6 CRR-NY IV B 365 Notes

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OFFICIAL COMPILATION OF CODES, RULES AND REGULATIONS OF THE STATE OF NEW YORK

TITLE 6. DEPARTMENT OF ENVIRONMENTAL CONSERVATION

CHAPTER IV. QUALITY SERVICES

SUBCHAPTER B. SOLID WASTES

PART 365. REGULATED MEDICAL WASTE AND OTHER INFECTIOUS WASTES

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(Statutory authority: Environmental Conservation Law, §§ 1-0101, 3-0301, 19-0301, 19-0303, 19-0306; art. 27, titles 1, 7, 15; art. 70, title 1; art. 71, titles 27, 35, 40, 44)

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SUBPART 365-1. RMW GENERATORS

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365-1.1 Applicability.

In addition to the requirements contained in Part 360 of this Title, this Subpart applies to generators of regulated medical waste (RMW) as defined in section 360.2 of this Title. These regulations apply to veterinary practices, animal research facilities, radiopharmacies, waste management facilities, and any other facilities or persons who generate RMW or other infectious waste. This Subpart does not apply to hospitals, residential health care facilities, diagnostic and treatment centers (defined in section 2801 of the Public Health Law) and clinical laboratories (defined in section 571 of the Public Health Law) except to the extent hospitals use bulk packaging or accept RMW from off-site.

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365-1.2 Management of RMW by the generator.

(a) Waste management plan.

(1) A generator of RMW is responsible for properly identifying and segregating the waste and must develop, document and implement policies and procedures specific to the management of RMW generated on-site, and for labeling RMW based on the planned method of treatment (*e.g.*, autoclave, incineration, etc.) off-site. The policies and procedures must include, but are not limited to:

(i) a description of the types, and method(s) for treatment or disposal of RMW generated on-site;

(ii) the procedures, including the employee training, for safe handling and transport of the RMW within the facility from the point of generation or acceptance to the point of storage and/or treatment;

(iii) a description of short and long term storage areas including, as applicable, patient care areas, laboratories, production and testing rooms, etc. which details the location, ventilation and capacity of each storage area, and the length of time waste is to be retained in each area;

(iv) the titles and contact information for persons responsible for monitoring compliance with the waste management plan;

(v) for facilities that treat RMW on-site, an operation plan for each treatment system employed; and

(vi) a contingency plan that addresses emergencies, spills, and other unexpected events.

(b) Containment and storage.

(1) RMW must be separated from other waste as soon as practicable at the point of generation prior to storage, treatment or disposal.

(2) Containers holding RMW that cannot be treated by an autoclave or other approved treatment technology must be labeled accordingly. The label must identify waste types and acceptable treatment method (*e.g.*, incinerate only, etc.).

(3) RMW that contains radioactive isotopes must be stored until decayed to a background radiation level prior to transport off-site, unless returned to the dispensing radiopharmacy or managed as a prohibited radioactive material.

(4) RMW must be contained in a primary container, defined in paragraph (13) of this subdivision.

(5) A sharps container must not be filled beyond the fill line indicated on the container.

(6) 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, defined in paragraph (14) of this subdivision, prior to off-site transport.

(7) Sharps containers must be removed from the patient care or use areas to a room or area designated for RMW storage when: the container has reached the fill line indicated on the container; the container generates odors or other evidence of putrification; or within 90 days of use, whichever occurs first.

(8) RMW, except sharps, may be held in patient care areas for a period not to exceed 24 hours and at a laboratory or other generation area for a period not to exceed 72 hours, at which time the RMW shall be moved to an RMW storage area. Notwithstanding these timeframes, RMW that generates odors or other evidence of putrification must be moved to a storage area as soon as practicable.

(9) An RMW storage area must be adequately sized for the volume of RMW generated between scheduled waste pick-ups by a transporter, or, for facilities treating the waste on-site, the volume of waste that can be treated on-site within a 24-hour period.

(10) An RMW storage area must:

(i) display prominent signage indicating the area 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;

(v) be appropriately ventilated; and

(vi) be of sufficient size to allow clear separation of RMW from any other waste, if waste other than RMW is stored in the same area.

(11) RMW must not be stored in a storage area for a period exceeding 30 days, except for a generator of less than 50 pounds of RMW per month that does not accept RMW for treatment from other facilities may store RMW for a period not exceeding 60 days. For bulk packaging storage must be in accordance with subparagraphs (14)(vi) and (vii) of this subdivision. For radiological RMW, the RMW may be stored for a period of time necessary to allow decay to a background radiation level, or if long lived must be managed as a prohibited radioactive material (including waste disposal).

(12) Prior to transport of RMW off-site for treatment, the:

(i) primary containers, except sharps containers, must be placed in a secondary container, and must be marked prominently with the universal biohazard symbol or the word Biohazard; and, if applicable, with an affixed label indicating that the contents require special handling (*e.g.*, incinerate only, etc.); and

(ii) primary containers must be labeled with the name and address of the generating facility when placed in a secondary container that is a bulk container used by multiple generators.

(13) Requirements for primary containers.

(i) Primary containers, with the exception of sharps containers, must be a plastic bag that complies with the standards prescribed by 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 Federal requirements.

(ii) The primary container for discarded sharps must be rigid, leak-proof on the sides and bottom, puncture-resistant and closable, and may serve as a secondary container for purposes of transport, provided it meets the definition of a secondary container.

(iii) Primary containers must not be filled in a manner that results in the breakage of the container.

(iv) Primary containers in laboratory and clinical settings must be kept in secure locations (*e.g.*, access restricted rooms) when in use and must be properly closed when moved to other locations. In other settings, primary containers must be properly closed at all times when not being filled.

(v) Only primary containers that have been approved for reuse by the United States Food and Drug Administration (FDA), may be reused.

(vi) Prior to transport off-site, RMW must be placed in commercially manufactured disposable (*e.g.*, fiberboard boxes that meet USDOT HMR specifications) or reusable secondary containers.

(14) Requirements for secondary containers.

(i) Secondary containers must comply with the standards prescribed by the USDOT found at at 49 CFR 173.134, 173.196, 173.197, and 173.199 as incorporated by reference in section 360.3 of this Title. Reusable secondary containers can include wheeled carts or roll-off bulk containers.

(ii) Reusable secondary containers must be inspected prior to return to use to verify that the containers are not defective and are cleaned and disinfected, have no cracks or other defects, and that the lid closes and, if available, the locking mechanism works. Reusable containers must be immediately cleaned and disinfected upon emptying if the liner is compromised, visual inspection yields evidence that the container's surface has come in contact with RMW prior to treatment, the contained waste includes cultures and/or stocks, or the contained waste has a highly infectious bioload.

(iii) Wheeled carts or bulk packaging used as secondary containers to contain RMW must be used exclusively to transport RMW.

(iv) 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 with enough absorbent material to absorb all liquid present and separated from other regulated medical waste by a leak-proof rigid barrier, divider or separate compartment.

(v) All wheeled carts and bulk outer packages used as secondary containers must be kept in a sanitary condition, disinfected before reuse, and must not be allowed to become putrescent.

(vi) 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 21 days if ambient temperatures are below 45 degrees Fahrenheit (7 degrees Centigrade) or for 14 days if above 45 degrees, whichever comes first, except that bulk packages that are putrescent must be immediately sent to the receiving facility.

(vii) 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.

(viii) Bulk outer packaging may not be used for the transport of cultures and stocks containing select agents or toxins of biological origin listed in 9 CFR part 121 and 42 CFR part 73 as incorporated by reference in section 360.3 of this Title.

(ix) All internal surfaces of a reusable secondary container, except for reusable sharps containers, must be completely protected by a disposable liner, which may also function as the primary container provided it meets the criteria for a primary container, or the secondary container serves

as both a primary and secondary container. The liner must be removed as a secured unit with the contained RMW and treated as RMW.

(15) Disposable single-use secondary containers, broken reusable containers or containers no longer in service must be treated as RMW unless decontaminated for recycling.

(16) RMW cannot be transferred from one container to another in a manner that compromises health and safety of the persons handling the RMW. RMW being moved from one container to another, or one location to another within a facility must, at a minimum, be secured in a primary container.

(17) Sharps or other secondary containers must not be opened for consolidation or other purposes unless the container is routinely reopened to add waste or the procedure has been approved as required by Subpart 365-2 of this Part.

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

(19) RMW must not be compacted or compressed unless it has undergone treatment in accordance with Subpart 365-2 of this Part.

(c) Transfer of RMW for off-site treatment.

(1) Generators of RMW must transfer the waste for off-site treatment only to a transporter authorized to transport RMW under Part 364 of this Title.

(2) Radiological RMW must be returned to the dispensing radiopharmacy, stored at the generator's location until the RMW has decayed to a background radiation level, or if long lived must be managed as a prohibited radioactive material (including waste disposal).

(3) A hard copy of a medical waste tracking form must accompany each load of RMW leaving the generator. The instructions on the tracking form must be followed.

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

(5) Any pharmaceutical waste that is unable to be separated at the site of generation must include a label that reads "Incinerate Only" on the secondary container and must be incinerated at an

authorized facility. Pharmaceutical waste may not be disposed in sanitary sewers, septic systems or waste water treatment systems.

(6) Secondary containers must be labeled in accordance with the definitions and applicable classification criteria (*e.g.,* RMW, Infectious Substances or Used Healthcare Products) required by 49 CFR 173.134, as incorporated by reference in section 360.3 of this Title. Each label must be printed on or affixed to a surface (other than the bottom) of the container and be located on the same surface of the container near the proper shipping name marking. Each label, whether printed on or affixed to a container, must be durable and weather resistant.

(7) If an infectious substance, secondary containers, except sharps containers, must be affixed with an “INFECTIOUS SUBSTANCE” label or marked with the fluorescent orange Universal “BIOHAZARD” symbol meeting the specification under 29 CFR 1910.1030(g)(1)(i) in accordance with 49 CFR 173.134, as incorporated by reference in section 360.3 of this Title, date of transport, and if applicable, that the contents (if containing pharmaceutical, chemical or pathological waste) require incineration. An “INFECTIOUS SUBSTANCE” label is not required on a non-bulk secondary container with a “BIOHAZARD” marking.

(d) Treatment of RMW on-site.

RMW treatment facilities located at the site of generation are subject to regulation under Subpart 365-2 of this Part.

(e) Recordkeeping and reporting.

(1) Recordkeeping. The following records must be maintained on-site for a minimum of three years and must be available for inspection and copying by the department.

(i) A record of RMW managed by quantity and category. Categories include cultures and stocks, human pathological waste, human blood and blood products, sharps, animal waste, and other (specify characteristics).

(ii) A record of how all RMW was managed, including treatment, if applicable. For treatment, copies of certificates of treatment must be retained. For shipment off-site for treatment, copies of tracking documents must be retained.

(iii) In addition, treatment facilities must comply with the recordkeeping requirements of Subpart 365-2 of this Part.

(2) Reporting. A report of the RMW generated annually, by quantity and category, must be submitted to the department upon request.

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SUBPART 365-2. RMW TREATMENT, STORAGE, AND TRANSFER FACILITIES

6 CRR-NY IV B 365 365-2 Notes

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6 CRR-NY 365-2.1

6 CRR-NY 365-2.1

365-2.1 Applicability.

(a) This Subpart applies to facilities that treat, store and transfer RMW other than those located at and operated by a hospital, residential health care facility, and diagnostic and treatment centers (defined in section 2801 of the Public Health Law) and clinical laboratories (defined in section 571 of the Public Health Law) that manage their own waste.

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365-2.2 Exempt facilities.

The following facilities are exempt from this Subpart:

(a) Sharps and pharmaceutical waste collection drop boxes and kiosks provided for collection from homeowners, provided the sharps collected are managed as RMW.

(b) Storage or transfer facilities operated by and located at the site of generation, which are regulated under Subpart 365-1 of this Part.

(c) Generators that source separate used medical devices that are proposed to be reused and that are sent directly to manufactures, remanufacturers, or reprocessors.

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365-2.3 Registered facilities.

Facilities of the following types must register with the department prior to treatment, storage or transfer of RMW, unless otherwise exempt. Facilities required to register with the department are subject to Part 360.15 of this Title but are not subject to section 360.19 of this Title.

(a) A storage facility for radiological RMW, including 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 Subpart 365-1 of this Part, radiological RMW destined for disposal must be stored at the radiopharmacy until radioisotopes have decayed to a background radiation level. 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) Storage areas for radiological RMW must be adequately sized for the volume of RMW generated between scheduled waste pick-ups by a transporter.

(4) Storage areas for radiological RMW must:

(i) display prominent signage indicating the area 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 vectors;

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

(v) be appropriately ventilated;

(vi) be of sufficient size to allow clear separation of RMW from any other waste, if waste other than RMW is stored in the same area; and

(vii) 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) Decayed radiological RMW that leaves the radiopharmacy must be accompanied by an RMW tracking document.

(b) A treatment facility, except for a biocontainment facility at a Biosafety Level 3 or 4 laboratory, located at the site of RMW generation, which treats less than 500 pounds of RMW per month from the on-site generator. The treatment facility cannot treat waste containing select agents or toxins of biological origin listed in 9 CFR part 121 or 42 CFR part 73 as incorporated by reference in section 360.3 of this Title. 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.

(2) The treatment of RMW must comply with sections 365-2.5, 365-2.6 and 365-2.7 of this Subpart.

(3) The facility must have procedures to segregate RMW to be treated from other waste.

(4) Each facility employee who will operate treatment equipment must be trained in the proper use of the treatment equipment.

(5) 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, validation and bio-challenge testing.

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

(c) Healthcare facilities licensed pursuant to the PHL that treat, store or dispose of RMW from other generators (pursuant to written agreements with or among other generators filed with the NYSDOH and the department) for treatment, or are not operated by the healthcare facility. The operator of the facility must have and adhere to an operation plan for the handling and disposal of RMW approved by the department. The operation plan must include the following:

(1) A method of receiving wastes which ensures that RMW is handled separately from other wastes until treatment or disposal is accomplished and which prevents unauthorized persons from having access to or contact with the waste.

(2) A method of unloading and processing of RMW which limits the number of persons handling the waste and minimizes the possibility of exposure of employees and the public using or visiting the facility to RMW.

(3) A method of decontaminating emptied reusable RMW containers, transport vehicles or facility equipment which are known or believed to be contaminated with regulated medical waste.

(4) The provision and required use of gloves and other protective clothing to protect any facility employee who handles RMW.

(5) The means of decontamination of any person having had bodily contact with RMW while transporting the waste to the treatment or disposal site or while handling or disposing of the waste at the site.

(6) A quantification of the maximum amount of RMW to be treated, stored, or disposed of per month.

(7) A new or revised operation plan for treatment, storage or disposal of RMW shall be prepared whenever there is an increase of more than 25 percent in the maximum quantity of RMW receiving treatment, storage or disposal per month by the facility or when changes are otherwise made in an existing operation plan.

(8) The treatment of RMW must comply with sections 365-2.5, 365-2.6 and 365-2.7 of this Subpart.

(9) The facility must have procedures to segregate RMW to be treated from other waste.

(10) Each facility employee who will operate treatment equipment must be trained in the proper use of the treatment equipment.

(11) 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, validation and bio-challenge testing.

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

(13) Approval for acceptance of RMW at a treatment, storage or disposal facility may be withdrawn by the department for noncompliance with the operation plan.

(14) As a condition of approval of a registration, any person who operates a facility for the treatment, storage and disposal of RMW shall provide proof of liability insurance or other form of financial security deemed sufficient by the department to meet all responsibilities in case of release of such waste causing damage.

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6 CRR-NY 365-2.4

365-2.4 Permit application requirements.

A facility that treats, stores or transfers RMW (including select agents or toxins of biological origin, and biocontainment facilities at a biosafety level 3 or 4 laboratory), which is not exempt or subject to the registration provisions of section 365-2.2 of this Part, must obtain a permit from the department. The permit application must include the requirements identified in this section and section 360.16 of this Title, and include a description of how the facility will comply with the operating requirements of section 360.19 of this Title, and sections 365-2.5, 365-2.6, 365-2.7 and 365-2.8 of this Subpart. An application for a permit under this section must include:

(a) A waste control plan that describes:

(1) the notification program to instruct the generators who will use the facility of the types of RMW that will be accepted and/or treated at the facility including 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. These quantities must be specified for each general category of RMW;

(2) the service area, that includes a list of all planning units and other generators that are served must be included;

(3) special waste management if any of the following wastes are accepted:

(i) reusable secondary containers including sharps containers;

(ii) reusable medical devices, disposed as RMW by the generator;

(iii) waste (including sharps) containing pharmaceuticals or other chemicals;

(iv) wastes from a biosafety level 3 or 4 laboratory; or

(v) waste containing select agents or toxins of biological origin listed in 9 CFR part 121 and 42 CFR part 73 or other infectious wastes.

(4) how the facility will ensure that it only receives RMW or other wastes capable of being managed at the facility;

(5) 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;

(6) the methods used to inspect all containers received to ensure that they are in compliance with this Subpart;

(7) the methods used to manage the waste that ensures odor, litter and vectors are controlled;

(8) how the facility will be managed to ensure compliance with all applicable storage requirements;

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

(10) how inventory will be managed; and

(11) the method that will be used to manage the required tracking forms.

(b) Operation and maintenance plan.

The operation and maintenance plan must include:

(1) a description of the overall operation of the facility including:

(i) a radioactive waste detection plan that includes procedures for detecting prohibited radioactive material; operation and maintenance documents for radiation detectors including investigation alarm set point settings and calibration methods; and response procedures to be implemented when radioactive waste is detected;

(ii) the method for unloading; and

(iii) the method for decontaminating emptied reusable RMW containers and facility equipment which are contaminated with RMW as follows:

(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, or exposure to a chemical disinfectant registered for use by the department and used according to the manufacturer’s label directions.

(2) a list of the type, purpose, size, capacity, and associated detention times for all RMW storage, treatment, and transfer equipment and structures, with supporting capacity calculations;

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

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

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

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

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

(8) a description of the daily cleaning and maintenance operations and scheduled downtime maintenance each year and anticipated schedules for major equipment replacement;

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

(10) a list of receiving facilities that will be used for treatment or disposal.

(c) 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 they must operate and to discover 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 how those risks can be minimized; and

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

(d) Contingency plan.

The plan must describe the actions that will be taken to address potential operational problems including, but not limited to, compromised packaging, 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 treatment or disposal should processing equipment be non-functional for a period longer than seven calendar days.

(e) A wash-water management plan.

The plan must describe 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 in contact with RMW and the method to collect, store, treat or dispose of wash-water.

(f) Treatment equipment description.

Treatment facilities must provide a detailed description of the treatment device(s) including:

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

(2) evidence of manufacturer efficacy testing, including the use of biological indicators analyzed by an independent laboratory;

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

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

(5) the procedures for and frequency of calibration of all instruments and controls;

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

(7) for facilities using an alternative treatment system, a copy of the New York State Department of Health (NYSDOH) approval issued to the system's manufacturer or operator.

(g) Validation plan for treatment systems.

The plan must describe the procedures for validation and bio-challenge testing including, but not limited, to the types of biological indicators employed, 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 sections 365-2.5, 365-2.6 and 365-2.7 of this Subpart.

(h) A certification that the facility conforms with existing local zoning laws or ordinances.

(1) Closure plan. The plan must describe how all the equipment and facility surfaces will be disinfected, tested for microbial inactivation and how the facility will be properly closed.

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6 CRR-NY 365-2.5

365-2.5 Design and operating requirements.

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, etc.), or waste which is not accompanied by a tracking document. The tracking form must be completed as required as specified in the instructions on the form.

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

(1) the investigation alarm setpoint of the radiation detector must be set at least two times but no greater than five times background radiation levels;

(2) the concentration of radiation in any waste received may not exceed 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;

(i) the radiation detector must be calibrated at least annually or more often as recommended by the manufacturer, and documentation describing the calibration must be maintained at the facility; and

(ii) each instance in which the radiation detector is triggered by a waste load must be documented and reported to the department by the next business day following the event. Recorded information must include the date the waste was received, transporter name, origin of the waste, truck number or other identifying marking, detector reading, disposition of the waste, and date of disposition.

(c) For storage and transfer facilities, the RMW must be maintained in the packaging as received, unless otherwise approved by the department. If any packages are broken, leaking or are otherwise compromised, the RMW must be handled as outlined in the contingency plan. The RMW may only be surrendered to a transporter permitted to transport RMW under Part 364 of this Title.

(d) Incoming RMW must be handled in accordance with the following criteria.

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

(2) RMW must be inspected prior to unloading to ensure the RMW has been packaged appropriately. If any packages are broken, leaking or otherwise compromised, the RMW must be handled as outlined in the contingency plan. Containers of RMW must not be opened for inspection unless authorized by the department.

(3) RMW shipment in bulk packaging cannot be accepted, unless approved by the department as part of the waste control plan.

(4) The facility must record the date of arrival of each waste load at the facility, the original generator identification, package type and weight or volume, and the intended disposition of the waste. These documents may be maintained electronically.

(e) RMW handling and storage.

(1) Entry to the facility must be secured and 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 during storage and with appropriate blocking and bracing when moved by a vehicle during transport.

(4) RMW storage and handling procedures must minimize potential occupational exposures and release to the environment.

(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 eight 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 waste control plan.

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

(8) RMW must not be processed to reduce the size prior to treatment, unless approved by the department as part of the operation and maintenance plan.

(9) RMW must not be compacted or compressed. RMW placed into bins for consolidation or treatment must be controlled to minimize aerosolization.

(10) Trash chutes or slides cannot 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) Storage of RMW that has the ability to become putrescent is limited to:

(i) three days if the RMW is stored at 45 degrees Fahrenheit (7 degrees Celsius) or greater;

(ii) seven days if the RMW is stored at less than 45 degrees Fahrenheit (7 degrees Celsius) but greater than 32 degrees Fahrenheit (0 degrees Celsius); and

(iii) thirty days if the RMW is stored at 32 degrees Fahrenheit (0 degrees Celsius) or lower.

(13) RMW which becomes putrescent must be treated, refrigerated, or removed from the facility as soon as practicable.

(14) Non-putrescent RMW can be stored above 45 degrees Fahrenheit (7 degrees Celsius) for a maximum of 15 days, and a maximum of 30 days if stored at or below 45 degrees Fahrenheit (7 degrees Celsius).

(15) Treated RMW must be removed from the facility within 30 days.

(16) The facility must be maintained in a clean and sanitary condition, and implement a written schedule of appropriate cleaning and disinfection.

(17) The unloading and loading areas must be adequately sized and designed 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 within a building and on a covered concrete or asphalt surface.

(f) RMW recovery and recycling.

Recovery of RMW for third-party reprocessing of medical devices, or for reuse or recycling of materials must comply with the following:

(1) RMW and used medical devices generated from neurosurgery cannot be recovered or recycled;

(2) used medical devices may be sent to a reprocessor for preparation for reuse without treatment;

(3) used medical devices source separated at healthcare facilities that are managed at RMW processing facilities must be transported directly to the manufacturer, reprocessor or remanufacturer;

(4) recovery, segregation and sorting of used medical devices from RMW received from healthcare facilities. Recovery, segregation and sorting must employ robotic or mechanical equipment, and control the release of microorganisms during processing;

(5) RMW to be recycled must be treated with an autoclave in accordance with the RMW treatment requirements of sections 365-2.6 and 365-2.7 of this Part prior to being sent for recycling;

(6) bio-challenge testing must be conducted in accordance with this Subpart for each load of waste treated before recycling. Bio-challenge testing must demonstrate no growth in ‘Bacillus’ spores for each load of waste proposed to be recycled;

(7) materials recovered for recycling from the RMW stream must be stored at the treatment facility until results of bio-challenge testing have been obtained. If results indicate that treatment was not sufficient, the materials must be treated again and retested.

6 CRR-NY 365-2.5

6 CRR-NY 365-2.6

6 CRR-NY 365-2.6

365-2.6 General treatment requirements.

In addition to the requirements in section 365-2.5 of this Subpart, RMW treatment facilities must comply with the following criteria:

(a) Except as provided in subdivisions (b) and (c) of this section, treatment of RMW must be by:

(1) discharge into a sanitary sewer system connected to a secondary treatment facility, if the waste is liquid or semi-solid, except as specifically prohibited by the NYSDOH, or by local law or ordinance;

(2) incineration in a RMW incineration facility regulated under Subpart 362-1 of this Title;

(3) decontamination by autoclaving in conformance with the requirements of this Subpart;

(4) decontamination by discharge to an effluent decontamination system approved by the department; or

(5) an alternative RMW treatment system approved by the NYSDOH.

(b) Restrictions on autoclave use.

(1) An autoclave cannot be used for treatment of RMW containing or mixed with hazardous waste and/or pharmaceuticals.

(2) An autoclave cannot be used for treatment of radiological RMW unless decayed to a background radiation level or the facility set alarm for radiation levels prior to treatment.

(3) An autoclave cannot be used for treatment of recognizable human organs or body parts, or animal body parts or carcasses unless in small quantities, and approved by the department, or provided the NYSDOH has approved the autoclave model as an alternative treatment technology for those wastes.

(4) An autoclave cannot be used for treatment of thermally resistant materials such as solidified liquids or bulk animal bedding having a volume of more than five cubic feet unless approved by the department or as an alternative treatment system by the NYSDOH.

(5) An autoclave cannot be used for the treatment of toxins of biological origin other than those listed by the Centers for Disease Control and Prevention in the *Biosafety in Microbiological and Biomedical Laboratories* publication as incorporated by reference in section 360.3 of this Title.

(c) Cultures and stocks.

(1) Cultures and stocks containing select agents or non-exempt quantities of toxins of biological origin listed in 9 CFR part 121 and 42 CFR part 73 as incorporated by reference in section 360.3 of this Title must be treated on-site by incineration, autoclaving, use of an alternative treatment system approved by the NYSDOH, or inactivation in accordance with the Federal Select Agent Program. However, if the generating facility does not have a predictable need for on-site treatment and the waste is incidental to the delivery of medical care or research, the generating facility can arrange for transportation of the select agents and toxins of biological origin to a facility authorized by the department to treat the waste. If the waste is shipped off-site for treatment, the generator must comply with Federal regulations regarding possession, use and transfer of select agents and toxins of biological origin found in 9 CFR part 121 and 42 CFR part 73 as incorporated by reference in section 360.3 of this Title.

(2) Cultures and stocks containing infectious agents other than those referenced in paragraph (1) of this subdivision may be transported off-site for treatment.

(d) Discarded sharps must be destroyed prior to disposal.

Sharps that have not come into contact with infectious agents do not need to be treated.

(e) Treatment facilities must have a response plan in place to be followed in the event the facility is notified or discovers that RMW has left the facility without required treatment.

(f) Treated RMW can be disposed of as MSW at a combustor, landfill or other disposal facility authorized by the department to accept RMW after treatment.

(g) Treated RMW must be accompanied by a NYSDOH certificate of treatment.

(h) Effective treatment of RMW.

Treatment of RMW must be demonstrated by no growth in viable ‘G. stearothermophilus’ spore concentration, or other biological indicator or measure of effectiveness acceptable to the department. In addition:

(1) for infectious agents including certain vegetative bacteria, fungi, lipophilic and hydrophilic viruses, parasites, mycobacteria, and similar organisms, no growth is required;

(2) for human tissues, human organs, or animal waste body parts, the treatment must render the waste visually unrecognizable;

(3) for sharps, the treatment must render the sharps unusable; and

(4) for toxins of biological origin, the treatment must inactivate the toxin.

(i) Validation testing prior to equipment use.

Prior to using an RMW treatment system, the facility must conduct validation testing. Written approval of validation and repeat validation test protocols and test results must be obtained from the department prior to acceptance of RMW for treatment. The department must be notified before all validation testing.

(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 document removal of all air from the autoclave and include one or more pre-vacuum cycles or depending on the autoclave one or more steam pulses;

(iii) the RMW 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; and

(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.

(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, moist heat, or hydrogen peroxide systems), ‘Bacillus atropheus’ (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 $\log_{10}$ 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) and, for thermal treatment systems, the D-value and the Z-value. The D-value must be 1.8 minutes and the Z-value must be no less than 50 degrees Fahrenheit (10 degrees Celsius);

(iii) be appropriate for the type of RMW 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 RMW load during each validation test, including at the coldest point 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 per cycle for 0-110 pounds of RMW per load;

(b) five biological indicators per cycle for 111-550 pounds of RMW per load;

(c) seven biological indicators per cycle for 551-1100 pounds of RMW per load;

(d) nine biological indicators per cycle for 1101-1650 pounds of RMW per load;

(e) eleven or more, as determined by the department, biological indicators per cycle for any treatment system greater than 1650 pounds of RMW per load; and

(f) one or more controls from the same lot or batch;

(vii) be wrapped in a paper towel and encased in cotton batting or in another carrier system designed to mimic the thermal resistance in the RMW before placement into the package to be treated with the RMW. Materials used to hold the indicator units must be similar to the RMW to be treated, provide effective protection from breakage, be loose in the bulk of the RMW and be easily retrievable at the end of each validation run; 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) Biological indicators requiring microbial bioassay to confirm efficacy must be quantitatively analyzed after the treatment cycle. All self-contained 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 must be independent of the facility owner or operator. No less than one-third of the biological indicators used during each validation test run must be analyzed by an independent laboratory.

(5) The system must employ process monitoring concurrent with biological indicators, including devices and instrumentation to record temperature and/or other critical operating parameters.

(6) Verification testing for commercially purchased biological indicators. Each lot or batch of biological indicators with a stated population must be tested prior to use at the facility. Each verification test must use a minimum of three indicators from the same lot or batch that must be sent to an independent laboratory.

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

(8) 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. Self-contained biological indicators with vent caps must not be used where liquids may accumulate and contaminate the indicators.

(j) Repeat validation testing.

Validation testing must be repeated when any of the following occurs. The department must be notified before validation occurs:

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

(2) failure to achieve microbial inactivation in at least 95 percent of the biological indicators during each treatment cycle during validation;

(3) any modifications to the treatment process operational parameters;

(4) a treatment device has been operational without a repeat validation for at least five years; or

(5) the treatment device has not been used for at least one year.

(k) RMW treatment system operation requirements.

(1) The facility must use controls appropriate for the treatment system (*e.g.*, 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) must be placed in or on the outside of RMW containers and distributed throughout the load, chamber, or vessel during treatment.

(3) Bio-challenge testing is required with each load for biocontainment facilities at BSL 3 or 4.

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

(5) 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.

(6) A general facility inspection must be undertaken at least annually to determine the operating condition of the process and control equipment. The annual inspection must be performed by a qualified individual such as a certified industrial hygienist or biosafety specialist, or a licensed professional engineer not affiliated with the facility. The results of the inspection must be included in the annual report.

(7) All emptied reusable RMW containers must be appropriately washed and disinfected after each use and facility equipment used for handling and processing the waste must be cleaned and decontaminated whenever it is visibly soiled or contaminated.

(8) If a treatment system fails to operate in accordance with the permitted and acceptable operating parameters (time, temperature, pressure, or chemical concentration), or if more than 5 percent of the biological indicators used during the treatment cycle fail or show growth, the facility must:

(i) discontinue use of the system, using emergency shutdown procedures if appropriate, until corrective action has been taken and then repeat the treatment cycle. Repeat validation or bio-challenge testing must be performed to verify that effective treatment can resume;

(ii) ensure that all RMW that was processed by the system since the last run when the unit was in compliance, is identified as untreated RMW and document that the RMW was properly retreated;

(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 RMW certified as treated RMW has left the facility, notify the waste transporter, the receiving facility, and the department as soon as practicable.

(l) 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 RMW treated, operating parameters, and the dates and results of calibration and testing. These records may be maintained electronically.

(m) 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 or mechanical delidder and dumping system. Lids may not be removed manually;

(2) reusable sharps containers and transport cages must be mechanically cleaned with an appropriate disinfectant prior to reuse;

(3) reusable sharps containers must be approved by the USFDA for reuse;

(4) reusable sharps containers removed from service must be managed as RMW or, if proposed to be recycled, cleaned and decontaminated; and

(5) all reusable containers, including sharps containers, must be tested using bio-challenge tests on an annual basis, in a manner approved by the department.

6 CRR-NY 365-2.6

6 CRR-NY 365-2.7

6 CRR-NY 365-2.7

365-2.7 Requirements for autoclaves used to treat RMW.

In addition to the requirements outlined in sections 365-2.5 and 365-2.6 of this Subpart, RMW treatment facilities that employ the use of autoclaves must comply with the following criteria:

(a) An autoclave that fails to meet the criteria for effective treatment pursuant to this section after validation testing at the site of installation cannot be used to treat RMW.

(b) A facility that seeks to operate an autoclave at other than the generally accepted operating parameters (*i.e.*, time, temperature and pressure) outlined in this section must obtain approval from the Department of Health as an alternative treatment method.

(c) The facility must be designed to promote safe and effective operation of the autoclave. The facility must have procedures to ensure:

(1) the autoclave meets the criteria in this Subpart for effective treatment of RMW;

(2) loads contain only those items or types of RMW for which effective treatment has been demonstrated by validation testing; and exclude RMW for which effective treatment by the system has not been demonstrated or is prohibited;

(3) each load is treated using residence time, temperature and pressure, and with one or more vacuum cycles that have been validated as effective for the treatment of RMW, and conditions of treatment are monitored and documented for each load;

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

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

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

(d) Monitoring autoclave operation.

(1) Parametric controls must be employed to monitor operating parameters automatically and continuously throughout the entire cycle, and generate a record of operating parameters for each cycle.

(2) Routine operational performance of an autoclave must be monitored by bio-challenge testing, conducted in accordance with subdivision (h) of this section using the validation protocol.

(3) If an autoclave fails to attain no growth in viable spores concentration upon bio-challenge testing or indicators fail to show expected results (*i.e.*, a color change), the load shall be handled as untreated RMW, and the facility must demonstrate, through a repeat of bio-challenge testing, that the autoclave effectively treats RMW before resuming its use for treatment purposes.

(e) Containment of RMW for treatment by autoclaving must be by a container or containment system designed to withstand the temperature and pressure of autoclaving, and may, except for sharps, consist solely of a bag.

(f) If the container or containment system does not, by design, allow steam to come into direct contact the RMW, the facility must take actions to ensure contact.

(g) Sharps treated by autoclaving must be destroyed prior to disposal.

(h) Routine bio-challenge testing for autoclaves.

An autoclave that has been validated and authorized to treat RMW must conduct routine bio-challenge testing as follows:

(1) during the first 30 days of actual operation, the first and third load each day must include biological indicators placed in the waste;

(2) after 30 days of operation, one load each day must include biological indicators placed in the waste;

(3) 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 will require repeat bio-challenge testing;

(4) bio-challenge testing must include at least one-third of the number of biological indicators that are required for validation or two indicators, whichever is greater;

(5) every 200 hours of operation, biological indicators used during bio-challenge testing must be evaluated by an independent laboratory; and

(6) bio-containment facilities at BSL 3 or 4 using pass-through treatment systems must conduct bio-challenge testing for each load of RMW.

6 CRR-NY 365-2.7

6 CRR-NY 365-2.8

6 CRR-NY 365-2.8

365-2.8 Recordkeeping and reporting requirements.

(a) Recordkeeping.

The following records must be maintained on-site for a minimum of three years and must be available for inspection and copying by the department.

(1) A record of RMW managed by quantity and category as specified by the generator on the container and treated at the facility. Categories include cultures and stocks, human pathological waste, human blood and blood products, sharps, animal waste, and other (specify characteristics).

(2) A record of how all RMW was managed, including treatment, if applicable. For treatment, copies of certificates of treatment must be retained. For shipment off-site for treatment, copies of tracking documents must be retained.

(3) In addition, treatment facilities must:

(i) retain hard copy or electronic records of validation testing and bio-challenge testing, including protocols and test results;

(ii) retain records of parametric monitoring (*e.g.*, the residence time, pressure and temperature of each load treated);

(iii) document each employee's participation in training and/or retraining in treatment equipment operations; and

(iv) document corrective actions.

(b) Reporting.

The facility must submit an annual report covering the previous calendar year, on forms prescribed by or acceptable to the department. The report must include:

(1) a summary of the RMW managed, by quantity and if feasible, by category as specified by the generator on the containers. Categories include cultures and stocks, human pathological waste, human blood and blood products, sharps, animal waste, and other (specify characteristics);

(2) a summary of all waste received that could not be managed at the facility and how it was handled;

(3) for storage and transfer facilities, an identification of the treatment facility that received the RMW; and

(4) for treatment facilities, report any issues that have been identified (*e.g.*, failure to attain operating requirements, equipment failures, etc.), and any corrective action taken including additional bio-challenge testing, management of spills, and special training for employees to resolve the issues.

6 CRR-NY 365-2.8

6 CRR-NY IV B 365 365-3 Notes

TITLE 6. DEPARTMENT OF ENVIRONMENTAL CONSERVATION

CHAPTER IV. QUALITY SERVICES

SUBCHAPTER B. SOLID WASTES

PART 365. REGULATED MEDICAL WASTE AND OTHER INFECTIOUS WASTES

SUBPART 365-3. OTHER INFECTIOUS WASTES

6 CRR-NY IV B 365 365-3 Notes

6 CRR-NY IV B 365 365-3 Notes

6 CRR-NY 365-3.1

6 CRR-NY 365-3.1

365-3.1 Applicability.

(a) This Subpart applies to any incidental waste that is not RMW but that has come into contact with an infectious agent. Incidental waste means any materials generated as a consequence of mitigating exposure to infectious agents (*e.g.*, including waste from work spaces, living spaces, and other similar locations prior to reoccupancy, etc.). For purposes of this Subpart, an infectious agent includes any agent classified as Risk Group 2, 3, or 4 by the National Institutes of Health in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, incorporated by reference in section 360.3 of this Title.

(b) A material containing an infectious agent at a concentration naturally occurring in the environment, contaminated foodstuffs, samples of foodstuff sent for routine laboratory analyses, environmental samples, and quality control samples are not regulated under this Subpart. Research laboratories conducting research on infectious agents, as defined in subdivision (a) of this section, are regulated by this Subpart.

6 CRR-NY 365-3.1

6 CRR-NY 365-3.2

6 CRR-NY 365-3.2

365-3.2 Exempt facilities.

The following facilities are exempt from this Subpart:

(a) Storage of waste that has come into contact with an infectious agent at the site of generation provided the storage period does not exceed 30 days and the storage criteria outlined in section

365-1.2 of this Part are followed. If the waste becomes putrescent, the waste must be removed from storage and sent for treatment as soon as practicable.

6 CRR-NY 365-3.2

6 CRR-NY 365-3.3

6 CRR-NY 365-3.3

365-3.3 Registration.

Facilities of the following types are subject to the registration provision of section 360.15 of this Title unless otherwise exempt. These facilities are not subject to section 360.19 of this Title but must comply with the following operating requirements:

(a) Storage of waste at the site of generation that has come into contact with an infectious agent. The storage must follow the criteria for RMW found in section 365-1.2 of this Part.

(b) Storage and transfer locations at locations other than at the site of the generation, in compliance with the following:

(1) each facility must be equipped with potable water and electricity and must implement procedures to minimize the potential for exposure and prevent the release or spread of infectious agents;

(2) the facility must limit the amount of time contaminated waste is staged to a maximum of 14 days, and must contain the waste;

(3) the facility must be secured and monitored;

(4) packaged untreated waste or waste that has not met specific treatment standards for microbial inactivation must be separated by waste type in labeled separate containers and locations from waste that has been treated;

(5) waste must be placed on an impermeable surface with the use of berms and absorbents as necessary to prevent a bioaerosol release;

(6) waste must remain in the original containers and the containers may not be opened at the registered facility;

(7) no additional mixing, pumping, altering of packaging or handling of waste which may lead to a discharge is allowed; and

(8) waste must be transported to an authorized facility for treatment or disposal in accordance with this Subpart.

(c) Temporary treatment devices used for 90 days or less, used to treat waste contaminated with infectious agents at the site of generation, provided the following conditions are met:

(1) Decontamination or treatment reduces or destroys infectious agents and tests are performed to confirm no growth of a viable infectious agent.

(2) The on-site treatment technology (autoclave, fumigation, alkaline hydrolysis, etc.) is effective in treating each of the waste streams that are treated.

(3) Process efficacy is demonstrated with validation testing prior to commencement of operations on the first deployment and bio-monitoring in accordance with section 365-2.6 of this Part.

(4) If elimination of the infectious agent cannot be confirmed, the waste is packaged and transported in accordance with section 365-3.4 of this Subpart.

6 CRR-NY 365-3.3

6 CRR-NY 365-3.4

6 CRR-NY 365-3.4

365-3.4 Criteria for off-site transport of waste that has come into contact with an infectious agent.

(a) The waste must be packaged using the criteria applicable to RMW, in both a primary and secondary container, as outlined in section 365-1.2(b) and (c) of this Part.

(b) Storage, treatment, or transfer of the waste, other than storage facilities outlined in sections 365-3.2(b) and 365-3.3(b) of this Subpart, must occur at an RMW treatment, storage, or transfer facility approved under Subpart 365-2 of this Part. The treatment system must be capable of treating the type and characteristics of the waste.

(c) The transporter of the waste must be permitted to transport RMW under Part 364 of this Title.

(d) The waste must comply with the tracking document requirements applicable to RMW specified in this Part.

6 CRR-NY 365-3.4