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6 NYCRR Part 365

**Biohazard Waste
Management Facilities**

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PART 365

BIOHAZARD WASTE MANAGEMENT FACILITIES

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SUBPART 365-1

GENERAL

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Section 365-1.1 Applicability

In addition to the requirements contained in Part 360 of this Title, this Part provides the requirements for the management of biohazard wastes, including regulated medical waste (RMW). These regulations may apply to veterinary practices, animal research facilities, radiopharmacies, trauma scene waste management practitioners, waste management facilities, and any other facilities or persons who generate, store, process, or treat biohazard waste.

Section 365-1.2 Exclusions

The following wastes are not considered biohazard waste for the purposes of this Part unless specifically designated by the Department of Health or the department.

(a) Human cadavers managed in accordance with Article 42 of the Public Health Law and the New York State Department of State rules for cemeteries and crematories.

(b) Discarded and essentially empty urine collection bags and tubing, urine specimen cups, urinary catheters, bedpans contaminated with feces, and urine bottles, unless the item was submitted as a clinical specimen for laboratory tests or the patient was found to have a disease transmitted through urine or feces.

(c) Tissue blocks of organs or tissues which have been fixed in paraffin or similar embedding materials for cytological or histological examination.

(d) Organs, tissue or recognizable body parts that have been removed during surgery or child birth, except a fetus, and retained by the patient for religious or other purposes provided that the organs, tissue or body parts are not provided to another person in any form, and are not a potential source of disease transmission, as determined by a health care professional.

(e) Items such as bandages, gauze, or cotton swabs or other similar absorbent materials unless they are saturated or would otherwise release blood or human body fluids, other than urine, if compressed.

(f) Housekeeping waste from hotels, except medical waste generated from treatment facilities at

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a hotel. Soiled bedding from commercial laundry facilities that is intended for reuse is not considered medical waste.

(g) Veterinary medical waste, if generated by the owner of a companion animal.

(h) Medical waste, including sharps, generated through the self-administration of medicine in a household. Waste containing cultures generated in the household are not excluded from this Part.

(i) Pharmaceutical waste generated in a household.

(j) Genetically modified or attenuated infectious agents and their products used in the diagnosis, treatment or immunization of human beings or animals or for research or production of biologicals, including attenuated vaccines, antigens and antitoxins that do not include a hazardous waste provided the following conditions are met and can be demonstrated by the generator:

(1) genetic modification or attenuation of an infectious agent has been conducted and the procedures to render the infectious agent non-infectious have been documented;

(2) genetic modification or attenuation has been verified by quantitative microbiological bioassay by an independent laboratory for each agent used; and

(3) the biological preparation derived from the genetically modified or attenuated organism does not include any hazardous waste.

(k) Trauma scene waste, provided it is separated from other waste and is packaged, stored, marked and managed in accordance with the criteria applicable to RMW outlined in section 365-1.4 of this Subpart.

(l) Items such as bandages, gauze, or cotton swabs or other similar absorbent materials that are saturated or would otherwise release blood or human body fluids if compressed and that are generated from cosmetology, ear piercing or tattooing, provided the waste is packaged in accordance with the criteria applicable to RMW outlined in section 365-1.4 of this Subpart.

Section 365-1.3 Exempt facilities

The following facilities are exempt from the registration and permitting requirements of this Part:

(a) Consolidation, storage, handling, or treatment facilities for RMW generated by, and located and operated at a facility defined in Section 281 of the New York State Public Health Law (PHL) including a hospital (except hospitals accepting RMW for processing from 6 NYCRR Part 364 transporters), residential health care facility, and/or diagnostic treatment center, or a clinical laboratory, as defined by Section 571 of the PHL, both of which sections of the PHL are

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incorporated by reference in section 360.3 of this Title. These facilities may accept RMW in small quantities (i.e., less than 50 pounds per month per generator) from affiliated off-site generators who self-transport RMW to the facility, provided these small generators first register with the department in accordance with Subpart 365-2 of this Part and Part 364 of this Title.

(b) Consolidation, storage or transfer of RMW or unused medications at a place of business that employs a nurse that provides home healthcare services. The waste must only be generated while dispensing medications or administering healthcare at individual households, and the volume of RMW and unused medications cannot exceed 50 pounds per month at the place of business. The waste must be packaged and treated as RMW.

(c) Handling, excluding treatment, and storage of biohazard waste at the site of generation if the requirements of section 365-1.4 of this Subpart are followed.

Section 365-1.4 Generator requirements

Generators of biohazard waste must comply with the following general requirements.

(a) The generator must have a written biohazard waste plan that contains policies and procedures specific to the management of biohazard waste. The policies and procedures must include procedures for safe handling of the waste within the facility. The plan must also include the following:

(1) a description of long-term (i.e., more than 72 hours) and short-term (i.e., less than 72 hours) storage areas which details the location, ventilation procedures and capacity of each storage area, and the length of time waste is to be retained in each area;

(2) contact information for persons responsible for monitoring compliance with the plan; and

(3) a contingency plan for emergencies and spill cleanup, including provisions for biohazard waste storage during emergency situations.

(b) Biohazard waste must be separated from other waste as soon as practicable after generation. Each of the following biohazard waste types must be disposed in separate primary containers and labeled in accordance with applicable state and federal regulations: high-risk waste containing infectious agents, anatomical waste (including tissues or organs), hazardous waste such as x-ray photographic fixer or developer (must be managed as hazardous waste), pharmaceutical waste requiring incineration (such as pharmaceutically contaminated sharps separated from non-pharmaceutically contaminated sharps), biologicals, mixed or dual wastes, and radioisotopes.

(c) Biohazard waste known to be contaminated with radioactive isotopes must be stored until the radioisotopes have decayed to a point that emitting ionizing radiation is at or below natural background levels or returned to a radiopharmacy.

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(d) Biohazard waste must be kept in a primary container that minimizes handling and the potential for human exposure to the waste, and protects the integrity of the waste packaging at all times.

(e) Biohazard waste containers must be kept separate, not in physical contact with other containers or wastes, and be leak free so that one container cannot contaminate another waste or its packaging.

(f) If treatment will occur off-site, biohazard waste must be packaged in primary and secondary containers prior to leaving the site of generation. The containers must meet the following criteria.

(1) Requirements for primary containers.

(i) Primary containers, with the exception of sharps containers, must be a plastic bag (including autoclavable bags), red in color, impervious to moisture, that complies with the single thickness and resistance standards prescribed by the United States Department of Transportation (USDOT) found at 49 CFR 173.196, 173.197 and 173.199, as incorporated by reference in section 360.3 of this Title, and is certified by the bag manufacturer to meet the federal requirements referenced in this paragraph.

(ii) Primary containers must have sufficient strength to resist ripping, tearing, or bursting under normal conditions of use and handling.

(iii) Primary containers must not be filled so that they result in failure at the sides or base of the package.

(iv) A primary container for discarded sharps must be rigid, leak-resistant, impervious to moisture, puncture-resistant and closable, and may serve as a secondary (outer) container for purposes of transport provided it meets the definition of a secondary container. Sharps containers must not be filled beyond the fill line indicated on the container.

(v) Biohazard waste fluids contained in leak-proof containers must be placed in a primary container, oriented in an upright position and secured to prevent leakage, and then placed in a secondary container prior to off-site transport.

(vi) Primary containers must be properly closed at all times when not being filled and marked prominently with the universal biohazard warning sign or the word "biohazard".

(vii) Primary containers, except containers that have been approved for reuse by an appropriate state or federal agency, may not be reused.

(viii) Prior to transport, off-site biohazard waste must be placed in commercially manufactured disposable (e.g., cardboard boxes) or reusable secondary containers. Reusable secondary containers can include wheeled carts or roll-off containers.

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(2) Requirements for secondary containers.

(i) Secondary containers must be constructed of materials that will hold and prevent breakage of the bag in storage and during handling, collection, or transportation and comply with the standards and testing requirements set forth by the USDOT and found at 49 CFR 173.197, as incorporated by reference in section 360.3 of this Title.

(ii) Secondary containers that are reusable must be constructed of smooth, easily cleanable materials that are impervious to liquids and resistant to corrosion by disinfection agents.

(iii) Secondary containers, except sharps containers, must be affixed with a label or imprint, indicating the name and address of the waste generator (in accordance with USDOT Title 49 CFR 173.197, as incorporated by reference in section 360.3 of this Title), date of transport, and marked prominently with signage indicating that the contents are biohazard waste, and if applicable, that the contents contain pharmaceutical, mixed or dual wastes or toxic drug waste.

(iv) Secondary containers must have the universal biohazard warning sign or the word “biohazard” on the lid and on all sides.

(v) All internal surfaces of reusable secondary containers, except sharps containers, must be completely protected by a disposable liner that is a red bag or other device that is removed with the waste.

(vi) Disposable, single-use secondary containers, broken reusable containers or those unable to be cleaned and disinfected, must be treated as biohazard waste unless otherwise authorized by the department.

(vii) A reusable sharps container serving as a secondary container must be either cleared or approved by the United States Food and Drug Administration (USFDA) and must be registered by the USFDA in accordance with the pre-market notification standards set forth at 21 CFR sections 807.81 through 807.100, as incorporated by reference in section 360.3 of this Title, as a medical device and must be permanently marked for reuse.

(viii) A reusable secondary container must be cleaned and disinfected with a department-approved disinfectant and used in accordance with the disinfectant’s manufacturer’s label whenever the liner is broken; evidence of waste is found on the container surface; the waste in the container includes cultures and/or stocks; the waste has a high bioburden; the container is a reusable suction canister or fluid cart that receives blood; or the container has been emptied and will be returned to a generator for reuse.

(ix) The cleaning and disinfection of reusable containers must remove all contamination. Cleaning and disinfection must include:

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(a) for cleaning, use of a detergent and sufficient agitation or pressure to remove visible contamination from a surface; and

(b) for disinfection, exposure to hot water at a temperature of at least 180 degrees Fahrenheit (82 degrees Celsius) for a minimum of 15 seconds, and exposure to a chemical disinfectant approved for use by the department and used according to the manufacturer's label directions.

(x) Reusable containers must not be opened for consolidation or other purposes unless the procedure has been approved by the department.

(xi) All reusable secondary containers must be inspected prior to returning for reuse to verify that the containers have been cleaned and disinfected, have no cracks or other defects, and that the locking mechanism works.

(xii) Bulk packaging used as a reusable secondary container such as a roll-off container must comply with the following requirements:

(a) bulk packaging must be staged at facilities in a manner approved by the department;

(b) bulk packaging may not be used for the disposal of liquid blood or blood products, sharps, pathological waste, or contaminated animal carcasses or body parts, unless the waste is properly contained in rigid primary containers and separated from other biohazard waste by a leak-proof rigid barrier, divider or separate compartment;

(c) each bulk package must have an interior and exterior surface that is smooth (except for cross members, supports, and door openings that are recessed or protruding in a roll-off container), non-porous and free of cracks, crevices and other defects which would inhibit disinfection operations;

(d) each bulk package that is a roll-off container must be able to be locked; have bottom and side joints that are fully welded or of seamless construction; have a six-inch fully welded or seamless steel barrier at the rear of the container floor before the rear door seal; have a plastic liner installed on the inside bottom surface to prevent the release of any liquid during all loading, unloading, and transportation operations; have a one-inch lip around the perimeter of each opening on the top of the container so that the latch doors fit over the lip to create a permanent barrier and prevent intrusion of water into the container; and have a permanent imprint on each end with an identifying number and the universal biohazard warning sign or the word "biohazard;"

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(e) all containers must be inspected for integrity when received at a facility. The inspection must include examination of all seals and joints;

(f) all bulk packages used as secondary containers must be kept in a sanitary condition and must not be allowed to become putrescent;

(g) bulk packages that are roll-off containers (except those used for pathological waste, blood or blood products, or animal waste) that will be sent off-site may only be stored at the site of generation until the container is filled or for 14 days, whichever comes first, except that bulk packages that are putrescent must be immediately sent to the receiving facility; and

(h) bulk packages that are roll-off containers used for pathological waste, blood or blood products, or animal waste that will be sent off-site may only be stored at the site of generation until the container is filled, or for seven days, whichever comes first. Bulk packages that are putrescent must be immediately sent to the receiving facility.

(xiii) Biohazard waste must not be transferred from one container to another (e.g., for consolidation or loading of a treatment system) in a manner that causes dust or other airborne particulates.

(g) Storage of biohazard waste begins when the waste container is taken out of active service. Short-term accumulation, for no longer than 24 hours, prior to placement in a waste storage area, is not subject to the criteria in this subdivision. All other storage must comply with the following criteria.

(1) Containers must be stored in an upright, stable and controlled manner that minimizes the potential for leakage. The top of the stacked containers must not be more than six feet above the level of the floor. The integrity of the containers must not be compromised by the manner of storage.

(2) Human pathological wastes or animal carcasses may only be stored within refrigerators or freezers.

(3) Sharps containers must be removed from patient care areas or laboratories to a room or area designated for biohazard waste storage when any of the following occur:

(i) the container has reached the fill line indicated on the container;

(ii) ninety (90) days have elapsed after placement of the first sharp in the container (except for radiopharmacies), or six months for sites that generate less than 50 pounds per month; or

(iii) the generation of odors or other evidence of putrefaction.

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(4) Biohazard waste, except sharps or anatomical waste, may be stored unrefrigerated as follows:

(i) in patient care until the container is filled or for seven days, whichever occurs first;

(ii) in the generation area at a clinical laboratory for a period not to exceed 72 hours;

(iii) at a research laboratory until the container is filled or for 30 days, whichever occurs first.

(5) Storage for a period not to exceed 45 days (60 days for sites that generate less than 50 pounds per month) is allowed if the waste is maintained at or below 0 degrees Fahrenheit (-18 degrees Celsius).

(6) Storage must occur in a manner that ensures that odors and litter, vermin and pest problems do not occur.

(7) Storage procedures must enable the identification and prioritization of wastes with higher risk.

(8) Upon the expiration of the allowable time periods for storage, the waste must be moved to a consolidation room or a common accumulation area, must be appropriately treated, or must be transported off-site. Biohazard waste may only be stored in a consolidation room or a common accumulation area for a maximum of seven days.

(9) All storage areas must be adequate for the volume of biohazard waste generated between scheduled waste pick-ups or, for facilities treating the waste on-site, for the volume of waste that can be treated on-site within a 24-hour period.

(10) All storage areas must:

(i) display prominent signage indicating the space is used to store biohazard waste;

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

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

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

(v) be appropriately ventilated.

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(h) Movement of biohazard waste within a facility from the point of generation to the point of storage or treatment must comply with the following criteria:

(1) Biohazard waste is moved covered in a wheeled cart or other appropriately covered conveyance system marked prominently with signage indicating that the contents are biohazard waste.

(2) Biohazard waste must not be moved within a facility by gravity alone (e.g., trash chutes or slides) without control of impact, and must not be compacted or compressed by mechanical or manual means.

(3) All loading, unloading, packaging and handling of biohazard waste must occur in areas with impermeable surfaces.

(4) All waste transported in a load containing biohazard waste must be treated as biohazard waste, unless the biohazard waste is separately contained in a secondary container, or is otherwise kept separate from the non-biohazard waste by leak-proof barriers.

(5) All biohazard waste that leaves the generator's location must be accompanied by a medical waste tracking document approved by the department. All packaging and labeling must be in accordance with standards set forth at 49 CFR 173.197, as incorporated by reference in section 360.3 of this Title.

(6) All biohazard waste must be transported either by a registered self-transporter or by a transporter permitted under Part 364 of this Title to a facility authorized or permitted to accept the waste for storage, transfer or treatment.

(i) Biohazard wastes that represent a greater risk including, but not limited to, wastes requiring Biosafety (BSL) Level 3 or 4 precautions and waste containing a select agent or toxin as specified in 42 CFR Part 73, must not leave the site of generation facility in an untreated form. These wastes require pretreatment or disinfection prior to off-site processing as RMW. Each generator must ensure that these wastes are pretreated, disinfected or inactivated prior to leaving the site of generation as follows:

(1) Biohazard waste contaminated with select agents and toxins or microbiological cultures containing infectious agents must be pretreated by disinfection, autoclaving, incineration or an alternative treatment system approved by the Department of Health.

(2) Biohazard waste contaminated with toxins and toxin waste solutions must be inactivated by incineration or extensive autoclaving (if applicable), or by soaking in suitable decontamination solutions, as determined by the department.

(j) Pharmaceutical waste and waste mixed with pharmaceutical waste and other similar biohazard

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waste management at the site of generation. The following wastes cannot be autoclaved and must be treated by a technology appropriate for the destruction of the type of RMW.

(1) Pharmaceutical waste, except as identified in subdivision (k) of this section.

(2) Mixed or dual wastes.

(3) RMW or other biohazard waste mixed with pharmaceutical waste.

(4) Toxic drug waste.

(k) Management of other pharmaceutical waste at the site of generation.

(1) Any biological drug waste, except biological drug waste containing hazardous wastes, may be treated with an autoclave or an approved alternative treatment system.

(2) Any controlled substance must be disposed in accordance with Department of Health regulations.

(3) Non-toxic drug wastes that contains no pharmaceutically active agents may be disposed as solid waste providing there is no needle attached.

(4) If pharmaceutical waste is mixed with materials that are regulated as hazardous waste, the entire mixture must be managed as hazardous waste.

(5) Any pharmaceutical waste that contains chemical agents in addition to biological agents must be managed in a manner acceptable to the department.

(l) Generators recovering or recycling biohazard waste in order to reprocess medical devices or to reuse or recycle materials must comply with subdivision 365-2.4(h) of this Subpart for management of this material.

(m) Recordkeeping at the site of generation. A paper or electronic record of the quantity and types of biohazard waste generated on-site, treated (if treatment on-site occurs) or disposed must be maintained and retained on-site by the generator for at least three years and must be available for inspection by the department. Documentation of all biohazard waste management incidents (e.g., leakage, incorrect placement of waste, etc.) and the corrective actions taken must also be retained for three years.

(n) Transport of biohazard waste. Transport of biohazard waste must be accompanied by a tracking document, approved by the department, from the point of generation to the point of receipt by the treatment facility. Transfer facilities must sign and date the tracking document when taking possession of the waste. Except for recognizable sharps, the tracking document is no longer required after the biohazard waste has been treated in accordance with this Part.

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(1) For shipments of biohazard waste to transfer or treatment facilities located outside New York State, the generator must assure that the receiving facility agrees to sign and return the tracking document to the generator and that any out-of-state transporter signs and forwards the tracking document to the receiving facility.

(2) Prior to the first shipment of biohazard waste, the generator must confirm by written or electronic communication from the designated transfer or treatment facility that it is authorized to accept the waste and has capacity to accept the quantity of waste.

(3) Prior to the first shipment of biohazard waste, the generator must confirm by written or electronic communication with the transporter(s) that they are authorized to deliver the RMW or other biohazard waste to the transfer or treatment facility.

(4) The generator must instruct the transporter that if an emergency arises which prevents delivery to the receiving facility, the transporter must contact the generator for authorization to deliver the biohazard waste to another authorized facility or return the shipment to the generator. The generator may give authorization to the transporter and must confirm the new arrangements with an alternate facility. The original tracking document may be used but an alternate disposal facility must be noted on the form by the transporter.

(5) The generator must distribute copies of the tracking document to the transporter upon pickup of the waste.

(6) No generator may provide a shipment of biohazard waste to a transporter unless the transporter has a valid permit issued under Part 364 of this Title which authorizes the transport of biohazard waste, or the transporter is otherwise exempt from the requirement of Part 364 of this Title.

(7) The generator must keep a copy of each complete tracking document for at least three years from the date the waste was accepted by the initial transporter. These documents must be available to the department upon request.

(8) A generator who does not receive a copy of the tracking document with the signature of the receiving facility within 35 days of the date of shipment must immediately contact the transporter and the receiving facility to determine the status of the shipment. If the generator has not received a signed copy of the tracking document within 45 days of shipment, a report must be submitted to the department and, in the case of interstate shipments, submitted to the appropriate recipient in the state in which the shipment was to be received. The report must include:

(i) a legible copy of the tracking document for the load that does not have confirmation of delivery; and

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(ii) a letter signed by the generator or the generator's authorized representative explaining the efforts taken to locate the biohazard waste and the results of those efforts.

SUBPART 365-2

REGULATED MEDICAL WASTE MANAGEMENT FACILITIES

- 365-2.1 Applicability**
- 365-2.2 Registered facilities**
- 365-2.3 Permit application requirements for transfer, processing, and/or treatment facilities**
- 365-2.4 Design and operating requirements for transfer, processing and/or treatment facilities**
- 365-2.5 Treatment requirements**
- 365-2.6 Recordkeeping and reporting requirements**

Section 365-2.1 Applicability

In addition to the requirements contained in Part 360 of this Title, this Subpart applies to any person who transfers, processes, or treats RMW.

This Subpart does not apply to:

- (a) household medical waste sharps collection facilities, which are regulated under Subpart 365-3 of this Part; and
- (b) biohazard waste that is not RMW, which is regulated under Subpart 365-4 of this Part.

Section 365-2.2 Registered facilities

The following facilities are subject to the registration provisions of section 360.15 of this Title and are not subject to section 360.19 of this Title:

- (a) The storage of used sharps or other used medical devices at a radiopharmacy, provided the sharps or other medical devices were dispensed by the radiopharmacy, and the following conditions are satisfied.

(1) In addition to the container requirements provided in section 365-1.4 of this Part, all radiological RMW destined for disposal must be stored at the radiopharmacy until radioisotopes have decayed to a point that emitting ionizing radiation is at or below natural background levels. Once decayed, the RMW can be stored for a maximum of 30 days.

(2) The radiopharmacy must have written policies and procedures for the safe handling and storage of the waste within the facility.

(3) All rooms or areas for storing RMW must be adequate for the volume of RMW generated

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between scheduled waste pick-ups by a transporter or, for facilities treating the waste on-site, adequate for the volume of waste that can be treated on-site within a 24-hour period.

(4) All rooms or areas for storing RMW must:

- (i) display prominent signage indicating the space is used to store RMW;
- (ii) be designed or equipped to prevent unauthorized access;
- (iii) be designed or located to protect waste from the elements, and prevent access by vermin;
- (iv) hold the waste at a temperature that prevents rapid decomposition and resultant odor generation, if necessary;
- (v) be appropriately ventilated, except for rooms under negative pressure, if putrescent wastes are handled; and
- (vi) allow containers to be stored in an upright, stable and controlled manner that minimizes the potential for leakage and human exposure to RMW. The top of the stacked containers must not be more than six feet above the level of the floor. The integrity of the containers must not be compromised by the manner of storage.

(5) RMW that leaves the radiopharmacy must be accompanied by an RMW tracking document.

(b) On-site treatment facilities for small quantity generators that handle less than 220 pounds of RMW per month of RMW. For the purpose of this subdivision, a small quantity generator does not include facilities that store or handle select agents and toxins at Biosafety Level 3 or 4, or facilities that have multiple treatment devices. The on-site treatment facility must comply with the following conditions.

(1) The facility has a written operation plan that demonstrates that the RMW will be managed in accordance with this subdivision. Also, the operation plan must contain a list of all wards, laboratories, laboratory modules, departments or functional areas where RMW is generated (e.g., research areas, veterinary, primary care, dental, acute care, affiliated clinics, etc.).

(2) The treatment of RMW must follow the standards found in sections 365-2.5 and 2.6 of this Subpart.

(3) The facility must have procedures to segregate RMW to be treated from other waste that will not be treated, including other RMW or solid waste.

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(4) The storage and handling of RMW prior to treatment must be in accordance with section 365-1.4 of this Part.

(5) Each facility employee who will operate treatment equipment must be trained in the proper use of the treatment equipment and must use appropriate personal protective equipment.

(6) The facility must maintain records for the operation of the treatment unit. A log must be maintained that includes the date, time, name of the employee operating the unit, the type and amount of RMW treated, and the dates and results of calibration and bio-challenge testing.

(7) The facility must maintain a contingency plan for emergencies and spill cleanup, which includes provisions for RMW storage during emergency situations.

(8) RMW, both treated and untreated, must be transported in accordance with Part 364 of this Title.

(c) On-site treatment facilities employing single-use container treatment. On-site treatment facilities that treat less than 50 pounds per month of RMW that employ single-use container treatment systems such as heat, irradiation, biological, chemical or encapsulation treatment technologies, provided:

(1) The container treatment system has been authorized by the Department of Health as an alternative treatment system under 10 NYCRR Subpart 70-4.

(2) RMW sharps must be both treated and destroyed prior to disposal in a landfill in New York State. Encapsulation is not a form of destruction for sharps.

(3) The treated RMW must be accompanied by a certificate of treatment form. The treated RMW must be transported to the disposal facility by a transporter registered or permitted by the department pursuant to Part 364 of this Title.

(4) A record of the treatment system used and the number of waste containers treated per month must be maintained by the facility for a period of three years.

Section 365-2.3 Permit application requirements for transfer, processing, and/or treatment facilities

Any facility for the transfer, processing, or treatment of RMW, which is not exempt pursuant to section 365-1.3 of this Part or subject to the registration provisions of section 365-2.2 of this Part must obtain a permit. The permit application must include the requirements identified in this section and section 360.16 of this Title, and a description of how the facility will comply with the operating requirements of section 360.19 of this Title, and sections 365-2.4, 2.5, and 2.6 of this Subpart.

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(a) A waste control plan that describes:

(1) the RMW that will be accepted and/or treated at the facility including the type, source, and quantity. A description of the service area that includes a list of all planning units and other generators that are served must be included. The description of the quantity must specify the expected average and maximum daily and annual amounts, on a weight and volume basis, for the first 10 years of operation of the facility. These quantities must be specified for each individual type of RMW and for the total amount of waste accepted. A special waste section must also be included if any of the following activities are proposed to be conducted:

(i) if reusable sharps containers are accepted at the facility for consolidation, a detailed description of the mechanical procedures that will be employed for consolidating those wastes, including unloading, storing, and loading must be included;

(ii) if reusable medical devices are sorted and recovered at the facility, including recovery as raw materials for recycling, a summary must be included that outlines the types of devices or materials that will be recovered, and the mechanical or robotic procedures that will be employed for recovery, storage, processing or treating the devices or materials; and

(iii) if the waste (including sharps) contains pharmaceuticals or if other chemicals are proposed to be stored, transferred or treated, the procedures for managing these wastes must be described in detail.

(2) how the facility will ensure that it only receives RMW, or other wastes capable of being managed at the facility and authorized by the department;

(3) how the facility will identify, store, and dispose of all waste received that cannot be managed at the facility, such as anatomical or pathological waste and other waste not authorized by the department. The description must include information for storing waste containing chemicals in a manner appropriate for its chemical properties;

(4) the methods used to ensure that all secondary containers handled at the facility are in compliance with the USDOT standards found at 49 CFR 173.197, as incorporated by reference in section 360.3 of this Title;

(5) the methods used to manage the waste that ensures odor, litter and vermin or pests are controlled;

(6) how the transfer, processing, or treatment will occur in a rotation based on identification of its type, age on arrival, date of arrival and duration of storage on-site;

(7) how the facility will handle spills, breached containers or contaminated equipment used for handling the waste; and

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(8) how inventory will be managed and the method that will be used to manage the required tracking forms.

(b) Treatment equipment and process description. Treatment facilities must provide a detailed description of the treatment device(s) including:

(1) an explanation of the equipment features (e.g., model number, capacity and material of construction), ancillary equipment, physical characteristics and function; and a drawing of the equipment showing piping and instrumentation;

(2) a listing of utility connections;

(3) evidence of manufacturer efficacy testing through the use of biological indicators by an independent laboratory;

(4) a list of the operating parameters (e.g., temperature, pressure, time, irradiation or chemical levels, etc.) that will be attained for microbial inactivation;

(5) frequency, location, and method for monitoring the operating parameters;

(6) procedures for and frequency of calibration of all instruments and controls and other preventive maintenance activities;

(7) procedures for loading the treatment device and unloading the treated waste; and

(8) a description of the controls [e.g., High Efficiency Particulate Air (HEPA) or charcoal filters, etc.] and their required replacement intervals and visual indicators used to prevent potential environmental emissions, occupational exposures or injuries.

(c) Operation and maintenance plan. The operation and maintenance plan must include:

(1) a description of the overall operation of the facility as follows:

(i) the method for unloading and processing of RMW; and

(ii) the method for decontaminating emptied reusable RMW containers, transport vehicles or facility equipment which are contaminated with RMW.

(2) a list of the type, purpose, size, capacity, and associated detention times for all waste handling, storage, consolidation and sorting equipment and structures, with supporting capacity calculations;

(3) a process flow diagram for RMW management during normal operation. The flow diagram must indicate the average and maximum daily quantity of material handled on a weight

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and volume basis;

(4) manufacturers' performance specifications for all major RMW handling equipment, which must include, for facilities using an alternative treatment system, a copy of the Department of Health approval issued to the system's manufacturer or operator;

(5) a description of all security measures used during operation of the facility;

(6) the operational procedures for each major facility component involved in RMW management;

(7) a description of monitoring and inspection that will be used to identify and correct equipment malfunctions or deteriorations, operator errors, and other malfunctions;

(8) a description of the proposed measures to handle RMW during periods of routine maintenance, emergencies, equipment breakdown, or facility start-up and shutdown;

(9) a list of the duration and timing of daily cleaning and maintenance and scheduled downtime maintenance each year and anticipated schedules for major equipment replacement;

(10) a description of how all equipment, PPE, or other items that have contacted RMW will be disinfected including identification of the disinfectant proposed to be used; and

(11) a list of receiving facilities that will be used for disposal.

(d) Personnel training and safety plan. The plan must include:

(1) a description of the employee training program that will be used to teach employees how to correctly operate the equipment that they must operate and to trouble-shoot problems with that equipment;

(2) a general awareness and familiarization component that outlines how each employee will become familiar with the risks associated with the handling of the RMW and with how those risks can be minimized; and

(3) a training component on how to manage compromised packaging and spills, or unauthorized wastes.

(e) Contingency plan. The plan must describe the actions that will be taken to address potential operational problems including, but not limited to, equipment malfunction or breakdown, delivery of unauthorized waste, waste not packaged appropriately, spills, fire, explosion, power failure, excessive noise, unacceptable odors, litter, and vectors. The plan must also include a contingency for disposal should processing equipment be non-functional for a period longer than seven calendar days.

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(f) Closure plan. The plan must describe how all the equipment and surfaces will be disinfected and how the facility will be closed.

(g) A validation and bio-challenge testing plan for treatment facilities. The plan must describe, in detail, the procedures for validation and bio-challenge testing, including, but not limited to the types of biological indicators employed in the tests, the timing of all testing, the location of all monitoring points, protocols and methods for monitoring, laboratory analytical techniques employed, and the laboratory(ies) that will be used for analyses. The plan must also provide sufficient information to address each of the applicable requirements identified in section 365-2.4 and section 365-2.5 of this Subpart.

(h) A wash water management plan that describes the facility's drainage system and the amount, with supporting calculations, of wash water emanating from the cleaning of areas, reusable containers or equipment that have come into contact with waste and the method to collect, store, and dispose of wash water.

(i) A certification that the facility conforms with applicable existing local zoning laws or ordinances and local solid waste management plans.

Section 365-2.4 Design and operating requirements for transfer, processing and/or treatment facilities

A facility required to obtain a permit under this Subpart must, in addition to the requirements identified in section 360.19 of this Title, design, construct, maintain, and operate the facility in compliance with the following criteria:

(a) An RMW tracking document must be received for each shipment of RMW accepted at the facility. The facility must not accept waste from unauthorized off-site sources (e.g., self-transporters, generators not authorized by the permit), or waste which is not accompanied by a tracking document.

(b) The facility must:

(1) ensure that only RMW delivered by a transporter authorized to transport RMW under Part 364 of this Title is received, unless otherwise approved by the department; and

(2) follow all directions on the tracking documents prior to accepting the waste.

(c) No facility may surrender a shipment of untreated RMW to a transporter unless the transporter has a valid permit issued under Part 364 of this Title which authorizes the transport of RMW.

(d) All incoming RMW must be handled in accordance with the following criteria:

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(1) RMW must not be accepted unless there is sufficient storage, transfer or treatment capacity.

(2) RMW must be inspected by facility staff prior to unloading to ensure that RMW has been packaged appropriately. Any broken packages must be handled in accordance with the approved contingency plan.

(3) No facility may accept a RMW shipment in bulk packaging, unless approved by the department.

(4) The facility must record the date of arrival of each waste load at the facility, the original generator identification, package type and weight, and the intended disposition of the waste.

(e) RMW handling and storage.

(1) Entry to the facility must be controlled at all times through the use of gates or other means.

(2) A sign must be conspicuously posted at each entrance to the facility that identifies the types of waste that are acceptable for delivery to the facility and the types of wastes that are not accepted at the facility. This sign must be a minimum of 12 inches high by 18 inches wide and have lettering a minimum of one inch in height. Signs that read "CAUTION - REGULATED MEDICAL WASTE. VISITORS AND UNAUTHORIZED PERSONNEL MUST REPORT TO THE OFFICE." must be posted at each entrance to the facility. These signs must include the universal biohazard warning symbol.

(3) RMW must be completely contained and secured with appropriate blocking and bracing during storage or when moved.

(4) RMW storage and handling procedures must minimize potential occupational exposures and environmental impacts.

(5) Containers must be stored in an upright, stable and controlled manner that minimizes the potential for leakage. The top of the stacked containers must not be more than 6 feet above the level of the floor. The containers must not be compromised by the manner of storage.

(6) Unauthorized wastes may be temporarily stored in areas specifically designed for these wastes on the facility site in accordance with the approved waste control plan.

(7) All facilities must be fully enclosed and must have an impermeable floor.

(8) RMW must not be processed to reduce the size of the RMW prior to treatment, unless approved by the department.

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(9) Manual or mechanical compaction or compression of RMW is prohibited.

(10) Trash chutes or slides must not be used to move RMW between containers, vehicles, or treatment devices unless the movement is controlled to maintain the integrity of the containers.

(11) Vehicles must be unloaded in a manner that does not cause containers to break or otherwise release RMW.

(12) Placement of RMW into bins or hoppers used to contain and load RMW into the treatment device, or consolidation containers, must be done under controlled conditions (e.g., under negative pressure, with air drawn away from the bin, hopper or consolidation container opening and passed through HEPA filters, or other methods approved by the department to control aerosols, etc.) wherever possible.

(13) Except for reusable containers authorized by the department to be opened, RMW containers must not be opened unless approved as part of the consolidation or treatment process.

(14) Storage of RMW that has the ability to become putrescent is limited to:

(i) three days after receipt at the facility if the RMW is stored at 45 degrees Fahrenheit (seven degrees Celcius). Nothing in this subparagraph exempts facilities that are subject to permit or registration requirements under another subpart.

(ii) seven days after receipt at the facility, if the RMW is stored at less than 45 degrees Fahrenheit (seven degrees Celsius); and

(iii) 30 days after receipt at the facility, if the RMW is stored in a freezer at less than 0 degrees Fahrenheit (-18 degrees Celsius);

(15) RMW waste which becomes putrescent must be treated, refrigerated, frozen, or removed from the facility within 12 hours of detection.

(16) Non-putrescent RMW can be stored for a maximum of seven days, at which time non-putrescent RMW must be immediately treated, refrigerated, frozen, or removed from the facility.

(17) Treated waste, except combustor ash or bone shadows, or reusable devices sorted from the RMW must be removed from the facility within seven days after treatment.

(18) Each facility must ensure that the worksite is maintained in a clean and sanitary condition, and implement a written schedule of appropriate cleaning and disinfection.

(19) Storage, transfer, and treatment areas containing RMW must be secured to prevent unauthorized access.

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(20) The unloading and loading areas must be adequate in size and design to facilitate efficient transfer of RMW to and from the collection vehicles and the unobstructed movement of vehicles. All unloading and loading must be performed on a concrete or asphalt surface.

(21) Floors must be free from standing water and waste debris. All drainage from cleaning areas must be collected and discharged in a manner acceptable to the department.

(f) Radiation monitoring. Radioactive waste detection procedures and requirements.

(1) A fixed radiation detection unit must be installed and operated at a location appropriate for the monitoring of all incoming RMW.

(2) The investigation alarm setpoint of the radiation detector must be set at least two times but no greater than five times site background radiation levels.

(3) Background radiation readings at the facility must be measured and recorded at least daily.

(4) Field checks of the radiation detector utilizing a known radiation source must be performed and recorded at least weekly.

(5) The radiation detector must be calibrated at least annually, and documentation describing the calibration must be maintained at the facility.

(6) Each instance in which the radiation detector is triggered by an RMW load must be documented. Information must include the date the waste was received, hauler name, origin of the waste, truck number or other identifying marking, detector reading, disposition of the waste, and date of disposition.

(7) Storage of RMW that triggers the radiological detection system beyond seven days is prohibited.

(8) Storage of RMW that triggers the radiological detection system must be secure, separate from other wastes, and appropriately shielded from employees or visitors, the environment, and vermin, and the storage area must be appropriately labeled.

(g) Sharps consolidation. Sharps consolidation prior to treatment must be conducted as follows:

(1) reusable sharps containers processed at the facility must be processed with an automated delidder and dumping system;

(2) reusable sharps containers and transport cages must be free of visible contamination and must be cleaned with a disinfectant registered for use by the department prior to reuse. Cleaning

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and disinfection must destroy bloodborne pathogens on inner and outer surfaces. Manual cleaning of reusable containers is not allowed;

(3) automated systems used for consolidation and cleaning of reusable sharps containers must be capable of treating the containers for a minimum of 15 seconds at 180 degrees Fahrenheit (82 degrees Celsius) during the wash cycle followed by exposure to a broad-spectrum antimicrobial agent registered for use by the department. All visible contamination must be removed;

(4) bio-challenge testing of the two-step cleaning and disinfection process for reusable containers must be done annually using a biological indicator or soil marker approved by the department;

(5) all reusable sharps containers must be approved by USFDA for reuse; and

(6) all reusable containers must be managed as RMW when removed from service.

(h) RMW recovery and recycling. Any recovery of RMW for third-party reprocessing of medical devices, or for reuse or recycling of materials must comply with the following:

(1) RMW generated from neurosurgery may not be recovered or recycled;

(2) recovery, segregation and sorting procedures must employ robotic or mechanical equipment or be treated in accordance with this Part prior to recovery, segregation or sorting. This equipment must be housed in a sealed physical containment device equipped with HEPA filtration systems capable of providing a negative pressure environment, be impervious to liquids and be used for all manipulations or sorting;

(3) recovery, segregation and sorting of RMW with robotic or mechanical equipment must minimize splashes or spills and include disinfectant sprays and other means such as PPE as needed to minimize worker exposure;

(4) untreated, recovered medical devices and recyclable materials are considered RMW and must either be disinfected or treated on-site in accordance with the RMW treatment requirements of this Subpart (i.e., autoclaving or an approved alternative treatment technology) prior to being sent off-site for third-party reprocessing, reuse or recycling.

(5) The mechanism for cleaning and disinfection of secondary containers must physically remove contamination. Cleaning and disinfection must include:

(i) for cleaning, use of a detergent and sufficient agitation or pressure to remove visible contamination from a surface; and

(ii) for disinfection, exposure to hot water at a temperature of at least 180 degrees Fahrenheit (82 degrees Celsius) for a minimum of 15 seconds, and exposure to a chemical

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disinfectant registered for use by the department used according to the manufacturer's label directions.

(6) If plastic, metal or other raw materials are recovered from the RMW stream for reuse or recycling, the waste must be handled, stored, treated and transferred separately from untreated and treated RMW, or recovered medical devices.

(7) Bio-challenge testing must be conducted in accordance with this Subpart for all treatment equipment (i.e., autoclaves or alternative treatment technologies) and for each load of waste where raw materials are proposed to be recovered for reuse or recycling. Bio-challenge testing must demonstrate a 6 log reduction in *Bacillus* spores for each load of waste proposed to be reused or recycled.

(8) Materials recovered for reuse or recycling from the RMW stream must be stored at the treatment facility until results of bio-challenge testing results have been obtained.

(9) All sharps must be rendered unrecognizable as intact sharps devices.

(10) A contingency procedure must be used for management of the waste in the event a 6 log reduction in *Bacillus* spores is not obtained or if sharps are not rendered unrecognizable.

(i) All treatment facilities must be operated in accordance with the following procedures:

(1) Loading devices must be automated or, if mechanical, designed and operated to maintain the integrity of the container being loaded into a treatment device.

(2) Process control instruments must be maintained in operable condition. All process instruments must be calibrated at the intervals recommended by the manufacturer, but not less than once per year.

(3) A general facility inspection must be undertaken at least annually to determine the operating condition of the process and control equipment. This annual inspection must be performed and a report prepared under the direction of an individual certified as an industrial hygienist with the American Board of Industrial Hygiene.

(4) All emptied reusable RMW containers, transport vehicles, and facility equipment must be appropriately washed and disinfected.

(5) The facility must implement a validation testing program in accordance with this Subpart and the approved validation and bio-challenge testing plan. The department must be notified at least two weeks prior to conducting validation testing at the facility. Waste will not be considered treated until the results of the testing programs have been approved, in writing, by the department.

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(j) Monitoring RMW treatment system operation must include both physical and microbiological methods that qualitatively and quantitatively assess one or more critical treatment parameters and that include:

(1) use of controls appropriate for the treatment system (i.e., real time monitoring devices that record process feed rate or flow, cycle time, pressure, temperature, pH, chemical or irradiation levels, etc.);

(2) biological monitors (e.g., thermochemical indicators and integrators such as autoclave tape, paper strips or small ampoules, thermocouples, wireless data loggers, etc., or other monitors suitable for the treatment technology) placed in or on the outside of RMW containers and distributed throughout the load, chamber, or vessel during treatment; and

(3) bio-challenge testing with each load that employs biological indicators that have a population and heat resistance level, or chemical or irradiation demand that is greater than the bioburden of the waste but that is able to verify compliance.

(k) RMW treatment system operation requirements.

(1) RMW treatment systems must not be used to treat RMW until the validation criteria identified in section 365-2.5 of this Subpart have been met and written approval from the department has been obtained.

(2) The treatment system must only be used to treat loads that contain those items or types of RMW for which effective treatment has been demonstrated by validation testing.

(3) Each load or batch must be treated using the treatment parameters that have been validated as effective for the treatment of the RMW, and conditions of treatment must be monitored and documented for each load or batch.

(4) If a treatment system fails to operate in accordance with the acceptable operating parameters, the facility must:

(i) discontinue use of the system, using emergency shutdown procedures if appropriate, until corrective action has been taken and, as determined by the department, repeat validation testing has verified that effective treatment can resume;

(ii) handle as untreated RMW all waste processed by the system since the last run where documented compliance with the requirements is available;

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

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

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(v) whenever a facility has reason to believe untreated waste certified as treated waste has left the facility, notify the waste transporter, the receiving facility, and the department immediately.

(l) RMW entering the treatment system must be in a container or containment system designed to withstand the operating conditions of the system, and may, except for sharps, consist solely of a bag.

(m) An operation log must be maintained for each treatment device. The log must record the date, time, name of operator, the type and amount of waste treated, operating parameters, and the dates and results of calibration and testing.

(n) Under no circumstances can a treatment system be operated at parameters less stringent than those established through efficacy testing by the manufacturer of the device or otherwise approved by the New York State Department of Health as an alternative treatment technology.

(o) Autoclaves or moist heat treatment systems. Autoclaves and treatment systems that use moist heat must expose the waste to saturated steam at temperatures sufficient to destroy the microorganisms throughout the load or batch during the standard treatment cycle. Demonstration of a minimum of a 4 log₁₀ reduction (6 log₁₀ reduction for *Bacillus anthracis*) of spores of resistant biological indicators must be conducted in accordance with section 365-2.5 of this Subpart. To conduct treatment with autoclaves or moist heat systems, the following is required:

(1) use of a pressure vessel, or an unpressurized treatment system that includes a size reduction (e.g., maceration) device;

(2) use of a temperature control system, an independent temperature sensor (located within the chamber), a thermostatic steam trap, a cycle timer and sequencing controller, a steam jacket or insulation, a door mechanism that prevents opening while under pressure or during operation, and a pressure indicator;

(3) direct contact between RMW and steam or heat transfer through the packaging with steam condensing directly on the RMW being treated;

(4) packaging of waste in steam or air permeable containers that are open, perforated or not sealed, or for low heat unpressurized moist heat systems (e.g., microwaves), in moving vessels exposed to size reduction (e.g., macerating) devices;

(5) removal of all air from the autoclave or moist heat systems (except microwaves) by employing three pre-vacuum cycles (or other demonstration that air is removed), or three steam pulses followed by vacuum extractions prior to the treatment hold phase of the cycle;

(6) steam (for autoclaves) supplied to the treatment system is at the point of saturation; and

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(7) for gravity displacement autoclaves, correct operation of the bottom drain and exit trap for removal of air; the rate of steam injected is added so that its natural buoyancy carries it upward, forcing the colder air down; and verify that there are no air pockets trapped near the top of the load.

(p) Alternative treatment systems must obtain New York State Department of Health approval as an alternative treatment technology. Operational parameters and testing procedures established and used during efficacy testing conducted for Department of Health approval must be utilized for the validation testing for site commissioning identified in section 365-2.5 of this Subpart.

(q) Treated waste may be disposed as solid waste at a combustion facility, landfill or other facility authorized by the department to accept treated RMW. Treated waste must be transported by an individual permitted under Part 364 of this Title. Sharps that are treated but not destroyed must be transported in accordance with Part 364 of this Title and must be accompanied by an RMW tracking document.

Section 365-2.5 Treatment requirements

Treatment of RMW is required prior to disposal. RMW must be treated at an approved RMW treatment facility.

(a) Special wastes.

(1) Cultures and stocks. Cultures and stocks (including culture dishes and devices for transferring, inoculating and mixing cultures) containing select agents or toxins, must be treated at the site of generation unless a facility lacking capability for on-site treatment generates the waste as an incident to the delivery of medical care. In that case, the generating facility must arrange for transport to a treatment facility. All other cultures and stocks may be taken off-site for treatment, unless on-site treatment is required by local health code.

(2) Sharps. Sharps that were in contact with infectious agents must be both treated and destroyed prior to disposal. Sharps not coming in contact with infectious agents do not have to be treated but must be destroyed.

(3) Pharmaceutical waste. Pharmaceutical waste and mixed and dual wastes that are disposed with RMW must be treated at an approved combustor or alternative treatment system, except as follows:

(i) mixed and dual wastes must be managed in accordance with 6 NYCRR Part 371 of this Title;

(ii) mixed and dual wastes combined with radioactive materials must be managed in

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accordance with Part 380 of this Title;

(iii) intravenous liquids may be disposed in the sanitary sewer, subject to local laws and regulations; and

(iv) biological drugs may be autoclaved.

(4) Tissues and organs. Human tissue, human organs, animal carcasses, animal organs, and/or animal body parts cannot be autoclaved unless the Department of Health has approved the autoclave model as an alternative treatment system by the Department of Health.

(5) Thermally resistant wastes. An autoclave used to treat thermally resistant waste (e.g., solidified liquids, bulk animal bedding) requires approval as an alternative treatment system by the Department of Health.

(6) BSL 3 or 4 waste. All solid waste generated within a containment area requiring BSL 3 or 4 precautions must be treated by a method approved by the department, at the site of generation.

(b) Treatment criteria. Except as outlined in subdivision (a) of this section, RMW must be treated by one of the following methods:

(1) Discharge of liquids or semi-liquids, blood or body fluids into a sewage treatment system that employs secondary treatment, except as specifically prohibited by the Department of Health, by local law or ordinance. Discharge to a septic system is not allowed. Facilities that treat liquid discharges with effluent decontamination systems (EDS) must conduct validation testing.

(2) Combustion in a facility or device authorized to accept RMW under a permit issued pursuant to Subpart 362-1 of this Title.

(3) Treatment in a gravity feed autoclave. Unless other operating parameters have been validated and approved by the Department of Health, the following operating parameters must be followed:

(i) a residence time of 60 minutes or longer at a temperature of at least 250 degrees Fahrenheit (121 degrees Celsius) measured in the coldest area of the waste as determined during validation testing, and a pressure of at least 15 pounds/square inch gauge (psig); or

(ii) a residence time of at least 45 minutes at a temperature at least 275 degrees Fahrenheit (135 degrees Celsius) measured in the coldest area of the waste as determined during validation testing, and a pressure of at least 31 psig.

(4) Treatment in a vacuum displacement autoclave. Unless other operating parameters have been validated and approved by the Department of Health, the following operating parameters

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must be followed:

(i) a residence time of at least 45 minutes at a temperature at least 250 degrees Fahrenheit (121 degrees Celsius) measured in the coldest area of the waste as determined during validation testing, and a pressure of at least 15 psig; or

(ii) a residence time of at least 30 minutes at a temperature at least 275 degrees Fahrenheit (135 degrees Celsius) measured in the coldest area of the waste as determined during validation testing, and a pressure of at least 31 psig.

(5) Treatment with an alternative treatment system approved by the Department of Health. Only the type of RMW specified in the Department of Health's approval may be treated using the approved technology. Only the model and specific alternative treatment system operating parameters that have been validated and approved by the Department of Health may be used for the treatment of RMW.

(c) Validation testing for site commissioning. Prior to using an autoclave or an alternative treatment system, including EDS, the facility must conduct validation testing that employs the use of process controls, process monitoring, and biological indicators during each validation test run. Written approval of validation test results must be obtained from the department prior to acceptance of RMW for treatment.

(1) The testing must include three separate treatment runs in accordance with the following requirements:

(i) the operational parameters used during the tests must be consistent with the parameters that will be used during routine operation of the treatment process (e.g., cycle duration, heat, chemical, or irradiation exposure time, chemical concentration, or other treatment parameters etc.);

(ii) for autoclaves, each test must include a minimum of three separate vacuums or demonstrate that air is removed;

(iii) the waste composition (e.g., porosity, liquids, solids, organic matter, thermal resistance and type of packaging etc.) and load configuration (e.g., packing density, orientation etc.) during the tests must be consistent with the waste properties and loading process during routine operation;

(iv) the moisture content (i.e., wet or dry) and volume of the waste during the tests must be consistent with the waste that will be treated during routine operation; and

(v) for EDS, the tests must represent the organic content, viscosity, and dwell time of the waste during routine operation.

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(2) To assess treatment performance, the system must employ commercially-prepared biological indicators from the same lot or batch, each containing spores of “*Geobacillus stearothermophilus*” (for steam or hydrogen peroxide systems), “*Bacillus atrophaeus*” (for dry heat or chemical systems) or an organism that demonstrates the necessary resistance for the treatment method, as determined by the department. The indicators must:

(i) have a minimum concentration of 6 log₁₀ spores. The concentration must be higher and more thermally resistant than the bioburden routinely associated with the waste;

(ii) include a supplier’s certificate of performance that identifies the organism (genus, species, strain and population), for thermal treatment systems, the D-value (decimal reduction value or thermal resistance) and the Z-value (the number of degrees of temperature required to change a D-value by one factor of ten). The D-value must be 1.8 minutes unless otherwise approved by the department and the Z-value must be no less than 50 degrees Fahrenheit (10 degrees Celsius).

(iii) be appropriate for the type of waste and device (i.e., self-contained, suspension or paper strip), including the shelf life, the carrier material and primary packaging, the culture medium (for self-contained biological indicators) and the media, growth and culture conditions (for non-self-contained biological indicators);

(iv) be compatible with the treatment process and have a resistance relative to the temperature, pressures, conditions, chemicals or irradiation used in the process, the infectious agents on a substrate, the type and density of the waste to be treated and its packaging;

(v) be placed throughout the waste load during each validation test, including at the coldest point (i.e., the worst-case position where the sum of all influences on microorganisms results in minimal inactivation for a defined waste load) in the treatment system. The department may also require alternative and/or supplemental indicators (e.g., thermocouples, etc.) to demonstrate chemical saturation, heat penetration or irradiation exposure and effectiveness of treatment;

(vi) comply with the following number of biological indicators in each validation test load:

(a) three biological indicators/cycle for 0-110 pounds waste load;

(b) five biological indicators/cycle for 111-550 pounds waste load;

(c) seven biological indicators/cycle for 551-1100 pounds waste load;

(d) nine biological indicators/cycle for 1101-1650 pounds waste load;

(e) 11 or more, as determined by the department, biological indicators/cycle

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for any treatment system greater than 1650 pounds of waste per load; and

(f) two or more controls from the same lot or batch as approved by the department;

(vii) be wrapped in a paper towel and encased in cotton batting or in another carrier system (e.g., including but not limited to net bags, tennis balls with holes in them, socks or alloy containers with holes in them, etc.) designed to mimic the thermal resistance in the waste before placement into the package to be treated with the waste. Materials used to hold the indicator units must be similar to the waste to be treated, provide effective protection from breakage, or otherwise being compromised, be loose in the bulk of the waste and be easily retrievable at the end of each validation run. Spore suspensions should be used where indicators are proposed to be in a fixed position; and

(viii) be wrapped in a thick layer of cotton wool, or equivalent to prevent direct conduction of heat from the metal if metal containers are used to contain the indicators.

(3) If multiple types of indicators are used in validation testing, no less than one third of the biological indicators used during each validation test run must be quantitatively analyzed after the treatment cycle using standard microbial bioassay methods. All other paired biological indicators used for test runs must be qualitatively analyzed for color change following incubation.

(4) Unless otherwise approved by the department, the laboratory used to analyze the results of the validation test of a treatment system must be independent of the facility owner or operator.

(5) The system must employ process monitoring concurrent with biological monitoring, including:

(i) thermochemical indicators (e.g., tape, paper strips, small ampoules, etc.) that the waste has been exposed to a certain temperature, but does not identify how long the waste was exposed or other parameters;

(ii) thermochemical integrators (e.g., wireless data loggers, thermocouples, etc.) that are placed in or on waste packages and that provide a measurable record of treatment conditions; and

(iii) real-time instrumentation integral to the treatment system (i.e., parametric monitoring devices) that reacts quantitatively in response to one or more critical operational treatment parameters and provides an electronic or paper record.

(6) Verification testing for commercially purchased biological indicators. Each lot or batch of commercial biological indicators with a stated population must be tested when received and prior to use for initial validation testing and any subsequent re-validation or bio-challenge testing, to verify the accuracy of the population count and thermal resistance identified in the supplier's certificate of performance. Each verification test must use a minimum of three

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indicators from the same lot or batch that must be sent to an independent laboratory approved by the department and evaluated for spore population and thermal resistance.

(7) All commercially purchased biological indicators must be stored in accordance with the manufacturer's specifications.

(8) Unless otherwise determined by the department, all lots or batches of commercially-purchased biological indicators stored for more than six months must be tested quarterly after the first six months following purchase to verify the stated population and thermal resistance. A minimum of three indicators must be quantitatively analyzed by an independent laboratory, which must report the number of spores per indicator and assess the thermal resistance.

(9) Commercially-purchased indicators in the form of paper strips must not be used in devices or areas where fluids can pool or puddle around the biological indicator.

(d) Effective treatment of RMW. Treatment of RMW must be demonstrated by a 4 log₁₀ or greater reduction in viable "*G. stearothermophilus*" spore concentration, or other biological indicator or measure of effectiveness for alternative and/or supplemental indicators as specified by the department. In certain situations where the waste poses a greater risk (e.g., a higher bioburden waste), the department may require a greater reduction. Appropriate measures that must be demonstrated during validation testing also include the following:

(1) for infectious agents including certain vegetative bacteria, fungi, lipophilic and hydrophilic viruses, parasites, mycobacteria, and similar organisms, a 6 log₁₀ reduction or greater must be demonstrated;

(2) for human pathological and animal waste, the treatment must destroy any human or animal tissue, organ or body part so that it is no longer visually recognizable;

(3) for cultures and stocks and sharps, the treatment must render any syringes, needles, culture dishes, devices or any other equipment or item unusable and no longer in their original shape and form;

(4) for toxins, the treatment must inactivate the substance so that it is no longer toxic (e.g., as determined by validation testing using specific toxin bioassays); and

(5) all physical and chemical monitors employed during the validation test must yield results that indicate the critical treatment parameters have been met.

(e) Repeat validation testing. Validation testing must be repeated when any of the following occurs:

(1) failure of any treatment process operational parameters such as time, temperature, or pressure during site commissioning;

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(2) failure to achieve microbial inactivation in each biological indicator during each treatment cycle during site commissioning;

(3) any modifications to any of the treatment process operational parameters, bioburden, waste mass, chemical type, concentration or contact time, irradiation or type of waste to be treated, or mechanical or engineering changes to the treatment system from those assessed during the site commissioning;

(4) a failure identified in paragraph (1) or (2) of this subdivision, during bio-challenge testing, or as identified by parametric controls, physical or chemical monitors, that occurs three or more times in a calendar year or during the first 30 days of actual operation or

(5) a treatment device has been operational without a repeat validation for at least five years.

(f) Routine bio-challenge testing for autoclaves. Unless otherwise approved by the department, each autoclave that has been validated and authorized to treat RMW must, at a minimum, for the first 30 days of actual operation, undergo bio-challenge testing for each load of waste. Each test must include the use of process controls and biological indicators, with each load of RMW. Following the first 30 days of actual operation, bio-challenge testing must be conducted at a minimum of once per day. After six months of successful operation with no failures in daily testing, bio-challenge testing may be conducted every 40 hours of operation. Any bio-challenge test failures during the first six months of actual operation will require a return to daily testing for at least 30 days. Bio-challenge testing must include at least one-third of the number of biological indicators that are required for the site commissioning validation test or two indicators, whichever is greater, unless otherwise determined by the department. Every 200 hours of operation, biological indicators used during bio-challenge testing must be evaluated by an independent laboratory. Bio-containment facilities using pass-through treatment systems must conduct bio-challenge testing for each load of RMW.

(g) Routine bio-challenge testing for alternative treatment systems. All facilities using alternative treatment systems must conduct bio-challenge testing. Alternative treatment systems that employ processes that are unable to inactivate bacterial spores during treatment of infectious organic materials must comply with bio-challenge testing requirements as determined by the department on a case-by-case basis.

(h) Certificate of treatment. Treated RMW must be accompanied by a Department of Health certificate of treatment.

Section 365-2.6 Recordkeeping and reporting requirements

The following requirements apply to all facilities required to obtain a registration or permit under this Part:

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(a) The facility must keep records as required by this Subpart and subdivision 360.19(1) of this Title.

(b) The facility must submit an annual report as required by paragraph 360.19(1)(3) of this Title, which contains, at a minimum:

(1) the quantity and type of waste received, by source, volume and weight. The data must include monthly summaries, and the annual totals;

(2) the quantity and type of untreatable, bypass, and unauthorized waste received, by volume and weight, and the disposal location(s) for these wastes. The data must include monthly summaries, and the annual totals;

(3) the quantity of treated waste, by volume and weight, and the location of disposal. The data must include monthly summaries, and the annual totals;

(4) a summary of all monitoring data (time, temperature, pressure, etc.) for each load processed in the treatment units, with a description of the location of all monitoring points that correlate to the data;

(5) a description of all biological indicator tests to verify the supplier's certificate of conformance, validation and bio-challenge testing or monitoring that occurred including:

(i) the date, location, and time of testing or measurements;

(ii) the name of the laboratory that performed the validation tests or measurements;

(iii) the date(s) analyses were performed;

(iv) analytical techniques or methods used;

(v) a copy of all analyses and results; and

(vi) a record of all calibrations on parametric monitoring devices; and

(6) a copy of the facility inspection report and a description of all incidents, including spills in transit, that required implementation of the contingency plan and the actions taken to abate the incidents.

SUBPART 365-3

HOUSEHOLD MEDICAL WASTE SHARPS COLLECTION FACILITIES

- 365-3.1 Applicability**
- 365-3.2 Exempt facilities**
- 365-3.3 Registered facilities**
- 365-3.4 Recordkeeping and reporting requirements**

Section 365-3.1 Applicability

In addition to the requirements contained in Part 360 of this Title, this Subpart applies to the collection, storage and handling of household medical waste sharps at locations other than a household.

Section 365-3.2 Exempt facilities

The following facilities are exempt from this Subpart:

- (a) Household medical waste sharps collection and storage facilities located at a hospital, residential health care facility, or diagnostic treatment center as defined by Section 2801 of the PHL, as incorporated by reference in section 360.3 of this Title, provided the sharps are transported to the facility by the household generator and the collected sharps are packaged, transported, and treated as RMW.

Section 365-3.3 Registered facilities

A secure tamper-proof collection station (e.g., kiosks, drop boxes or other containers) for the collection and storage of household-generated medical waste sharps is subject to the registration provisions of section 360.15 of this Title. In lieu of the criteria in section 360.19 of this Title, except for subdivision 360.19(1), the facility must comply with the criteria in section 365-3.4 of this Subpart and the following requirements:

- (a) the facility participating as a household medical waste sharps collection facility must be registered with the Department of Health's AIDS Institute under the Safe Sharps Collection Program as a collection site;
- (b) the facility must have a plan that contains policies and procedures specific to the management of household medical waste sharps in accordance with the Department of Health approval. The policies and procedures must include provisions for safe drop-off and handling of sharps. The plan must also include the contact information for persons responsible for monitoring compliance with the plan;

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- (c) only household-generated sharps (including lancets, hypodermic needles and syringes) may be accepted by the facility. Sharps generated by a licensed health care provider offering services in the home are not considered household-generated;
- (d) household sharps delivered to the facility must be contained in sealed, rigid, puncture resistant, leak-proof and closable containers. Loose sharps may not be accepted at the facility. The facility may provide personal sharps containers as necessary for clients that use the facility;
- (e) personal sharps containers must be deposited directly into the secure and tamper proof collection station and can only be removed by appropriately trained authorized personnel;
- (f) containers must not be filled beyond the fill line indicated on the container;
- (g) collection areas must be monitored and have other provisions during operation to prohibit unauthorized access;
- (h) the storage of sharps containers at the facility is limited to a maximum of 30 days after first placement of a sharp;
- (i) the sharps must be packaged, transported, treated, and managed as RMW in accordance with Subpart 365-2 of this Part; and
- (j) owners of multiple facilities registered in accordance with this Subpart may consolidate collected sharps at one location, provided the storage does not exceed 220 pounds per month.

Section 365-3.4 Recordkeeping and reporting requirements

- (a) Any facility subject to this Subpart must keep records as required by subdivision 360.19(1) of this Title.
- (b) Any facility subject to this Subpart is not required to submit an annual report as required by paragraph 360.19(1)(3) of this Title.

SUBPART 365-4

OTHER BIOHAZARD WASTE MANAGEMENT FACILITIES

- 365-4.1** **Applicability**
- 365-4.2** **Exempt facilities**
- 365-4.3** **Permit application requirements for transfer, processing, and/or treatment facilities**
- 365-4.4** **Design and operating requirements for transfer, processing, and/or treatment facilities**
- 365-4.5** **Treatment requirements**
- 365-4.6** **Recordkeeping and reporting requirements**

Section 365-4.1 **Applicability**

In addition to the requirements contained in Part 360 of this Title, this Subpart applies to facilities that store, handle, or treat biohazard waste that is not regulated medical waste. This Subpart does not apply to household medical waste sharps collection facilities.

Section 365-4.2 **Exempt facilities**

Rendering facilities for animal tissue that are capable of treating infectious agents are exempt from this Subpart.

Section 365-4.3 **Permit application requirements for transfer, processing, and/or treatment facilities**

Any facility for the transfer, processing, or treatment of biohazard waste, which is not exempt pursuant to sections 365-1.3 or 365-4.2 of this Part or subject to the registration provisions of section 365-2.2 of this Part, must obtain a permit. The permit application must include the requirements identified in this section and section 360.16 of this Title, and a description of how the facility will comply with the operating requirements of section 360.19 of this Title, and sections 365-4.4, 365-4.5, and 365-4.6 of this Subpart.

(a) A waste control plan that describes:

(1) the biohazard waste that will be accepted and/or treated at the facility including the type, source, and quantity. The description of the quantity must specify the expected average and maximum daily and annual amounts, on a weight and volume basis;

(2) how the facility will ensure that it only receives biohazard waste, or other wastes capable of being managed at the facility;

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(3) how the facility will identify, store, and dispose of all waste received that cannot be managed at the facility, such as solid waste, anatomical or pathological waste and other waste not authorized by the department. The description must include information for storing waste in a manner appropriate for its biological or chemical properties;

(4) the methods used to manage the biohazard waste that ensure odor, litter and vermin or pests are controlled;

(5) how the transfer, processing, or treatment of the biohazard waste will occur in a rotation based on identification of its type, age on arrival, date of arrival and duration of storage on-site;

(6) how the facility will handle spills, breached containers or contaminated equipment used for handling the biohazard waste; and

(7) how inventory will be managed and the method that will be used to manage the required tracking forms.

(b) Treatment equipment and process description. Treatment facilities must provide a detailed description of the treatment device(s) including:

(1) an explanation of the equipment features (e.g., model number, capacity and material construction, etc.), ancillary equipment, physical characteristics and function; a drawing of the equipment showing piping and instrumentation;

(2) a listing of utility connections;

(3) evidence of manufacturer efficacy testing, if required by the department, through the use of biological indicators by an independent laboratory;

(4) a list of the operating parameters for microbial inactivation and the frequency, location, and method for monitoring the operating parameters;

(5) procedures for and frequency of calibration of all instruments and controls and other preventive maintenance activities;

(6) procedures for loading the treatment device and unloading the treated waste; and

(7) a description of the controls [e.g., High Efficiency Particulate Air (HEPA) or charcoal filters, etc.] and their required replacement intervals and visual indicators used to prevent potential environmental emissions, occupational exposures or injuries.

(c) Operation and maintenance plan. The operation and maintenance plan must include:

(1) a description of the overall operation of the facility as follows:

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- (i) a method of unloading and processing of biohazard waste; and
 - (ii) a method of decontaminating emptied reusable biohazard waste containers, transport vehicles or facility equipment which are contaminated with biohazard waste.
- (2) a listing of the type, purpose, size, capacity, and associated detention times for all biohazard waste handling, storage, consolidation and sorting equipment and structures, with supporting capacity calculations;
 - (3) a process flow diagram for biohazard waste management during normal operation. The flow diagram must indicate the average and maximum daily quantity of material handled on a weight and volume basis;
 - (4) manufacturers' performance specifications for all major handling equipment;
 - (5) the operational procedures for each major facility component involved in biohazard waste management;
 - (6) a description of the proposed measures to handle biohazard waste during periods of routine maintenance;
 - (7) a list of the duration and timing of daily cleaning and maintenance and scheduled downtime maintenance each year and anticipated schedules for major equipment replacement;
 - (8) a description of how all equipment, PPE, or other items that have contacted biohazard waste will be disinfected including identification of the disinfectant proposed to be used; and
 - (9) a list of receiving facilities that will be used for disposal.
- (d) Personnel training and safety plan. The plan must include:
- (1) a description of the employee training program that will be used to teach employees how to correctly operate the equipment that they must operate and to trouble-shoot problems with that equipment;
 - (2) a general awareness and familiarization component that outlines how each employee will become familiar with the risks associated with the handling of the biohazard waste and how those risks can be minimized; and
 - (3) a training component on how to manage compromised packaging and spills, or emergency situations.
- (e) Contingency plan. The plan must describe the actions that will be taken to address potential operational problems including, but not limited to, equipment malfunction or breakdown, delivery of unauthorized waste, waste not packaged appropriately, spills, fire, explosion, power failure,

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excessive noise, unacceptable odors, litter, and vectors. The plan must also include a contingency for disposal should processing equipment be non-functional for a period longer than 7 calendar days.

(f) Closure plan. The plan must describe how all equipment will be disinfected and how the facility will be closed.

(g) A validation and bio-challenge testing plan for treatment facilities, if required by the department. The plan must describe, in detail, the procedures for validation and bio-challenge testing, including, but not limited to the types of biological indicators employed in the tests, the timing of all testing, the location of all monitoring points, protocols and methods for monitoring, laboratory analytical techniques employed, and the laboratory(ies) that will be used for analyses. The plan must also provide sufficient information to address each of the applicable requirements identified in section 365-4.4 and section 365-4.5 of this Subpart.

(h) A wash water management plan that describes the facility's drainage system and the amount, with supporting calculations, of wash water emanating from the cleaning of areas, reusable containers or equipment that have come into contact with waste and the method to collect, store, and dispose of wash water.

Section 365-4.4 Design and operating requirements for transfer, processing and/or treatment facilities

A facility required to obtain a permit under this Subpart must, in addition to the requirements identified in section 360.20 of this Title, design, construct, maintain, and operate the facility in compliance with the following criteria:

(a) A biohazard waste tracking document must be received for each shipment of biohazard waste accepted at the facility. The facility must not accept waste from unauthorized off-site sources (e.g., self-transporters, generators not authorized by the permit), or waste which is not accompanied by a tracking document.

(b) The facility must:

(1) ensure that only biohazard waste transported by an authorized transporter under Part 364 of this Title is received unless otherwise approved by the department; and

(2) follow all directions on the biohazard waste tracking documents prior to accepting the waste.

(c) No facility may surrender a shipment of untreated biohazard waste to a transporter unless the transporter has a valid permit issued under Part 364 of this Title which authorizes the transport of biohazard waste.

(d) All incoming biohazard waste must be handled in accordance with the following criteria:

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(1) Biohazard waste must not be accepted unless there is sufficient storage, transfer or treatment capacity.

(2) Biohazard waste must be inspected by facility staff prior to unloading to ensure that RMW has been packaged appropriately. Any broken packages must be handled in accordance with the approved contingency plan.

(3) No facility may accept a biohazard waste shipment in bulk packaging, unless approved by the department.

(4) The facility must record the date of arrival of each waste load at the facility, the original generator identification, package type and weight, and the intended disposition of the waste.

(e) Biohazard waste handling and storage.

(1) Entry to the facility must be controlled at all times through the use of gates or other means.

(2) Biohazard waste must be completely contained and secured with appropriate blocking and bracing during storage or when moved.

(3) Biohazard waste storage and handling procedures must minimize potential occupational exposures and environmental impacts. Waste must not be compressed or compacted during storage.

(4) Containers must be stored in an upright, stable and controlled manner that minimizes the potential for leakage and human exposure to biohazard waste. The top of the stacked containers must not be more than six feet above the level of the floor. The containers must not be compromised by the manner of storage.

(5) Unauthorized wastes may be temporarily stored in areas specifically designed for these wastes on the facility site in accordance with the approved waste control plan.

(6) All facilities must be fully enclosed with an impermeable surface for the floor, unless composting has been approved for the management of animal mortalities. Composting facilities must follow the criteria outlined in section 361-3.5 of this Title that apply to source separated organics.

(7) Biohazard waste must not be processed to reduce the size of the biohazard waste prior to treatment, unless approved by the department.

(8) Vehicles must be unloaded in a manner that does not cause containers to break or otherwise release biohazard waste.

(9) Biohazard waste placed into bins or hoppers used to contain and load biohazard waste into

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the treatment device, or consolidation containers, must be done under controlled conditions (e.g., under negative pressure, with air drawn away from the bin, hopper or consolidation container opening and passed through HEPA filters, or other methods approved by the department to control aerosols) wherever possible.

(10) Except for reusable containers authorized by the department to be opened, biohazard waste containers must not be opened unless such procedure is part of the approved consolidation or treatment process.

(11) Storage of biohazard waste that has the ability to become putrescent is limited to:

(i) three days after receipt at the facility if the biohazard waste is stored at 45 degrees Fahrenheit (seven degrees Celsius) or above;

(ii) seven days after receipt at the facility, if the biohazard waste is stored at less than 45 degrees Fahrenheit (seven degrees Celsius); and

(iii) 30 days after receipt at the facility, if the biohazard waste is stored in a freezer at less than 0 degrees Fahrenheit (-18 degrees Celsius);

(12) Biohazard waste which becomes putrescent must be treated, refrigerated, frozen, or removed from the facility within 12 hours of detection.

(13) Non-putrescent biohazard waste can be stored for a maximum of 30 days, at which time non-putrescent waste must be immediately treated, refrigerated, frozen, or removed from the facility.

(14) Treated waste, except combustor ash or bone shadows, or reusable devices sorted from the biohazard waste must be removed from the facility within seven days after treatment.

(15) Each facility must ensure that the worksite is maintained in a clean and sanitary condition, and implement a written schedule of appropriate cleaning and disinfection.

(16) Storage, transfer, and treatment areas containing biohazard waste must be secured to prevent unauthorized access.

(17) The unloading and loading areas must be adequate in size and design to facilitate efficient transfer of biohazard waste to and from the collection vehicles and the unobstructed movement of vehicles. All unloading and loading must be performed on a concrete or asphalt surface.

(18) Floors must be free from standing water and waste debris. All drainage from cleaning areas must be collected and discharged in a manner acceptable to the department.

(f) All treatment facilities must be operated in accordance with the following procedures:

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(1) Loading devices must be automated or, if mechanical, designed and operated to maintain the integrity of the container being loaded into a treatment device.

(2) Process control instruments must be maintained in operable condition. All process instruments must be calibrated at the intervals recommended by the manufacturer, but not less than once per year.

(3) All emptied reusable biohazard waste containers, transport vehicles, and facility equipment must be appropriately washed and disinfected.

(4) If required by the department, the facility must implement a validation testing program in accordance with this Subpart and the approved validation and bio-challenge testing plan. The department must be notified at least two weeks prior to conducting validation testing at the facility. Operation of the facility beyond start-up and validation testing is not authorized until the results of the testing programs have been approved, in writing, by the department.

(g) Monitoring biohazard waste treatment system operation must include both physical and microbiological methods that qualitatively and quantitatively assess one or more critical treatment parameters and that include:

(1) use of controls appropriate for the treatment system (i.e., real-time monitoring devices that record process feed rate or flow, cycle time, pressure, temperature, pH, chemical or irradiation levels, etc.);

(2) biological monitors, if required (e.g., thermochemical indicators and integrators such as autoclave tape, paper strips or small ampoules, thermocouples, wireless data loggers, etc., or other monitors suitable for the treatment technology) placed in or on the outside of biohazard waste containers and distributed throughout the load, chamber, or vessel during treatment; and

(3) bio-challenge testing, if required, with each load that employs biological indicators that have a population and heat resistance level, or chemical or irradiation demand that is greater than the bioburden of the waste but that is able to verify compliance.

(h) Biohazard waste treatment system operation requirements.

(1) Treatment systems must not be used until the criteria used for treatment and verification of the ability of the equipment to meet the criteria have been approved in writing by the department.

(2) The treatment system must only be used to treat loads that contain those items or types of biohazard waste for which effective treatment has been demonstrated.

(3) Each load or batch must be treated using the treatment parameters that have been validated as effective for the treatment of the biohazard waste, and conditions of treatment must be monitored and documented for each load or batch.

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(4) If a treatment system fails to operate in accordance with the acceptable operating parameters, the facility must:

(i) discontinue use of the system, using emergency shutdown procedures if appropriate, until corrective action has been taken and, as determined by the department, repeat validation testing has verified that effective treatment can resume;

(ii) handle all waste processed by the system since the last run where documented compliance with the requirements is available as untreated biohazard waste;

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

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

(v) whenever a facility has reason to believe untreated waste certified as treated waste has left the facility, notify the waste transporter, the receiving facility, and the department immediately.

(i) Biohazard waste entering the treatment system must be in a container or containment system designed to withstand the operating conditions of the system.

(j) An operation log must be maintained at each treatment system device that is complete for the preceding one-year period. The log must record the date, time, name of operator, the type and approximate amount of waste treated, and operating parameters.

(k) Autoclaves or moist heat treatment systems. Autoclaves and treatment systems that use moist heat must expose the waste to saturated steam at temperatures sufficient to destroy the microorganisms throughout the load or batch during the standard treatment cycle. Demonstration of a minimum of a 4 log₁₀ reduction of 6 log₁₀ spores of resistant biological indicators must be conducted in accordance with section 365-4.5 of this Part. To conduct treatment with autoclaves or moist heat systems, the following is required:

(1) use of a pressure vessel, or an unpressurized treatment system that includes a size reduction (maceration) device;

(2) use of a temperature control system, an independent temperature sensor (located within the chamber), a thermostatic steam trap, a cycle timer and sequencing controller, a steam jacket or insulation, a door mechanism that prevents opening while under pressure or during operation, and a pressure indicator;

(3) direct contact between waste and steam or heat transfer through the packaging with steam condensing directly on the waste being treated;

(4) packaging of waste in steam or air permeable containers that are open, perforated or not

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sealed, or for low heat unpressurized moist heat systems (e.g., microwaves), in moving vessels exposed to macerating devices;

(5) removal of all air from the autoclave or moist heat systems (except microwaves) by employing three pre-vacuum cycles (or other demonstration that air is removed), or three steam pulses followed by vacuum extractions prior to the treatment hold phase of the cycle;

(6) steam (for autoclaves) supplied to the treatment system is at the point of saturation; and

(7) for gravity displacement autoclaves, correct operation of the bottom drain and exit trap for removal of air; the rate of steam injected is added so that its natural buoyancy carries it upward, forcing the colder air down; and verify that there are no air pockets trapped near the top of the load.

(l) Alternative treatment systems must obtain Department of Health approval as an alternative treatment technology. Operational parameters and testing procedures established and used during efficacy testing conducted for Department of Health approval must be utilized for the validation testing for site commissioning identified in section 365-4.5.

(m) Treated waste may be disposed as solid waste at a combustion facility, landfill or other facility authorized by the department to accept biohazard waste after it has been treated. Treated waste must be transported by a transporter permitted under Part 364 of this Title.

Section 365-4.5 Treatment requirements

Treatment of biohazard waste is required prior to disposal. The type of treatment allowed will depend on the infectious agent or toxin present and will be determined by the department, in consultation with the Department of Health. In some cases, as determined by the department, additional treatment may be required before disposal is allowed. Examples of treatment that may be approved include:

(1) Combustion in a facility or device authorized to accept RMW under a permit issued pursuant to Subpart 362-1 of this Title.

(2) Treatment in an autoclave (except animal carcasses) permitted under this Part to handle RMW.

(3) Degradation of animal carcasses or similar wastes by alkaline hydrolysis in a manner in which tissues are dissolved and bones and teeth are softened and the following operating criteria are met:

(i) A sodium hydroxide (NaOH) or potassium hydroxide (KOH) solution (or combination thereof) is used in an amount that assures approximate molar equivalency to the weight, type and composition of the animal or other waste to be digested. In the case of high fat in the animal waste that neutralizes the base, the added base is adjusted to the current fat content of the

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material.

(ii) The animal or other waste and alkali mixture are heated to a core temperature of at least 302 degrees Fahrenheit (150 degrees Celsius) for at least 6 hours (for prions) or as otherwise authorized by the department without interruption and at a pressure (absolute) of at least 4 bars.

(iii) The process is carried out in a batch mode and the material in the vessel is constantly mixed.

(iv) The waste is treated in such a manner that the time, temperature, and pressure requirements are achieved at the same time.

(v) If the liquid residue is discharged to a sewer system, the receiving sewage treatment plant must employ secondary treatment and the local authority must approve the discharge.

(4) Degradation at rendering facilities that are capable of treating the infectious agent.

(5) Composting of the waste under the Class A pathogen reduction criteria outlined in Subpart 361-3 of this Title.

(6) An alternative treatment system provided the system has been approved for the treatment by the Department of Health.

Section 365-4.6 Recordkeeping and reporting requirements

(a) The facility must keep records as required by this Subpart and subdivision 360.19(1) of this Title.

(b) The facility must submit an annual report as required by paragraph 360.19(1)(3) of this Title, which contains, at a minimum:

(1) the quantity and type of waste received, by source, volume and weight. The data must include monthly summaries, and the annual totals;

(2) the quantity and type of untreatable, bypass, and unauthorized waste received, by volume and weight, and the disposal location(s) for these wastes. The data must include monthly summaries, and the annual totals;

(3) the quantity of treated waste, by volume and weight, and the location of disposal. The data must include monthly summaries, and the annual totals;

(4) a summary of all monitoring data (time, temperature, pressure, etc.) for each load processed in the treatment units, with a description of the location of all monitoring points that correlate to the data;

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(5) a description of all incidents, including spills in transit, that required implementation of the contingency plan and the actions taken to abate the incidents.