



## Ohio Administrative Code

### Rule 3745-570-200 General requirements for infectious waste treatment facilities.

Effective: April 6, 2025

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(A) The owner or operator shall conduct all construction and operations at the infectious waste treatment facility in compliance with all applicable authorizing documents.

(B) Facility management plan. Unless sodium hypochlorite is exclusively utilized for the treatment of cultures in compliance with rule 3745-570-204 of the Administrative Code, prior to acceptance of infectious waste the owner or operator shall develop, maintain, and implement a facility management plan that complies with the following:

(1) The plan includes copies of the following:

(a) Applicable authorizing documents for the infectious waste treatment facility.

(b) The manufacturer's equipment specifications, owner's manual, and maintenance schedule for each treatment unit.

(c) The schedule for the monitoring and recording device calibration or replacement.

(d) The maintenance and repair log for each treatment unit.

(e) Infectious waste spill containment and clean-up procedures.

(f) The facility contingency plan that at a minimum contains the following:

(i) A table of contents.

(ii) The name, address, and telephone number of the facility to which the plan applies.

(iii) A purpose statement.



(iv) Designation of an emergency coordinator and alternate emergency coordinator, their contact information, and a description of their responsibilities.

(v) Designation of alternative infectious waste treatment facilities and, if the alternative infectious waste treatment facilities are owned or operated by another owner or operator, documentation that infectious wastes from the treatment facility will be accepted by the alternative treatment facility.

(vi) A description of storage, handling, refrigeration, and freezing procedures, including the procedures the owner or operator will implement to send the untreated infectious waste to an alternative infectious waste treatment facility designated in accordance with paragraph (B)(1)(f)(v) of this rule in the event of a violation of paragraph (F)(1)(a) or (F)(1)(b) of rule 3745-570-31 of the Administrative Code.

(vii) A proposed schedule for responding to an emergency.

(g) Emergency telephone numbers for the following:

(i) The emergency coordinator and an alternate coordinator.

(ii) The local fire department.

(iii) The local emergency management office, if applicable.

(iv) The local health department.

(v) The local police department.

(vi) The local Ohio EPA district office.

(h) A section for recording the results of biological challenge testing and applicable validation testing.



- (i) Start-up, loading, operating, shut down, and equipment malfunction procedures for each treatment unit.
  - (j) A section for daily logs as specified in paragraph (C) of this rule.
  - (k) All strip charts, graphs, spreadsheets, and treatment parameter records, with each record dated.
  - (l) The disposal papers for the treated infectious waste completed in accordance with rule 3745-570-130 of the Administrative Code.
  - (m) Copies of contingency plan paperwork showing where infectious waste went if not treated at the infectious waste treatment facility.
  - (n) A training certification statement for each employee who operates the infectious waste treatment unit or loads infectious waste into the infectious waste treatment unit that the employee received annual training in accordance with paragraph (B)(3) of this rule that is maintained for the duration of employment.
- (2) The plan is maintained in accordance with the following:
- (a) By calendar year, at a minimum including the current calendar year and the two previous calendar years.
  - (b) The plan for the current calendar year is maintained in a designated area on the premises of the infectious waste treatment unit.
  - (c) The facility management plans for the two previous calendar years may be located and maintained in other accessible areas so long as a notation is made in the current year's facility management plan identifying the location of the past facility management plans.
  - (d) Such that the facility management plans are accessible to employees during working hours.
- (3) The plan includes an annual training schedule that at a minimum provides for instruction on the



contents of the facility management plan to each employee who will operate the infectious waste treatment unit or load the infectious waste treatment unit. A written training certification statement attesting that the employee received training shall be signed and dated by each employee upon completing the training and the owner or operator.

(C) Daily log of operations.

(1) Unless sodium hypochlorite is exclusively utilized for the treatment of cultures in compliance with rule 3745-570-204 of the Administrative Code, the owner or operator shall use and maintain a daily log of operations on forms prescribed by the director, or an alternative form that contains all of the specified information, for each treatment unit that at a minimum includes the following:

- (a) The name of the person operating each treatment unit.
- (b) An indication of whether the load was for validation, biological challenge testing, or treatment.
- (c) The date and time each load of infectious waste was charged into each treatment unit.
- (d) The date and time each treatment cycle started and ended.
- (e) The date and time the treatment unit was unloaded.
- (f) Any documentation associated with the monitoring of infectious waste treatment parameters required by each approved infectious waste treatment method.

(2) Information produced by the treatment unit may substitute for the daily log provided all the information specified in paragraphs (C)(1)(a) to (C)(1)(f) of this rule is readily available to Ohio EPA and the approved health district.

(D) Annual report. Not later than February first of each year, the owner or operator of a licensed infectious waste treatment facility shall submit an annual report to Ohio EPA and the approved health district that at a minimum includes the following:



- (1) The name, address, and telephone number of the infectious waste treatment facility.
  - (2) The name, email address, and telephone number of the contact person for the infectious waste treatment facility.
  - (3) The hours of operation for the infectious waste treatment facility.
  - (4) The total quantity of infectious waste treated at the infectious waste treatment facility monthly for each state and country of origin.
  - (5) All biological challenge testing results that do not demonstrate achievement of the performance standard for treatment, documentation of how infectious waste from the treatment unit that failed to demonstrate achievement of the performance standard for treatment was managed, and actions taken by the owner or operator to ensure that the treatment unit attains the performance standard for treatment.
- (E) Record keeping. The owner or operator shall retain and provide records as follows:
- (1) Except as otherwise provided in this paragraph, retain all records for a period of not less than five years, with that period beginning on the date of recording, sample, or measurement. Retention periods are extended during the course of any unresolved litigation or when requested by Ohio EPA.
  - (2) Provide Ohio EPA and the approved health district access to, and copies of, all records upon request.
- (F) Construction. The owner or operator shall construct and maintain the treatment facility in a manner that ensures the following:
- (1) All-weather access roads withstand the anticipated degree of use and allow passage of vehicles with minimum erosion and dust generation.
  - (2) The infectious waste handling areas are equipped with non-absorbent floors that are not overlaid with an absorbent covering.



(3) Proper slopes and drainage are established and maintained to prevent the ponding of liquids in the infectious waste handling areas.

(G) General operational requirements. The owner or operator shall ensure operations are conducted in accordance with the following:

(1) Handle and store infectious waste in accordance with rule 3745-570-31 of the Administrative Code.

(2) Ensure no hazardous waste is accepted.

(3) Refrain from treating waste in a manner that is prohibited by the Ohio department of health or the U.S. nuclear regulatory commission.

(4) Locate and maintain a copy of the operating and loading procedures for each infectious waste treatment unit in the immediate area of that infectious waste treatment unit and make a copy of those procedures readily available to the personnel operating the infectious waste treatment unit.

(5) Ensure that all personnel operating the infectious waste treatment unit are trained on the contents of the facility management plan in accordance with paragraph (B)(3) of this rule prior to operating the infectious waste treatment unit.

(6) Restrict access to infectious waste handling areas to authorized personnel using signs or a locking mechanism.

(7) Perform validation testing for each new treatment unit to demonstrate the ability of the treatment unit to achieve the performance standard using the approved treatment method prior to using the treatment unit to treat infectious waste or introducing a new waste type to an existing treatment unit.

(8) Perform validation testing for each treatment unit intended for use in the treatment of select agents, ensuring that the test loads are packaged in the same manner as wastes contaminated with a select agent.



(9) Perform biological challenge testing on each load of waste containing select agents and hold the waste on-site until challenge testing confirms the achievement of the performance standard for treatment.

(10) Perform validation testing to demonstrate the ability of the infectious waste treatment unit to achieve the performance standard if the infectious waste treatment unit has not been used for the treatment of infectious waste for more than three hundred sixty-five days.

(11) Load infectious waste into the treatment unit in such a manner as not to compact, puncture, or otherwise damage the containers.

(12) Manage sharps and re-usable sharps containers in a manner that eliminates the potential of the sharps to cause lacerations or puncture wounds during treatment, handling, storage, and disposal and in accordance with the following:

(a) Open sharps containers specifically designed for re-use using only mechanical means.

(b) Mechanically dump contents of re-usable sharps containers into a secondary container immediately prior to loading into a treatment unit.

(c) Manage the empty, re-usable sharps container in accordance with rule 3745-570-31 of the Administrative Code.

(13) Ensure infectious waste is not loaded into the treatment unit during periods of precipitation unless the infectious waste and the waste loading operations are protected from the precipitation.

(14) Manage all waste contained within the treatment unit as infectious waste in accordance with rule 3745-570-31 of the Administrative Code if any of the following occur:

(a) Treatment of the infectious waste does not conform to the approved treatment method as specified in rule 3745-570-201 of the Administrative Code.



(b) A malfunction of the treatment unit.

(15) Ensure that wastewater resulting from a spill of infectious waste is not disposed into a storm sewer and handled in accordance with either of the following:

(a) Discharged into a disposal system permitted in accordance with Chapter 6111. of the Revised Code provided the discharge is not inconsistent with that permit.

(b) Absorbed and handled as infectious waste.

(16) Ensure infectious waste intended for recycling is managed in accordance with the following:

(a) Infectious waste is treated using an autoclave in accordance with rule 3745-570-203 of the Administrative Code.

(b) Biological challenge testing is conducted for each load of infectious waste treated before recycling.

(c) Treated infectious waste that is intended for recycling is stored at the treatment facility until the results of the biological challenge testing have been obtained. The owner or operator shall re-treat the infectious waste and repeat the biological challenge testing when results indicate that the biological challenge testing failed.

(17) Comply with rules 3745-570-125 and 3745-570-222 of the Administrative Code when any infectious waste treatment facility intends to discontinue treating infectious waste at any facility or premises.

[Comment: The owner or operator is subject to the applicable packaging requirements contained in 29 C.F.R. Part 1910.1030, 49 C.F.R. Part 173, and 49 C.F.R. Part 178, as amended through July 2023.]

(H) The owner or operator shall ensure that infectious waste that has been treated in accordance with this rule is managed as follows:





- (1) Disposed at a licensed solid waste disposal facility or in such a facility in another state operating in compliance with state and federal regulations, unless the treated wastes have been managed in accordance with paragraph (G)(15) of this rule.
- (2) Accompanied with disposal papers as specified in rule 3745-570-130 of the Administrative Code.