ADVISORY NO. 10.5: REGULATIONS FOR AUTOCLAVE USE, MAINTENANCE AND RECORDKEEPING

INTRODUCTION

Using an autoclave to sterilize infectious waste is one method of treatment that is approved by the Ohio EPA. There are many requirements that accompany maintaining an autoclave to treat infectious waste. Contact the Environmental Health & Safety office at 556-4968 if you would like to pursue this treatment option.

The local Health Department (Cincinnati, Hamilton County, Clermont County) enforces the infectious waste regulations for the Ohio EPA. The inspection checklist in Appendix C is used for the required quarterly inspections for infectious waste treatment facilities. There are some items that are not permitted to be treated in an autoclave:

**radioactive waste* (contact Radiation Safety at 558-4110)
**hazardous waste* (see advisory 7.3 – Management of Hazardous Waste)
pathological waste (organs, body parts, carcasses – contact Work Control at 558-2500)
sharps waste (call EH&S at 556-4968 for disposal)

* - Mixed waste streams (infectious/radioactive, infectious/chemical, chemical/radioactive) are difficult to dispose of due to the multiple regulations applied to the waste (NRC, RCRA, EPA, etc.). Generators should attempt to address the issue of mixed waste prior to generation of the material to avoid problems and/or possible citations related to disposal, storage times, treatment technologies, et al.

AUTOCLAVE REQUIREMENTS

The operator of the autoclave treatment facility must comply with the following guidelines and criteria established in the Ohio Administrative Code 3745-27-32 (Standards For the Operation of Infectious Waste Treatment Facilities) regarding the following areas:

- Methods and Operations
- General Facility Requirements (Facility Management Plan)
- Shipping Papers
- Handling/Storage of Infectious Waste
- Permitting and Licensing

METHODS AND OPERATIONS

The owner or operator of any facility utilizing autoclaving as a treatment technology shall comply with the following:

(a) All autoclaves shall operate at a minimum temperature of 121°C or 250°F at a minimum of 15 psi gauge pressure for a minimum of 60 minutes during a treatment cycle (see Appendix A for other time/temperature/pressure requirements)
(b) Autoclaves shall not be loaded beyond the total treatable volume of infectious wastes
(c) Autoclaves shall not treat pathological wastes, including without limitation, human and animal tissues, organs, and body parts, that are contaminated with or are likely to be contaminated with infectious agents, removed or obtained during surgery or autopsy or for diagnostic evaluation and gross anatomical wastes such as human or animal limbs and sections containing bone, and animal carcasses, except small sections of tissue that are only several cells wide used for microscopic evaluation
(d) Produce and maintain a permanent record of the chamber temperature utilizing a temperature recording device permanently connected to the unit. The device shall permanently record a data point at a maximum of every two minutes. The temperature shall be displayed for visual monitoring. In the event of a temperature recording device failure, the owner or operator shall:
(i) Manually record the chamber temperature, at a maximum, once every ten minutes until the exhaust cycle is initiated. The temperature shall be manually recorded for no longer than the time necessary to repair the mechanical failure. The operator shall demonstrate proof that repair parts have been ordered if requested by the Ohio EPA or approved health department; and
(ii) Discontinue use of the autoclave for the treatment of infectious wastes until repaired if failure or malfunction occurs in the temperature measuring device.

(e) Demonstrate the achievement of the performance standard by the treatment unit for the treatment of infectious wastes. The owner or operator shall perform this by checking the daily operation of the pressure and temperature monitoring devices by:

(i) Recording into the daily log, the actual gauge readings of temperature and pressure and not the manual settings of the treatment unit, during the treatment cycle of a load of infectious wastes

(ii) Use the **pressure/steam temperature table in the appendix B of this advisory** to confirm that the temperature or pressure readings obtained from the gauges are within either ±2 degrees or ±2 pounds per square inch (PSI) from either the temperature or pressure readings in the referenced table. If the temperature or pressure monitoring devices are not within ±2 degrees or ±2 pounds per square inch (PSI) in accordance with the pressure/steam temperature table located in the appendix of this rule, then the owner or operator shall select one of the following options. The owner or operator shall continue use of one of these options until such time that the autoclave is repaired or calibrated:

(a) Discontinue use of the autoclave for the treatment of infectious wastes; or

(b) Perform weekly (every seventh day that the autoclave is used for treatment) quality assurance (spore) testing. If the weekly quality assurance testing fails, discontinue use of the autoclave for the treatment of infectious wastes until the autoclave is able to operate in accordance with the pressure/steam temperature table located in Appendix B of this rule. Infectious wastes placed within the unit during and after the failed spore testing shall not be considered treated and shall be handled as infectious wastes.

(f) Utilize an independent company to calibrate/repair the autoclave chamber pressure gauge, temperature recording device, or temperature measuring device in accordance with the following:

(i) The manufacturer's maintenance schedule, specifications, or recommendations; or

(ii) A calibration schedule as determined by the facility, with, at a minimum, annually, if the manufacturer's specifications are not available.

QUALITY ASSURANCE (SPORE TESTING)

The owner/operator of the autoclave shall perform monthly quality assurance (spore) testing every calendar month in which the autoclave is used for the treatment of infectious wastes to ensure the capability of the autoclave to achieve the performance standard of a minimum four log10 reduction of Bacillus stearothermophilus spores by:

(a) Using a challenge population of spores as either spore strips with a population of at least 1.0×10 Bacillus stearothermophilus spores, ampules containing at least 1.0×10 Bacillus stearothermophilus spores per milliliter or a commercially available steam pack which contains a population of at least 1.0×10 Bacillus stearothermophilus spores. The owner or operator shall ensure that the Bacillus stearothermophilus spore testing methodology does not result in the denaturation of the proteins within the inoculating media;

(b) Composing the waste load of containers of both infectious wastes and non-infectious wastes. The majority of the waste load may consist of infectious wastes. However, at least three test containers shall consist of material such as newspaper, plastic backed absorbent pads, or general refuse placed into either boxes, bags, or sharps containers representative of normal or anticipated use for that autoclave unit. A spore strip or ampule shall be placed in the center of each test container. In the event that the autoclave will not hold three containers of wastes, then each test container shall contain a spore strip or ampule. Alternatively, commercially available steam packs may be placed into the three representative containers instead of the newspaper, plastic backed absorbent pads, or general refuse

(c) Treating the waste load containing the challenge population of spores in the same manner as the daily operation of the autoclave for the treatment of infectious wastes. This would include the same temperature, pressure, time, and total treatable volume. The quality assurance testing shall be performed at the same combinations of temperature, pressure, and time, as the validation testing;

(d) Recording the following information during the monthly quality assurance testing:

(i) The date;

(ii) The time the treatment cycle started.

(iii) The time the treatment cycle ended.

(iv) The chart or graph of the chamber temperature produced by the permanently connected temperature recording device;

(v) The name of the person who loaded the autoclave and the name of the person performing laboratory analysis of the challenge population of spores;

(vi) A diagram depicting the pattern of infectious waste loading and location of the challenge population of spores during the testing except those units which have rotating treatment chambers are not required to diagram the pattern of waste loading;

(vii) The total treatable volume of infectious wastes used during the quality assurance testing

(viii) The autoclave chamber pressure, as displayed by the permanently connected gauge, during the treatment cycle.

(ix) The incubation temperature and time (in days) of the challenge population of spores, in accordance with the manufacturer's recommendation for optimal growth; and

(x) The results of spore growth during incubation for a period of seven days or for the maximum period of time as specified by the manufacturer of the spore test. The results of spore growth shall be recorded as indicated by the development of turbidity in the

growth media. The development of turbidity in the growth media is indicative of growth of the challenge population of spores present unless other morphological or metabolic testing indicates that the growth is due to a contaminating microorganism.

(e) Remove and incubate the challenge population of spores used in the quality assurance testing for either seven days or for the maximum period of time as specified by the manufacturer of the spore test. If any of the challenge population of spores used to perform the testing is positive for growth at any time during the incubation period, the unit has failed to achieve the performance standard required for treatment. Infectious wastes placed within the unit during and after the spore testing shall not be considered treated and shall be handled as infectious wastes. The autoclave unit shall not be used for further treatment of infectious wastes until the problem has been determined and rectified and another successful quality assurance test performed. The rectification may require the operator to increase the minimum temperature and/or pressure requirements or cycle time; and

(f) Perform the quality assurance testing, upon request by, and in the presence of, the Ohio EPA or approved health department to verify that the written operating procedures as located in the facility management plan are sufficient to meet the performance standard of a four log10 reduction in Bacillus stearothermophilus spores. If so directed, the owner or operator shall use twice as many spore tests in the same location in the autoclave and permit the Ohio EPA or approved health department to remove and separately incubate one-half of the spore tests.

GENERAL FACILITY REQUIREMENTS (Facility Management Plan)

This documentation must be kept with each autoclave unit (for at least three years) and must include the following:

General Requirements**:**

1) Management Plan

- all environmental regulations pertaining to infectious waste, solid waste, wastewater, and air pollution control
- applicable infectious waste, solid waste, wastewater and air permits
- owner's manual, maintenance schedule, equipment specifications
- calibration or replacement schedule for temperature devices
- maintenance/repair log for all service
- spill containment and cleanup procedures
- contingency plan
- QA/validation testing results
- start-up, loading, operating, shutdown, malfunction procedures
- emergency telephone numbers (internal and external)
- daily logs
- temperature charts, graphs and manual recordings (for three years)
- disposal shipping papers
- training certification statement for each employee who operates, loads or unloads the unit

2) Operator training

- signed document stating that each employee that loads, operates or unloads the unit has been trained in the procedures necessary to perform these tasks safely and as intended

3) Operator (Daily) Log

- time/date/operator of each load; time/date/operator who unloads the autoclave
- whether run was for validation, QA or usual treatment
- pressure and temperature readings

4) A copy of the unit's operating and loading procedures

5) Waste may remain inside the unit (mechanical failure or jamming) until the problem is corrected unless the waste becomes putrescent

6) Construction and operations documents

7) Construct and maintain
- access roads
- concrete or asphalt floors in all areas
- proper slopes and drainage

8) Load treatment units to prevent compaction or puncture of the containers

9) Loading area must be sheltered from precipitation (or not loaded during this time)

10) Properly contain and dispose of wastewater resulting from the spill of infectious waste or the cleanup of a spill of infectious waste. Proper disposal includes discharge to a disposal system IAW Chapter 6111 of the Revised Code (not disposal via a storm sewer).

11) Restrict access to all areas

12) Do not treat waste prohibited by the Ohio Department of Health or the Nuclear Regulatory Commission.

13) Do not treat waste prohibited by hazardous waste regulations (RCRA, etc.).

Spill Containment & Cleanup

Spill Kits must contain the following: biohazard bags, absorbent, disinfectant (bleach), latex gloves and other personal protective equipment deemed necessary (goggles, lab coat, tyvek, suit, etc), first aid kit, and boundary tape.

Cleanup Procedures
- use appropriate protective equipment for cleaning infectious waste spills
- limit access to the area
- place broken containers and spillage inside biohazard bags
- use absorbents to collect liquids; manage absorbent materials as infectious waste
- clean and disinfect the area and all nondisposable items
- manage disposable items as infectious waste
- replenish the spill kit
- call EH&S (556-4968) for emergency assistance
- report all spills to the EH&S office

SHIPPING PAPER SYSTEM

A “disposal shipping paper” is a record of the treated infectious waste being transported and shall accompany the waste from the treatment facility to the disposal facility. The disposal shipping paper shall:
- Be prepared by the treatment facility (or generator) and be approved by the Environmental Health & Safety Office
- Be legible and complete and kept on file for three years (a copy of each disposal shipping paper must be forwarded to EH&S at mail location 0218)
- Be signed, dated, and given to the transporter by the treatment facility before the waste is removed from the premises

The disposal shipping paper shall contain the following information:
- the name, address, telephone number, and dated signature of the infectious waste treatment facility/generator
- the name, address, telephone number, and dated signature of the owner or operator of the solid waste disposal facility
- a certification by the owner/operator of the treatment facility that the waste have been treated IAW Ohio Administrative Code 3745-45-32

STORAGE/HANDLING OF INFECTIOUS WASTE

Infectious waste storage and handling areas must comply with the following procedures and have the required documentation:

- maintain integrity of the packaging
- maintain waste in a nonputrescent state
- lock outside storage areas to prevent unauthorized access; label all storage areas with international biohazard symbol
- contain all spills and follow spill cleanup procedures
- protect infectious waste from animals and prevent it from becoming a breeding place for insects or rodents
- do not store waste for more than fourteen days
- do not store more than seven times the maximum daily throughput capacity
- maintain a contingency plan with the following information:
    - Designation of an Emergency Coordinator and an Alternate Emergency Coordinator
    - Table of Contents
    - Facility ID
    - Purpose Statement
    - Emergency Response Equipment
    - A designation of alternative treatment facilities
    - Responsibilities of the Emergency Coordinator
    - Storage and Handling Procedures
    - Refrigeration requirements IAW Rule 3745-27-31 of the Ohio Administrative Code (46°F or less)
    - Implementation of response
    - Internal notification
    - Provide a posting of emergency procedures

PERMITTING AND LICENSING

Treating waste from other infectious waste generators requires a permit and license through the Ohio EPA as a “commercial treatment facility”. A generator of infectious waste that treats only their waste is exempt from permitting and licensing requirements under the rules of OAC 3745-27-32. Contact Environmental Health & Safety at 556-4968 for further information.

APPENDIX A

ALTERNATIVE TIME/TEMPERATURE REQUIREMENTS (Validation Testing)

The owner or operator of an autoclave who uses combinations during the treatment cycle, other than the minimum time, temperature, and pressure requirements, as specified in paragraph (a) (Methods and Operations), to treat infectious wastes may do so provided that achievement of the performance standard is demonstrated by validation testing, prior to use for the treatment of infectious wastes.

(a) For the purposes of this advisory, the treatment cycle is that combination of time, temperature, and pressure needed to achieve the performance standard of a four log (base ten) reduction in Bacillus stearothermophilus spores. The treatment cycle does not include the time needed to bring the chamber up to the operating temperature/pressure or the time it takes for the autoclave to exhaust and allow opening of the chamber

(b) The total treatable volume of infectious wastes used in either the validation (or quality assurance) testing shall be the total volume of wastes that can be treated per treatment cycle. The total treatable volume of infectious wastes may be calculated by using any one of the following:

(i) The manufacturer's specification for the total volume of the autoclave; or

(ii) A lesser estimate based upon the manufacturer's specification of the total volume of the autoclave; or

(iii) An actual calculation of the total treatable volume at each validation or quality assurance test. Listing the number of bags, boxes, and/or other containers of infectious wastes used during the testing, and adding the volumes of those containers shall calculate the total treatable volume.

Example Calculation for Treatable Volume: The autoclave test load consisted of three bags and four boxes. The volume of each container is: bag = 3 cubic feet, box = 2.5 cubic feet. Therefore, the total treatable volume of wastes in the quality assurance test load and hence, the maximum amount of wastes that can be treated at any one time is [(3)(3)+(4)(2.5)] = 19 cubic feet

(c) Record the following information during the validation testing:

- a written statement indicating the autoclave pressure, temperature and treatment cycle time that the owner/operator is attempting to validate for the treatment of infectious waste, along with:

(i) The date;

(ii) The time the treatment cycle started.

(iii) The time the treatment cycle ended.

(iv) The chart or graph of the chamber temperature produced by the permanently connected temperature recording device;

(v) The name of the person who loaded the autoclave and the name of the person performing laboratory analysis of the challenge population of spores;

(vi) A diagram depicting the pattern of infectious waste loading and location of the challenge population of spores during the testing except those units which have rotating treatment chambers are not required to diagram the pattern of waste loading;

(vii) The total treatable volume of infectious wastes used during the validation testing

(viii) The autoclave chamber pressure, as displayed by the permanently connected gauge, during the treatment cycle.

(ix) The incubation temperature and time (in days) of the challenge population of spores, in accordance with the manufacturer's recommendation for optimal growth; and

(x) The results of spore growth during incubation for a period of seven days or for the maximum period of time as specified by the manufacturer of the spore test. The results of spore growth shall be recorded as indicated by the development of turbidity in the growth media. The development of turbidity in the growth media is indicative of growth of the challenge population of spores present unless other morphological or metabolic testing indicates that the growth is due to a contaminating microorganism.

APPENDIX B

GAUGE PRESSURE VS. TEMPERATURE OF SATURATED STEAM

Gauge Pressure (psi)	Temp (F)	Temp (C)	Gauge Pressure (psi)	Temp (F)	Temp (C)	Gauge Pressure (psi)	Temp (F)	Temp (C)
0	212.0	100.0	45	292.4	144.7	90	331.2	166.2
1	215.4	101.9	46	293.5	145.3	91	331.8	166.6
2	218.5	103.6	47	294.6	145.9	92	332.5	166.9
3	221.5	105.3	48	295.6	146.4	93	333.2	167.3
4	224.5	106.9	49	296.7	147.1	94	333.9	167.7
5	227.4	108.6	50	297.7	147.6	95	334.6	168.1
6	230.0	110.0	51	298.7	148.2	96	335.3	168.5
7	232.4	111.3	52	299.7	148.7	97	335.9	168.8
8	234.8	112.7	53	300.6	149.2	98	336.6	169.2
9	237.1	113.9	54	301.6	149.8	99	337.2	169.6
10	239.4	115.2	55	302.6	150.3	100	337.9	169.9
11	241.6	116.4	56	303.6	150.9	101	338.5	170.3
12	243.7	117.6	57	304.5	151.4	102	339.2	170.7
13	245.8	118.8	58	305.5	151.9	103	339.8	171.0
14	247.9	119.9	59	306.4	152.4	104	340.5	171.4
15	249.8	121.0	60	307.4	153.0	105	341.1	171.7
16	251.7	122.1	61	308.3	153.5	106	341.7	172.1
17	253.6	123.1	62	309.2	154.0	107	342.3	172.4
18	255.4	124.1	63	310.1	154.5	108	342.9	172.7
19	257.2	125.1	64	311.0	155.0	109	343.5	173.1
20	258.8	126.0	65	311.9	155.5	110	344.2	173.4
21	260.6	127.0	66	312.8	156.0	111	344.8	173.8
22	262.3	127.9	67	313.7	156.5	112	345.4	174.1
23	263.8	128.8	68	314.5	156.9	113	346.0	174.4
24	265.3	129.6	69	315.3	157.4	114	346.6	174.8
25	266.8	130.4	70	316.1	157.8	115	347.2	175.1
26	268.3	131.3	71	316.9	158.3	116	347.8	175.4
27	269.9	132.2	72	317.7	158.7	117	348.3	175.7
28	271.4	133.0	73	318.5	159.2	118	348.9	176.1
29	272.7	133.7	74	319.3	159.6	119	349.5	176.4
30	274.0	134.4	75	320.1	160.1	120	350.1	176.7
31	275.4	135.2	76	320.9	160.5	121	350.6	177.0
32	276.7	135.9	77	321.7	160.9	122	351.2	177.3
33	278.1	136.7	78	322.5	161.4	123	351.8	177.7
34	279.4	137.4	79	323.3	161.8	124	352.3	177.9
35	280.7	138.2	80	324.1	162.3	125	352.9	178.3
36	281.9	138.8	81	324.9	162.7	126	353.5	178.6
37	283.2	139.6	82	325.6	163.1	127	354.0	178.9
38	284.4	140.2	83	326.3	163.5	128	354.5	179.2
39	285.6	140.9	84	327.0	163.9	129	355.1	179.5
40	286.7	141.5	85	327.7	164.3	130	355.6	179.8
41	287.9	142.2	86	328.4	164.7	131	356.2	180.1
42	289.0	142.8	87	329.1	165.1			
43	290.2	143.4	88	329.8	165.4			
44	291.3	144.1	89	330.5	165.8			

APPENDIX C

Infectious Waste Treatment Facility Inspection Checklist – Autoclave

Facility Name:_____ID #_____Date:_____County:_____
Facility Address:_____Facility Phone #:_____
Operator Name:_____Operator Phone #:_____
Corporate Address:_____ Corp. Phone # (if diff.):_____
Health District:_____Inspector(s):_____

Is this facility being operated in compliance with the following regulations (YES or NO)? Place an X in the appropriate column to denote compliance status. Placing an X in the NO column indicates that a violation has been noted. Write N/A on the lines that are not applicable.
This checklist is not all inclusive of regulations applicable to Infectious Waste Treatment Facility operations. Please refer to the attached notice of violation letter for a detailed explanation of any violations noted here.

This is a: ( ) Comprehensive Inspection ( ) Partial Inspection ( ) Comments on Back

YES / NO

3745-27-32(D) Autoclaving

(D) (1) Approved Method

___/___ (D)(1)(a) Minimum 121°C (15 psi) for 60 minutes
___/___ (D)(1)(b) Other time/temperature with validation
___/___ (D)(1)(e) Do not load beyond max. treatable volume
___/___ (D)(1)(f) No gross anatomicals unless validated
___/___ (D)(2)(a) Produce and maintain permanent temperature records
___/___ (D)(2)(b) Temperature/pressure correspondence
___/___ (D)(2)(c) Independent calibration
___/___ (D)(3) Monthly quality assurance spore testing
___/___ (D)(4) If applicable, validation testing

(I) General Facility Requirements

___/___ (I)(1) Record retention for 3 years
___/___ (I)(2) Complete facility management plan
___/___ (I)(3) Trained Operators
___/___ (I)(4) Daily Logs
___/___ (I)(5) Operating procedures available
___/___ (I)(7) Constructed and operating in accordance with authorizing documents
___/___ (I)(8) Construction/maintenance of access roads
___/___ (I)(9) Proper floors
___/___ (I)(10) Waste not compacted or punctured
___/___ (I)(11) Sheltered loading
___/___ (I)(12) Proper disposal of wastewater
___/___ (I)(13) Proper slopes / drainage
___/___ (I)(14) Restricted access
___/___ (I)(15) Shall not treat radioactive waste
___/___ (I)(16) Shall not treat hazardous waste
___/___ (I)(18) Spill containment and clean-up kits
___/___ (I)(18)(b) Appropriate disinfectants
___/___ (I)(19) Clean-up procedure
___/___ (I)(20) Handling treated waste
___/___ (I)(21) Treated sharps management

YES / NO

3745-27-33 Shipping Paper System

(B) Treatment shipping paper

___/___ Complete and legible
___/___ Shipping paper on file 3 years

(C) Disposal shipping paper

___/___ Complete and legible
___/___ Shipping paper on file 3 years

3745-27-35 Standards for Handling Inf. Waste

(A) In-Use and Stored Containers

___/___ (1) Maintain integrity of packaging
___/___ (2) Outside storage areas locked
___/___ (3) Lock or visibly label with signs or int'l. biohazard symbol posted at all access points
___/___ (4) Contain and clean-up spills

(B) Management of Inf. Waste Within Containers

___/___ (1) Maintain non-putrescent state
___/___ (2) Putrescent IW refrigerated / frozen & treated ASAP
___/___ (3) Protect from animals and insects
___/___ (4) Spill containment / clean-up

(C) Treatment facility requirements

___/___ (1) Fourteen day maximum storage
___/___ (2) Not more than 7x daily throughput stored
___/___ (3) Contingency plan maintained as part of facility management plan

3745-37-01 License (COMMERCIAL FACILITIES ONLY)

___/___ (B) Valid license