

**Infectious Waste Treatment Facility Guidance Document - Autoclaving**  
OHIO EPA DIVISION OF SOLID AND INFECTIOUS WASTE MANAGEMENT (DSIWM)

The Ohio EPA Division of Solid and Infectious Waste Management has specific regulations regarding the treatment of infectious waste. All facilities that treat infectious waste must meet the applicable requirements under rules 3745-27-32, 3745-27-33, 3745-27-34, 3745-27-35 and 3745-27-39 of the Ohio Administrative Code. The statutory authority for these regulations can be found in sections 3734.02 and 3734.021 of the Ohio Revised Code. This guidance document is intended to provide general information on the proper treatment of infectious waste and is not meant as a replacement for the Ohio Administrative Code. Additionally, readers should note that this guidance document does not address any other federal, state, or local environmental regulations that may be applicable to autoclaves.

The following is an outline of paragraphs of different Ohio Administrative Code (OAC) Rules administered by the Division of Solid and Infectious Waste Management that are applicable to infectious waste treatment facilities utilizing autoclaving:

3745-27-32 (A)	OWNER/OPERATOR REQUIREMENTS
3745-27-32 (D)	APPROVED METHOD, STATEWIDE
3745-27-32 (D)(1)	METHODOLOGY
3745-27-32 (D)(2)	SPECIFIC OPERATIONAL CRITERIA
3745-27-32 (D)(3)	QUALITY ASSURANCE
3745-27-32 (D)(4)	VALIDATION TESTING
3745-27-32 (I)	GENERAL FACILITY REQUIREMENTS
3745-27-32 (I)(1)	RECORDS RETENTION
3745-27-32 (I)(2)	FACILITY MANAGEMENT PLAN
3745-27-32 (I)(3)	OPERATOR TRAINING
3745-27-32 (I)(4)	DAILY LOG REQUIREMENTS
3745-27-32 (I)(5)	OPERATING AND LOADING PROCEDURES
3745-27-32 (I)(6)	TREATMENT UNIT MALFUNCTION
3745-27-32 (I)(7-13)	CONSTRUCTION REQUIREMENTS
3745-27-32 (I)(14)	RESTRICTED HANDLING AREAS
3745-27-32 (I)(15)	U.S. NRC PROHIBITION
3745-27-32 (I)(16)	HAZARDOUS WASTE PROHIBITION
3745-27-32 (I)(17)	ANNUAL REPORT (FOR LICENSED FACILITIES)
3745-27-32 (I)(18)	SPILL CONTAINMENT AND CLEAN-UP KIT
3745-27-32 (I)(19)	SPILL CLEAN-UP PROCEDURE
3745-27-32 (I)(20)	DISPOSAL OF TREATED INFECTIOUS WASTE
3745-27-32 (I)(21)	SHARPS MANAGEMENT
3745-27-32 (I)(23)	CLOSURE REQUIREMENTS
3745-27-32 (I)(22)	QUALITY ASSURANCE FOR UNITS
3745-27-32 (I)(24-25)	PERMITTING AND LICENSING EXEMPTION
3745-27-33 (B)	TREATMENT SHIPPING PAPERS
3745-27-33 (C)	DISPOSAL SHIPPING PAPERS
3745-27-34 (C)	WASTE CONTAINER HANDLING
3745-27-35 (ALL)	STORAGE REQUIREMENTS
3745-27-37 (ALL)	PERMIT-TO-INSTALL (commercial only)
3745-27-39 (ALL)	CLOSURE REQUIREMENTS
3745-37-01 thru -07	LICENSING PROCEDURES (commercial only)
3745-28-07	HOST FEES (commercial only)

#### Terminology

**Captive Treatment Facilities** - As used in this guidance document a captive facility is an infectious waste treatment facility that is exempt from permitting and licensing requirements through programs administered by the Division of Solid and Infectious Waste Management (DSIWM). Captive facilities

are not exempt from being listed on an infectious waste generator's registration certificate (a license and a registration are entirely different). Note that depending upon the type of facility, other permits (air or wastewater) may be necessary. DSIWM permitting and licensing exemptions apply if the treatment facility exclusively treats infectious waste produced by the owner or operator of the treatment facility. It does not matter if the infectious waste was produced on the same premises as the treatment facility, only that the waste was produced by the same entity. Additionally, a hospital is still considered a captive facility if it also accepts for treatment infectious waste produced by: 1) small generators who have staff privileges at that hospital and dispose of only sharps; 2) emergency medical service organizations, as defined in Revised Code 4765.01; or 3) individuals who produce infectious wastes during their own treatment.

**Commercial Treatment Facilities** - As used in this guidance document a commercial treatment facility is a treatment facility that treats infectious waste produced by others and does not meet the three hospital exemption criteria mentioned above. Commercial treatment facilities are required to obtain a permit-to-install from DSIWM (as well as all other permits), before a new facility is constructed or an existing facility is modified. Commercial facilities are also required to obtain an annual operating license from either the local board of health or the Ohio EPA.

**Operator** - As used in conjunction with Rule 3745-27-32 of the Ohio Administrative Code (OAC), the "operator" is the person responsible for on-site supervision of technical operations and maintenance of the treatment unit(s) or facility. It also includes the person(s) who has the authority to make discretionary decisions about the daily operation of the treatment facility.

#### Owner/Operator Requirements (Paragraph (A) of OAC 3745-27-32)

The owner or operator of either a captive or commercial facility must treat all infectious waste received for treatment in accordance with the approved treatment method for autoclaving as specified in paragraph (D)(1) of OAC Rule 3745-27-32. Additionally, the owner or operator must comply with all facility operating criteria found in paragraphs (D)(2) and (D)(3) and general facility requirements found in paragraph (I) of OAC Rule 3745-27-32.

#### Methodology (Paragraph (D)(1) of OAC 3745-27-32)

Autoclaving of infectious waste must occur in an autoclave that is operated at a minimum temperature of 250°F (121°C) for a minimum of 60 minutes. If the autoclave operator wishes to treat infectious waste at a temperature, time, or pressure below these minimums, then the autoclave must first go through validation testing in accordance with the provisions of paragraph (D)(4) of OAC Rule 3745-27-32.

The following are examples of various temperature/time combinations and whether the operator would have to do validation testing:

- 1) 270°F (27 psi) for 45 minutes - Would require validation testing
- 2) 240°F (10 psi) for 90 minutes - Would require validation testing
- 3) 270°F (27 psi) for 65 minutes - Would not require validation testing

Autoclaves shall not be loaded beyond the maximum total treatable volume of infectious waste as determined by any one of the following:

- 1) The manufacturer's specifications stated for the autoclave unit
- 2) A lesser volume as determined by the owner / operator which is based upon the manufacturer's specifications for the autoclave unit
- 3) An actual calculation of the volume of the unit by the owner / operator as determined by manually calculating the number of boxes, bags, etc. which are placed into the autoclave unit.

Gross anatomical wastes, such as human or animal limbs which contain bone, shall not be treated by autoclaving unless the autoclave operator demonstrates through specific testing that these types of wastes can be successfully treated.

#### Specific Operational Criteria (Paragraph (D)(2) of OAC 3745-27-32)

The owner or operator of all autoclave treatment facilities must keep a copy of the following information for a period of at least three years in the facility management plan:

- 1) Temperature Charts - A permanent record of the autoclave chamber temperature must be made using a temperature recorder. The temperature recorder must plot a data point at least every two minutes. In the event of failure of the recorder, the chamber temperature must be manually recorded at least every ten minutes until the exhaust cycle starts. In the event the thermocouple fails, the autoclave cannot be used to treat infectious waste until repaired.
- 2) Daily Operational Logs - The operator must check daily and record into the daily operating log (see General Operations section above for the daily log requirements) the temperature and pressure of readings from one load of infectious waste. After recording these values, the operator must check these two values against the corresponding values found in the appendix to OAC Rule 3745-27-32. If either of the following is observed:
  - a. the temperature is not within two degrees (either way) of the printed value for that pressure, **or**
  - b. the pressure is not within two pounds per square inch (either way) of the printed value for that temperature

then the operator must either:

- a. discontinue use of the autoclave for the treatment of infectious waste until such time that the autoclave unit is repaired and has demonstrated achievement of the performance standard through successfully completed quality assurance testing;  
**or**
- b. perform weekly (every seventh day that the autoclave is used for treatment) quality assurance testing.

If the autoclave fails the weekly quality assurance testing then the operator is required to discontinue use of the autoclave for the treatment of infectious wastes until such time that the autoclave unit is repaired and has demonstrated achievement of the performance standard through successfully completed quality assurance testing.

- 3) Documentation of Instrument Calibration- The owner or operator must calibrate/repair the autoclave chamber pressure gauge, temperature recording device, or temperature measuring device, per the manufacturer's specifications, recommendations, or maintenance schedule. Should a manufacturer's specifications, recommendations or maintenance schedule not be available; an annual calibration schedule should be developed by the facility. Additionally, these instruments must be calibrated when the temperature/pressure do not correspond to each other as noted in the paragraph above.

#### Quality Assurance (Paragraphs (D)(3) of OAC 3745-27-32)

Quality assurance testing is performed on all autoclaves every calendar month in which the autoclave is used for the treatment of infectious wastes. The testing ensures that the autoclave is capable of achieving the performance standard of a minimum four log<sub>10</sub> reduction of *Bacillus stearothermophilus* spores.

- a) Those operators who choose to run their autoclaves at or above the minimum temperature of 250°F (15psi) and the minimum time of 60 minutes must perform monthly quality assurance testing. The results of the monthly spore test must be included in the quality assurance log.
- b) Those operators who choose to run their autoclave using parameters other than those stated above (minimum temperature of 250°F [15psi] and the minimum time of 60 minutes) must first perform validation testing to ensure that the autoclave is capable of thoroughly treating the entire load of infectious waste using these alternative parameters.

After a successful validation test has been performed, the autoclave operator must perform monthly quality assurance testing. The recorded results of both the validation testing and the monthly quality assurance testing must be included in the quality assurance log.

#### Validation Testing (Paragraphs (D)(4) of OAC 3745-27-32)

Validation testing is performed prior to use of the autoclave for the treatment of infectious wastes for those operators who choose to operate their autoclaves using alternative combinations of time, temperature and / or pressure. Validation testing is a check to ensure that the alternative combination will result in the achievement of the performance standard for treatment.

Validation testing differs from quality assurance testing in that quality assurance testing is an on-going monitor, performed monthly to ensure that the autoclave is continually achieving the performance standard. Validation testing is only to be performed once, prior to use of the autoclave to treat infectious wastes, when the autoclave operates under parameters other than 250°F (15psi) and 60 minutes. Validation testing is not an on-going monthly test.

#### General Facility Requirements (Paragraphs (I) of OAC 3745-27-32)

In addition to the autoclave specific operational requirements above, all autoclave facilities must also comply with the following general requirements:

- 1) All records referenced in OAC 3745-27-32 are to be retained for three years in the facility management plan.
- 2) Develop and update a facility management plan that is to be maintained on the premises of the treatment facility. The management plan must be kept in one general area on the premises of the treatment facility. The management plan may be made up of several different volumes or binders, but all parts must be maintained in one general area. The management plan must contain the following bits of information:
  - a) all applicable environmental regulations pertaining to infectious waste, solid waste, wastewater, and air pollution control.
  - b) all applicable infectious waste, solid waste, wastewater, and air permits.
  - c) owner's manual and maintenance schedule for the treatment unit and the manufacturer's equipment specifications.
  - d) the calibration or replacement schedule for the temperature monitoring and recording devices as specified or recommended by the manufacturer.
  - e) a maintenance and repair log documenting all service to each treatment unit.
  - f) infectious waste spill containment and clean-up procedures
  - g) a facility contingency plan that addresses how the facility will remain in compliance with the infectious waste regulations in the event that the treatment unit(s) cannot be used. The plan should also clearly identify the plan's emergency coordinator and list this person's phone number.
  - h) the results of all required quality assurance and/or validation testing requirements.

- i) all treatment units' start-up, loading, operating, shut down, and equipment malfunction procedures.
- j) the emergency telephone numbers for the facility emergency coordinator, the fire department, any existing local emergency management office, the local health department, the police department, and the Ohio EPA district office.
- k) If applicable, the daily logs which must be kept for each treatment unit for three years.
- l) all temperature strip charts, graphs, or manual recordings. Each chart, graph, or recording must be dated and maintained for three years.
- m) disposal shipping papers for the treated waste.
- n) a training certification statement for each current employee who operates or loads infectious waste into the treatment unit.

**Note:** The documentation required in a) through k) must be accessible to employees during working hours. This rule does not prohibit additional copies of various volumes of the management plan from being made and located in other areas for ease of access. However, there is only one official facility management plan and it must be located in one general work area. All of the current calendar year's facility management plan information is to be located in the same physical area. For ease of maintenance, any previous year's facility management plan information may be maintained in other accessible areas or multiple rooms depending on the amount of available space at the facility. A notation must be made in the current year's facility management plan regarding the location of any past calendar year's information.

- 3) Before she/he is responsible for either operating or loading a treatment unit, each employee must receive training regarding the contents of the facility management plan. A written certification statement attesting that the employee received the training must be signed and dated by each employee and the facility owner or operator.
- 4) Infectious waste autoclave operators are required to keep a charging log for each unit that includes the date, the time the first load of waste was loaded into the unit, the time the last load of waste was loaded into the unit, the name of each operator and the time of day each operator first loaded waste into the unit. Additionally, the log must contain the manual autoclave pressure and temperature reading that is required to be made once each day.
- 5) Keep a copy of each treatment unit's operating and loading procedures available to the operators in the treatment unit area.
- 6) Manage all infectious waste that may have been processed outside the treatment unit's operating parameters for proper treatment as untreated infectious waste. Wastes that may remain inside the treatment unit due to mechanical failure or jamming can remain there until the problem is corrected unless the waste becomes putrescent or becomes a food source or breeding place for rodents or insects.
- 7) All construction and operations must be done in strict compliance with applicable authorizing documents. These documents include, permits to install, plan approvals, alterations concurred with in writing by Ohio EPA, the annual operating license, court orders, and finding and orders issued to the Ohio EPA Director.
- 8) Construct and maintain:
  - a) all weather access roads to withstand use with the minimum amount of erosion and dust produced.
  - b) concrete or asphalt floors in the treatment unit loading area, vehicle unloading area, treatment area, infectious waste storage areas, ash storage areas, and vehicle and reusable container storage areas. The concrete or asphalt floors can be overlaid with a nonabsorbent covering.

- c) proper slopes and drainage to prevent the ponding of liquids in storage, treatment, ash management, and vehicle and container decontamination areas.
- 10) Load treatment units in such a manner as to prevent the compaction or puncture of infectious waste containers.
  - 11) Do not load the treatment unit during periods of precipitation unless the loading area is sheltered from the weather.
  - 12) Properly contain and dispose of wastewater resulting from the spill of infectious waste or the clean-up of a spill of infectious waste. Proper disposal includes discharge to a disposal system in accordance with Chapter 6111. of the Revised Code or absorption and handling as infectious waste. Proper disposal does not include disposal via a storm sewer.
  - 14) Restrict access to the storage, loading and unloading, vehicle and container decontamination, and treatment areas to authorized personnel. Areas can be restricted by the use of signs or key access.
  - 15) Not treat wastes that are prohibited to be disposed of this manner by the Ohio Department of Health or the Nuclear Regulatory Commission.
  - 16) Not treat wastes that are prohibited to be disposed of in this manner by hazardous waste regulations (OAC Chapter 3745-50 through 3745-69).
  - 17) Licensed (commercial) treatment facilities must submit an annual report to the Director of the Ohio EPA and approved local health district no later than **February 1st** of each year. The report consists of monthly totals of infectious waste treated as well as other information deemed necessary by the Director. Note that captive treatment facilities do not have to submit an annual report.
  - 18) Spill containment and cleanup - The specific contents of a spill containment kit are outlined in this rule. At a minimum, a kit consists of biohazard bags, chemical disinfectant, absorbent material, and protective clothing. Approved disinfectants are those registered with the U.S. EPA as hospital disinfectants that are also tuberculocidal. Also approved is a ten percent volume/volume of household bleach.
  - 19) A specific procedure for the cleanup of a spill of infectious waste is outlined in this paragraph. The key points of the cleanup procedure are as follows:
    - clean-up crew must wear the appropriate protective equipment
    - access to the spill area must be restricted
    - broken containers and the spilled material placed into overpack bags
    - use absorbent material to collect liquids if necessary
    - clean the contaminated area
    - after cleaning, apply either a 10% bleach solution for 10 minutes, or if using a tuberculocidal hospital disinfectant follow manufacturer's instructions for effectiveness against mycobacteria.
    - clean and disinfect any nondisposable items used in the cleanup
    - manage disposable protective clothing as infectious waste
    - replenish items in the spill kit
    - call for help as needed in accordance with emergency numbers listed in the management plan
  - 20) Treated infectious wastes are disposed as solid wastes in a licensed solid waste disposal facility.

- 21) All sharps must be managed so that the potential is eliminated for those wastes to cause lacerations or puncture wounds during handling, transportation, and disposal.
- 22) Perform quality assurance testing on any autoclave treatment unit that has not been used for the treatment of infectious wastes for one year or more prior to resumed use.
- 23) Operators of any large generator treatment facilities who intend to discontinue treating infectious waste must comply with OAC rules 3745-27-36 and 3745-27-39.

#### Shipping Papers (OAC Rule 3745-27-33)

Commercial treatment facilities cannot accept infectious wastes generated by large generators (generators of fifty pounds or more of infectious waste in any one month) unless accompanied by a treatment shipping paper. Small generator (less than fifty pounds in a month) waste, other than cultures, may be transported and treated without a treatment shipping paper. The treatment shipping paper must be returned to the generator.

Captive treatment facilities can accept infectious waste without a treatment shipping paper. Generators who transport their own waste to their treatment facility are not required to use a treatment shipping paper. Additionally, those hospitals that wish to accept and treat infectious waste from individuals, emergency medical organizations and small generators with staff privileges disposing of sharps are not required to use treatment shipping papers.

All treatment facilities shall prepare a disposal shipping paper to accompany the treated infectious wastes to a licensed solid waste disposal facility (landfill). A disposal shipping paper must also be created for wastes received from a small generator or a large generator and treated at the facility. Please note that if the treated infectious waste first goes through a solid waste transfer facility, the transfer facility should not be signing and keeping the disposal shipping paper. Instead, the disposal shipping paper should continue to accompany the disposal paper to the ultimate disposal facility.

#### Packaging (OAC Rule 3745-27-34)

Treatment facilities shall only accept infectious wastes that have been packaged utilizing the biohazard bags that meet the 165 gram minimum Dropped Dart Impact Resistance Test and the 25 pound water carry test and are securely tied or sealed. Infectious wastes treated at a premises other than where generated must either be double bagged or utilize a single bag within a container. The use of a container that is rigid, sturdy, labeled on two opposite sides with the international biohazard symbol is optional. Sharps containers must be rigid, leak resistant, puncture resistant, and tightly closed to prevent loss of contents. The contents of the spill containment and cleanup kit shall reflect the packaging requirements. The prohibition against damaging any containers of infectious waste shall be strictly adhered to.

#### Handling (OAC Rule 3745-27-35)

All facilities that treat infectious waste are required to comply with the general storage regulations of maintaining the integrity of packaging, maintaining the waste in a nonputrescent state, locking outside storage areas, locking or labeling designated storage areas, and storing in an area that affords protection from animals and does not provide a breeding place or food source for insects or rodents. Treatment facilities also have specific storage requirements in addition to the general storage conditions. Specifically, a treatment facility may not store infectious waste more than fourteen days. A treatment facility may not store more than seven times the maximum daily throughput capacity. A generator who treats his/her own waste on-site must comply with the treatment facility storage regulations once the infectious wastes are in a centralized storage area directly prior to treatment. A contingency plan for the removal of infectious waste to an alternate treatment facility is also required.

### Permit to Install Application (OAC Rule 3745-27-37)

This rule requires that all new commercial infectious waste treatment facilities, or existing commercial treatment facilities that wish to modify the facility, obtain approval of a permit to install from Ohio EPA prior to construction or modification. The application requires submittal of detail engineering plans and specifications in addition to a narrative section. Specific criteria for approval are listed, such as previous compliance history and compliance with the disclosure statement requirements of sections 3734.40 to 3734.43 of the Revised Code. There is also a requirement for a ten year anniversary permit review to ensure that the facility continues to meet the best available technology as being applied to infectious waste in the State of Ohio.

A permit-to-install is not required to construct a new, or modify an existing, captive treatment facility. However, note that in order for an existing captive facility to become a commercial treatment facility (acceptance of waste that does not meet the exemptions) a permit-to-install would first have to be obtained.

### Final Closure of Infectious Waste Treatment Facilities (OAC Rule 3745-27-39)

This rule addresses issues involved in closing an infectious waste treatment facility. The language is very similar to the final closure requirements currently in rule for solid waste incinerators and transfer facilities. The rule provides guidance that pertains to a notification process, cleanup specifications and types of disinfectants used.

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THE REST OF THESE REQUIREMENTS ONLY APPLY TO COMMERCIAL INFECTIOUS WASTE TREATMENT FACILITIES (However, please note that the Technical Assistance Contacts are available to all)

### License Requirement (OAC Rule 3745-37-01)

An Ohio EPA annual operating license is required to operate an infectious waste treatment facility that accepts infectious waste not generated on premises owned or operated by the owners or operators of the treatment facility. The license may be either an infectious waste treatment facility license or a solid waste license with a notation that the facility also treats infectious wastes.

### License Application (OAC Rule 3745-37-02)

This rule specifies the application procedure. License applications are made to the Board of Health maintaining an Ohio EPA approved program, or, in the case of a health district not on the Director's approved list, to the Director of the Ohio EPA.

### Criteria for Issuance (OAC Rule 3745-37-03)

Licenses are issued based upon specific criteria such as having obtained a permit to install, operations for the previous year in substantial compliance with statute, and that the operator of the facility is competent and qualified.

### Action on the Application (OAC Rule 3745-37-04)

The Board of Health or the Director of the Ohio EPA must take action on a request for a license within ninety days of receipt of the completed application.

### Expiration of License (OAC Rule 3745-37-05)

All licenses expire on December 31 of the year in which they become effective.

### Transfer of Licenses (OAC Rule 3745-37-06)

A person holding a license may not transfer the license without notifying the Board of Health and the Director of the Ohio EPA at least 120 days prior to the transfer date. The license transfer shall not be effective until approved by the Board of Health and the Director. A license may not be transferred from one facility to another.

### Procedures for Action on a License (OAC Rule 3745-37-07)

Any action by the Board of Health and the Director of the Ohio EPA must be in accordance with the appropriate chapters of the Revised Code and the Administrative Code.

### Host Fees (OAC Rules 3745-28-01 and 3745-28-07)

The local municipality or township in which a commercial facility is located may pass a resolution enacting a fee (maximum of \$5.00 per ton) on all infectious waste treated. The fee cannot be collected until at least 60 days after passage of the ordinance or resolution. The collected fee must be used to: 1) provide financial assurance to the local board of health for enforcement of infectious waste provisions; 2) provide for local emergency response services for the facility or transportation of waste to the facility; 3) provide funding to the township or local municipality for environmental monitoring programs in relation to the facility.

### Technical Assistance Contacts

For further information regarding the Ohio EPA Division of Solid and Infectious Waste Management's regulations on infectious waste treatment facilities, please contact any of the following:

- 1) A registered sanitarian in your local health department. Currently 95 of the 150 local health districts have an approved program with the Ohio EPA and perform compliance monitoring and enforcement of the Ohio EPA's regulations. The phone number for your local health department can be obtained from your local phone directory.
- 2) An inspector in the Ohio EPA District Office - Division of Solid and Infectious Waste Management. Phone numbers and addresses for the District Offices are:
 

Northwest Ohio -	(419) 352-8461 -	347 North Dunbridge, Bowling Green, OH 43402
Northeast Ohio -	(330) 963-1200 -	2110 Aurora Road, Twinsburg, OH 44087
Central Ohio -	(614) 728-3778 -	3232 Alum Creek Drive, Columbus, OH 43207
Southwest Ohio -	(937) 285-6357 -	401 E. Fifth Street, Dayton, OH 45402
Southeast Ohio -	(740) 385-8501 -	2195 Front Street, Logan, OH 43138
- 3) An infectious waste specialist in the Ohio EPA central office who can be reached by telephone at 614-644-2621 or write to: Ohio EPA - DSIWM; Infectious Waste Specialist; P.O. Box 1049; Columbus, OH 43216-1049.

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