration verification and recalibration of parametric controls; monitoring by challenge testing or other demonstration that treatment has been attained; and preventative maintenance of engineering controls (e.g., charcoal and/or HEPA filters) and diagnostic procedures for electronic controls (e.g., integrated computers and mechanical components);

(5) occupational exposure is minimized, and physical injury to operators is prevented during loading, the cycle, and unloading the autoclave; and

(6) personnel are knowledgeable about routine operation of the autoclave, are kept current with manufacturer recommendations for operation, and have been instructed in emergency procedures for handling malfunctioning systems and untreated waste. Training programs shall mandate initial training and retraining at least once per calendar year and as necessary for presenting updates on operational information.

(d) Any modification of an approved operation plan with potential to substantially alter treatment efficacy shall be submitted to the Department for approval. Prior to approving a modified plan, the Department may require that validation testing be conducted again by the facility, and the results submitted for Department review.

(e) Whenever an autoclave fails to operate in accordance with pre-established operating parameters, the facility shall:

(1) discontinue use of the autoclave, using emergency shutdown procedures if appropriate, until corrective action has been taken and validation testing has verified that effective treatment can resume;

(2) handle as untreated all regulated medical waste processed by the system since the last effective March 15, 2006

previous run under documented compliance with such requirements;

(3) document the failure, including date and autoclave identifier;

(4) document the facility response, including corrective action; and

(5) whenever a facility has reason to believe untreated waste certified as treated waste has left the facility, notify the waste transporter as soon as practicable, and notify the Department within seventy-two (72) hours of the waste's leaving the facility.

(f) Monitoring autoclave operation. (1) parametric controls shall be employed to monitor operating parameters automatically and continuously throughout the entire cycle, and generate a record of operating parameters for each cycle; or

(2) in the absence of parametric controls, routine operational performance of an autoclave shall be monitored by: (i) challenge testing, conducted every forty (40) hours of autoclave operation or once a week, whichever occurs first, using the same protocol as was approved by the Department for validation testing, and (ii) time/temperature-sensitive materials used in each load. No autoclave that fails to attain 4 log₁₀ reduction in viable spores concentration upon challenge testing shall be used to treat regulated medical waste. Whenever time/temperature-sensitive materials fail to show expected results (i.e., a color change), the load shall be handled as untreated waste, and the facility shall demonstrate, through a repeat of validation testing, that the autoclave effectively treats regulated medical waste before resuming its use for treatment purposes.

(g) Containment of regulated medical waste for treatment by autoclaving shall be by a container or containment system designed to withstand the temperature and pressure of autoclaving, and may, except for sharps, consist solely of a red bag.

(h) If the container or containment system does not, by design, allow steam to come into direct contact with waste material, the operator shall take action to ensure such contact.

(i) Sharps treated by autoclaving shall be destroyed prior to disposal.

70-3.3 Generally accepted and alternative operating parameters. (a) Unless other operating parameters have been approved pursuant to subdivision (c) below, operating parameters for treating of regulated medical waste in a gravity-feed autoclave shall be:

(1) at least sixty (60) minutes residence time at a temperature at least one hundred twenty-one (121) degrees Celsius and a pressure of fifteen pounds per square inch (15 psig); or

(2) at least forty-five (45) minutes residence time at a temperature at least one hundred thirty-five (135) degrees Celsius and a pressure of thirty-one pounds per square inch (31 psig).

(b) Unless other operating parameters have been approved pursuant to subdivision (c) below, operating parameters for treating regulated medical waste in a vacuum-displacement autoclave shall be:

(1) at least forty-five (45) minutes residence time at a temperature at least one hundred twenty-one (121) degrees Celsius and a pressure of fifteen pounds per square inch (15 psig); or

(2) at least thirty (30) minutes residence time at a temperature at least one hundred thirty-five (135) degrees Celsius and a pressure of thirty-one pounds per square inch (31 psig).

(c) No facility shall treat regulated medical waste using an autoclave at operating parameters other than those prescribed in subdivision (a) or (b) above, unless the treatment method has been approved by the Department as an alternative treatment technology pursuant to section 70-5 of this Part.

70-3.4 Record keeping. (a) Each facility shall retain for three (3) years records of: validation testing and challenge testing, including protocols and test results; routine system's monitoring; and,

where applicable, Department approval as an alternative treatment technology.

(b) Each facility shall document each employee's participation in training and/or retraining in autoclave operations, and shall retain such records for three (3) years.

(c) Documentation of corrective action, including that required by section 70-3.2, of this Subpart, shall be retained for three (3) years.

(d) Documentation of any modification to an approved operation plan, regardless of whether the modification is subject to Department approval pursuant to this section, shall be retained three (3) years from discontinuance of the modified plan.

(e) Documentation of the residence time, pressure and temperature of each load treated shall be retained for three (3) years.

(f) All records required pursuant to this section shall be made available for inspection and copying by the Department.

Subpart 70-4

Requirements for Alternative Regulated Medical Waste Treatment Systems

Sec.

70-4.1 Approval of technology

70-4.2 Operational requirements

70-4.3 Validation testing

70-4.4 Record keeping

Section 70-4.1 Approval of technology. (a) No alternative treatment system shall be used to treat regulated medical waste without approval by the Commissioner of Health of the treatment technology pursuant to Subpart 70-5 of this Part. In the approval of an alternative treatment technology, the Department shall specify the scope of the approval, including, but not limited to, the type(s) of waste and/or waste composition for which the system has been approved.

(b) No regulated medical waste other than that of a type and composition specified in the Commissioner of Health's approval of an alternative treatment technology shall be treated using the approved technology.

(c) No facility shall use an alternative treatment system to render harmless, dispose of or otherwise handle, in the same or different loads than regulated medical waste, material other than the regulated medical waste for which the system received approval, unless the facility, jointly with the system manufacturer, demonstrates to the Department that the system is effective in treating regulated medical waste and that the system is not impacted adversely by the facility's use of the

effective March 15, 2006

system for purposes other than treating regulated medical waste.

(d) An autoclave used to treat human tissue(s), human and animal organs, and/or animal body parts shall require approval as an alternative treatment system pursuant to Subpart 70-5 of this Part. An autoclave operated at a residence time, temperature and/or pressure other than those prescribed in section 70-3 shall require approval as an alternative treatment system pursuant to Subpart 70-5 of this Part.

70-4.2 Operational requirements. (a) Each facility seeking to operate an alternative regulated medical waste treatment system shall develop an operation plan, and shall submit such plan to the Department for review and approval prior to using the system to treat regulated medical waste. Any change in procedures related to the operation of the system shall be reflected in a modified plan, which shall be dated with each revision.

(b) No alternative regulated medical waste treatment system shall be used to treat regulated medical waste without Department approval of the facility's operation plan and any modifications made to such plan on or after the effective date of this regulation. The operation plan shall be submitted to the Department for approval at least sixty (60) days prior to the anticipated start-up date of the system.

(c) The operation plan shall be designed to promote safe and effective operation of the alternative treatment system. The operation plan shall include, minimally, procedures to ensure:

(1) the system as situated on-site of the facility meets Department criteria for effective treatment of regulated medical waste (i.e., the protocol for validation testing and a summary of the results);

(2) loads contain only those items or types of waste for which effective treatment by the

system has been demonstrated by efficacy testing and verified by validation testing; and exclude waste materials for which effective treatment by the system has not been demonstrated and/or is prohibited pursuant to section 70-2.3 of this Subpart, and materials expressly excluded in the Commissioner's notice of approval treatment;

(3) each load is treated using operating parameters that have been demonstrated as effective for the treatment of regulated medical waste, and conditions of treatment are monitored and documented for each load;

(4) the effectiveness of treatment is maintained, by including, as applicable, procedures for and frequency of calibration verification and recalibration of parametric controls; monitoring by challenge testing or other demonstration that treatment has been attained; and preventive maintenance of engineering controls. (e.g., charcoal and/or HEPA filters) and diagnostic procedures for electronic controls (e.g., integrated computers and mechanical components);

(5) occupational exposure is minimized and physical injury to operators is prevented during loading, the cycle, and unloading of the system; and

(6) personnel are knowledgeable about routine operation of the system, are kept current with system manufacturer recommendations for operation, and have been instructed in emergency procedures for handling malfunctioning systems and untreated waste. Training programs shall mandate initial training and retraining at least once per calendar year and as necessary for presenting updates on operational information.

(d) Any modification of an approved operation plan altering treatment efficacy shall be submitted to the Department for approval prior to implementation. Prior to approving a modified plan, the Department may require efficacy and/or validation testing, using a protocol approved pursuant to section 70-4.3 (b) of this Subpart. The Department may require the submission of

additional information and data specific to the alternative treatment system as may be pertinent to a demonstration of on-going safety and efficacy.

(e) No alternative regulated medical waste treatment system shall be placed into operation prior to implementation of an approved operation plan.

(f) An alternative regulated medical waste treatment system shall be operated in accordance with the system manufacturer's instructions and the approved operation plan. Should a system fail during operation, the operating facility shall:

(1) discontinue use of the system, using emergency shutdown procedures if appropriate, until corrective action is taken and verified through parametric controls; validation testing, including but not limited to, biological indicators; or other demonstration that treatment has been attained;

(2) handle as untreated all regulated medical waste processed by the system since the last previous run under documented compliance with such requirements;

(3) document the failure, including date and system identifier;

(4) document the facility response, including corrective action;

(5) whenever a facility has reason to believe untreated waste certified as treated waste has left the facility; notify the waste transporter immediately upon discovery of the incident, at least within a maximum of two business days and notify the Department within seventy-two (72) hours of the waste's leaving the facility.

(g) For systems that employ parametric controls for automatic and continuous monitoring, the facility shall generate a record of monitoring that identifies operating parameters throughout the cycle. In the absence of such controls, the operational performance of an alternative regulated medical waste system shall be monitored by challenge testing pursuant to a protocol included in the

facility's operation plan and approved by the Department.

(h) No person shall load, operate and/or unload an alternative regulated medical waste treatment system without documented training and retraining in the activities performed.

Documentation shall include the date, location and content of all training sessions, as well as an attestation, by signature of trainer and trainee, that such training or retraining was conducted.

70-4.3 Validation testing. (a) A facility seeking to operate a regulated medical waste treatment system that employs an approved alternative technology shall establish and implement a protocol for validation testing that minimally includes procedures to simulate actual system operation conditions, including, but not limited to, the composition and volume of waste to be treated per load. The validation testing protocol shall be approved by the Department prior to initiation of testing.

(b) Validation testing shall be performed using the Department-approved protocol at the installation site of an approved alternative regulated medical waste treatment system. Validation testing data shall be submitted for Department review and approval along with the operation plan.

70-4.4 Record keeping. (a) Each facility shall document efficacy and validation testing, including testing protocols and results, and routine system monitoring, and shall retain such records for three (3) years.

(b) Each facility shall document, in the personnel file of each employee, participation in system training and/or retraining, and retain such records for three (3) years.

(c) Documentation of corrective action, including that required by section 70-4.2 of this Subpart, shall be retained for three (3) years.

(d) Each facility shall document any modification to an approved operation plan and retain such records for three (3) years from discontinuance of the modified plan.

(e) The facility in which the alternative treatment system is situated shall maintain a copy of the Department's letter notifying the manufacturer of the alternative treatment technology approval and any appendices or amendments thereto for as long as the system is operational.

(f) All records required pursuant to this section shall be made available for inspection and copying by the Department.

Subpart 70-5

Approval of Alternative Treatment Technologies for Use in New York State

Sec.

70-5.1 Treatment technology approval

70-5.2 Limitations and voiding of approval.

Section 70-5.1 Treatment technology approval. (a) No alternative regulated medical waste treatment system shall be used in New York State unless the Commissioner of Health has approved the system's technology pursuant to this Subpart. The system manufacturer, as applicant for technology approval, shall:

- (1) submit an application on forms prescribed by the Commissioner of Health;
- (2) demonstrate that the system's operation does not pose a threat to public health or safety, including documentation that any chemical used in the system has been registered and approved by the New York State Department of Environmental Conservation for use in New York State;
- (3) provide documentation that any chemical used in system to treat regulated medical waste has been registered with the federal Environmental Protection Agency;
- (4) establish the system's operating parameters through efficacy testing, and demonstrate that the system effectively treats regulated medical waste. Unless precluded by system design: (i) efficacy testing shall be conducted on an actual full-scale working model of the system, rather than a simulation, or other substitution in scale or in kind, and (ii) such testing shall employ surrogate test loads, varying in organic to non-organic and solid to liquid compositions. Such surrogate test loads shall include mycobacterium species and/or other appropriate indicators as determined by the

Department, that has been strategically placed throughout the test loads; and

(5) agree to provide all facilities in New York State that use the alternative treatment system with a copy of the Department's technology approval letter, and any appendices or amendments thereto for the period in which the system is in use in New York State.

(b) Whenever *Mycobacterium* species is used as a biological indicator, effective treatment shall be demonstrated by a 6 log₁₀ reduction in viable cell concentrations; *Bacillus atrophaeus* or *Geobacillus stearothermophilus* are used as a biological indicator, effective treatment shall be demonstrated a 4 log₁₀ reduction in viable spores concentration. No alternative treatment system that fails to attain such reductions or fails to demonstrate that the waste has been treated shall be used to treat regulated medical waste.

(c) The Department may require that the system undergo supplemental efficacy testing using organisms or agents other than those identified in (b) above, and may require the manufacturer to demonstrate that the technology meets manufacturer's claims for effective treatment of non-typical bioloads or materials, for example, new and emerging pathogens or pathological waste.

70-5.2 Limitations and voiding of approval. (a)(1) Approval shall be limited to the specific system model or version authorized by the Commissioner of Health, and shall be valid for a period not to exceed two (2) years, renewable every two (2) years;

(2) a renewal application shall be filed no later than one hundred and eighty (180) calendar days prior to expiration of an existing approval; and

(3) each renewal application shall identify all installations of approved technology(ies) for the applicant manufacturer in New York State.

(b) Approval shall be limited to the waste materials and components, operating parameters effective March 15, 2006

and conditions, including the introduction of other materials into a load, specified in the efficacy testing data submitted to and approved by the Department.

(c) Approval shall become void upon any change to the system by the manufacturer that may adversely affect the system's efficacy, as determined by the Department. Such change shall include, but not be limited to, claims that the technology is able to render harmless, dispose of, or otherwise handle wastes and materials, concurrent with regulated medical waste loads or in different loads, other than the type(s) of regulated medical waste for which the technology was approved.

(d) The Department may require the submission of additional information and specific data as may be pertinent to demonstrating safety and efficacy of the alternative technology.