Ohio Administrative Code

Rule 3745-27-32 Standards for the operation of infectious waste treatment facilities.

Effective: March 1, 2013

(A) The owner or operator of an infectious waste treatment facility shall treat all infectious wastes in accordance with an approved infectious waste treatment method. Infectious waste treatment facilities are licensed infectious waste treatment facilities and all large generators who treat infectious wastes on-site. Treatment shall occur in accordance with all paragraphs in this rule applicable to that particular treatment technology and paragraph (I) of this rule. The following is a list of infectious waste treatment methods approved in the state of Ohio:

(1) Incineration, as specified in paragraphs (C) and (I) of this rule;

(2) Autoclaving, as specified in paragraphs (D) and (I) of this rule;

(3) Chemical treatment utilizing a sodium hypochlorite solution for cultures, as specified in paragraphs (E) and (I) of this rule;

(4) Applied heat encapsulation for sharps, as specified in paragraphs (F) and (I) of this rule;

(5) Chemical treatment utilizing peracetic acid and grinding, as specified in paragraphs (G) and (I) of this rule; and

(6) Alternative treatment technologies approved by the director. The owner or operator of any infectious waste treatment facility utilizing either a statewide or a site-specific alternative infectious waste treatment technology approved by the director in accordance with rule 3745-27-38 of the Administrative Code shall comply with the director's approval letter for that treatment technology and paragraph (I) of this rule.

(B) All small generators who choose to treat infectious wastes on the premises where they are generated shall comply with the following applicable paragraphs in this rule. Treatment shall occur using an approved infectious waste treatment method and in accordance with paragraph (C)(1),

(D)(1), (E)(1), (F)(1) or (G)(1) of this rule or in accordance with a director's approval letter issued in accordance with rule 3745-27-38 of the Administrative Code.

(C) Incineration. The owner or operator of any infectious waste treatment facility utilizing incineration as a treatment technology shall comply with the following:

(1) Methodology. The owner or operator shall use methods, techniques, and practices for the treatment of infectious wastes in accordance with the following:

(a) All incineration shall occur in a multi-chamber incinerator which provides complete combustion of the wastes, excluding metallic, glass, and ceramic items;

(b) A minimum temperature of one thousand two hundred degrees Fahrenheit in the primary chamber and a minimum of one thousand six hundred degrees Fahrenheit with a minimum one second residence time in the secondary chamber shall be maintained;

[Comment: Additional temperature, residence time, and compliance testing requirements may be necessary to achieve appropriate air emission standards in accordance with Chapter 3704. of the Revised Code.]

(c) Each incinerator shall be equipped with a mechanical process(es) to prevent the charging of infectious wastes into the incinerator until the minimum temperatures required in paragraph (C)(1)(b) of this rule are achieved;

(d) Incinerators shall have automatic auxiliary burners that are capable, excluding the heat content of the wastes, of independently maintaining the secondary chamber temperature at the minimum of one thousand six hundred degrees Fahrenheit;

(e) Incinerators shall not be charged beyond either:

(i) The maximum hourly waste capacity. For the purposes of this rule, the maximum hourly waste capacity is the same as the hourly capacity as stated in the permit to operate issued by Ohio EPA, division of air pollution control; or

(ii) The design capacity as determined by the manufacturer, if no permit to operate is issued by Ohio EPA, division of air pollution control.

(f) Wastes not combusted to ash, except for metallic, glass, and ceramic items, shall be handled and treated as infectious wastes and may be reincinerated.

(2) Specific operational criteria. The owner or operator shall design, construct, and operate the equipment for the treatment of infectious wastes in accordance with the following:

(a) Store all ash from the incinerator in a leakproof, closed container. The ash shall be free of liquids before disposal;

(b) Any ash spilled outside of the treatment unit shall be managed as treated infectious wastes unless the owner or operator has reason to manage such wastes as hazardous waste;

(c) The owner or operator shall:

(i) Characterize the ash resulting from the treatment of infectious wastes as either a solid waste or a hazardous waste by:

(a) Separately testing fly ash and bottom ash for metals, and;

(b) Obtaining representative samples of bottom and fly ash utilizing the "simple random sampling method" described in the "U.S. EPA Test Methods for Evaluating Solid Waste, third edition (SW846)," chapter nine. The samples shall be collected and tested quarterly, or more frequently as required by Ohio EPA, for the toxicity characteristic leaching procedure (TCLP) for metals utilizing an independent analytical laboratory using the methodology specified in the "hazardous waste rules" as defined in paragraph (A) of 3745-50-10 of the Administrative Code.

(ii) Manage the ash in accordance with the applicable solid waste or hazardous waste requirements in Chapter 3734. of the Revised Code and the rules adopted thereunder.

[Comment: Pursuant to paragraph (I) of this rule, the owner or operator of an incinerator must maintain for a three year period the dated permanent recordings of primary and secondary chamber temperatures, documentation of calibration or replacement of the temperature measuring or recording devices, results of Bacillus species spore testing, if so required, and the results of fly and bottom ash testing.]

(3) Quality assurance. The owner or operator of the infectious waste treatment technology shall use the following quality assurance testing requirements to demonstrate that the treatment unit is capable of attaining the performance standard as specified in this rule for the treatment of infectious wastes:

(a) Produce and maintain a permanent record of primary and secondary chamber temperatures utilizing continuous temperature recorders. Chamber temperatures shall also be displayed for visual monitoring. In the event of a temperature recorder failure the owner or operator shall:

(i) Manually record the chamber temperature(s). The chamber temperature(s) shall be manually recorded immediately after each charge of infectious waste and, at a maximum, once every ten minutes thereafter until the burn down cycle is initiated. Manual recording of the temperature(s) shall continue until repair of the recording device. The operator shall demonstrate proof that repair parts have been ordered if requested by Ohio EPA or approved health department; and

[Comment: Temperature recordings taken after a charge of infectious waste that occurred sooner than ten minutes from the previous charge of infectious waste fulfills the maximum ten minute temperature recording requirement.]

(ii) Discontinue use of the incinerator, until repaired, for the treatment of infectious wastes if failure has occurred in the temperature measuring device, such as a thermocouple or thermocouple wiring.

(b) Utilize an independent company to calibrate, repair or replace primary and secondary chamber temperature recording devices or temperature measuring devices 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, annual calibrations, if

the manufacturer's specifications are not available.

(c) Sample, upon written notification by Ohio EPA, stack gas and the resulting bottom ash after the addition of Bacillus species spores to a load of infectious waste. Sampling shall be accomplished in accordance with the protocol provided by Ohio EPA.

(4) Comply with paragraph (I) of this rule.

(D) Autoclaving. The owner or operator of any infectious waste treatment facility utilizing autoclaving as a treatment technology shall comply with the following:

(1) Methodology. The owner or operator shall use methods, techniques, and practices for the treatment of infectious wastes in accordance with the following:

(a) All autoclaves shall operate at a minimum temperature of one hundred twenty-one degrees Centigrade or two hundred fifty degrees Fahrenheit at a minimum of fifteen pounds per square inch gauge pressure for a minimum of sixty minutes during a treatment cycle; or

(b) 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 (D)(1)(a) of this rule, to treat infectious wastes may do so provided that achievement of the performance standard is demonstrated by validation testing, as outlined in paragraph (D)(4) of this rule, prior to use for the treatment of infectious wastes; and

[Comment: Although autoclaving has been approved for statewide use pursuant to section 3734.021 of the Revised Code, the capability of autoclave units to treat infectious wastes is variable. The variability is due to a number of factors such as: type of wastes treated; the size and density of the waste load; the packaging of the waste; gravity versus vacuum displacement of the air in the chamber; and steam quality. Hence, this rule provides for a process by which autoclaves that are capable of treating infectious wastes at operating parameters below the specified minimum parameters may be approved for use at the lower operating parameters.]

(c) For the purposes of this rule, 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 or pressure nor the time it takes for the autoclave to exhaust and allow opening of the chamber; and

(d) 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. The total treatable volume shall be calculated by listing the number of bags, boxes, or sharps containers of infectious wastes used during the testing, and adding the volumes of those containers.

[Comment: an example to actually calculate the total treatable volume. The autoclave test load consisted of three bags, four boxes, and six sharps containers. The volume of each container is: bag = 3 cubic feet, box = 2.5 cubic feet, sharps container = 0.21 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))+((6)(0.21))] = 20.26 cubic feet.]

(e) Autoclaves shall not be loaded beyond the total treatable volume of infectious wastes, as defined in paragraph (D)(1)(d) of this rule; and

(f) 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, utilizing autoclaving unless the owner or operator:

(i) Submits a protocol to Ohio EPA for approval prior to validation testing to demonstrate that the autoclave unit can effectively achieve the performance standard of a minimum four log (base ten) reduction of a challenge population of Bacillus stearothermophilus spores;

(ii) Demonstrates, through the use of a protocol acceptable to Ohio EPA, that the autoclave unit can effectively achieve the performance standard of a minimum four log (base ten) reduction of a challenge population of Bacillus stearothermophilus spores within such wastes; and

(iii) Receives approval from Ohio EPA to operate the unit to treat pathological wastes.

(2) Specific operational criteria. The owner or operator shall design, construct, and operate the equipment for the treatment of infectious wastes in accordance with the following:

(a) 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 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, such as a thermocouple or thermocouple wiring.

(b) 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 in the following manner:

(i) Record into the daily log, as required in paragraph (I) of this rule, 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; and

(ii) Use the gauge pressure versus temperature of saturated steam table in the appendix to this rule 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 gauge pressure versus temperature of saturated steam table located in the appendix to this rule, then the owner or operator shall select one of the following options. The owner or operator may continue use of the autoclave until such time that the autoclave is repaired or calibrated in accordance with paragraph (D)(2)(c) of this rule:

(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 testing in accordance with paragraph (D)(3) of this rule. 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 gauge pressure versus temperature of saturated steam table located in the appendix to 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.

[Comment: Any autoclave that does not operate within the gauge pressure versus temperature of saturated steam table parameters located in the appendix to this rule and fails the weekly quality assurance testing is to be calibrated. See paragraph (D)(2)(b) of this rule.]

(c) Utilize an independent company to calibrate or 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.

[Comment: A direct relationship exists between the pressure and temperature of saturated steam. If either the temperature recording or pressure device begins to give false readings, then the autoclave owner or operator will be able to note this since the published known values will no longer match the observed values. However, the owner or operator will not know if the pressure or temperature value is incorrect and may have to have both instruments evaluated by an independent company.]

(3) Quality assurance. The owner or operator shall perform quality assurance testing to demonstrate the capability of the autoclave to achieve the performance standard of a minimum four log (base ten) reduction of Bacillus stearothermophilus spores. The quality assurance testing for autoclaves shall be performed monthly, in accordance with the following provisions:

(a) Perform monthly quality assurance 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 log (base ten) reduction of Bacillus stearothermophilus spores;

(b) Use a challenge population of spores as either spore strips with a population of at least 1.0×10^4 Bacillus stearothermophilus spores, ampules containing at least 1.0×10^4 Bacillus stearothermophilus spores per milliliter or a commercially available steam pack which contains a population of at least 1.0×10^4 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;

[Comment: For quality assurance testing, Ohio EPA has set the performance standard for the treatment of infectious wastes by autoclaving to be a four log (base ten) reduction of Bacillus stearothermophilus spores. The quality assurance is designed to be a qualitative (growth or no growth) system. If the owner or operator uses strips or ampules with a greater spore population, then the treatment unit must still achieve a complete kill of all spores.]

(c) Compose 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;

(d) Treat 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;

(e) Record the following information during the monthly quality assurance testing:

(i) The date;

(ii) The time the treatment cycle started, as specified in paragraph (D)(1) of this rule;

(iii) The time the treatment cycle ended, as specified in paragraph (D)(1) of this rule;

(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 as defined in paragraph (D)(1) of this rule;

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

treatment cycle as specified in paragraph (D)(1) of this rule;

(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.

(f) 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 are 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 or pressure requirements or cycle time; and

(g) Perform the quality assurance testing, upon request by, and in the presence of, 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 fourlog (base ten) 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 Ohio EPA or approved health department to remove and separately incubate one-half of the spore tests.

[Comment: autoclave owners or operators treating infectious wastes in accordance with the specifications in this rule must maintain, for a three year period, the dated permanent recordings of autoclave chamber temperatures, documentation of the calibrations of the temperature measuring devices performed by an independent company, documentation of the monthly checks on the

measuring device, and the results of the monthly quality assurance testing using a challenge population of spores.]

(4) Validation testing. The owner or operator shall perform validation testing to demonstrate the capability of the autoclave to achieve the performance standard of a minimum four log (base ten) reduction of Bacillus stearothermophilus spores. The validation testing for autoclaves shall be performed in accordance with the following provisions:

[Comment: Validation testing is performed prior to use for treatment by an operator who wishes to use an alternative combination to the time, temperature, and pressure requirements specified in paragraph (D)(1)(a) of this rule. Validation testing is a check to ensure that the alternate combination will result in the achievement of the performance standard for treatment. Quality assurance testing is an on-going monitor, performed monthly, of the autoclave's continuing ability to attain the performance standard for treatment.]

(a) Perform validation testing to ensure that the autoclave, using combinations of temperature, pressure, and time other than the minimums specified in paragraph (D)(1)(a) of this rule, is capable of achieving the performance standard of a minimum four log (base ten) reduction of Bacillus stearothermophilus spores;

(b) Use a challenge population of spores as either spore strips with a population of at least 1.0×10^4 Bacillus stearothermophilus spores, ampules containing at least 1.0×10^4 Bacillus stearothermophilus spores per milliliter or a commercially available steam pack which contains a population of at least 1.0×10^4 Bacillus stearothermophillus 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;

[Comment: For validation testing, Ohio EPA has set the performance standard for the treatment of infectious wastes by autoclaving to be a four log (base ten) reduction of Bacillus stearothermophilus spores. The validation testing is designed to be a qualitative (growth or no growth) system. If the owner or operator uses strips or ampules with a greater spore population, then the treatment unit must still achieve a complete kill of all spores.]

(c) Compose the validation testing waste load of containers of non-infectious wastes. The waste load for testing shall consist of materials other than infectious wastes, such as newspaper, plastic backed absorbent pads, or general refuse placed into boxes, bags, or sharps containers which are representative of the normal or anticipated use for that autoclave unit. A challenge population of spores shall be placed in the center of each test container;

(d) Treat the waste load containing the challenge population of spores in the same manner as the autoclave will be used during daily operations for the treatment of infectious wastes. This would include the same temperature, pressure, time, and total treatable volume;

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

(i) A written statement indicating the autoclave pressure, temperature, and treatment cycle time that the facility owner or operator is attempting to validate for the treatment of infectious wastes;

(ii) The date;

(iii) The time the treatment cycle started, as specified in paragraph (D)(1) of this rule;

(iv) The time the treatment cycle ended, as specified in paragraph (D)(1) of this rule;

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

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

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

(viii) The total treatable volume of infectious wastes used during the validation testing as defined in paragraph (D)(1) of this rule. Once a total treatable volume of infectious wastes that an autoclave has

been validated to treat has been established, infectious waste loads of lesser than the established total treatable volume may be treated without further validation;

(ix) The autoclave chamber pressure, as recorded by the permanently connected gauge, during the treatment cycle as specified in paragraph (D)(1) of this rule;

(x) The challenge population of spores shall be incubated in accordance with the manufacturer's recommendation for optimal growth; and

(xi) The results of spore growth during incubation shall be recorded daily, 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 unless other morphological or metabolic testing indicates that the growth is due to a contaminating microorganism.

(f) Remove and incubate the challenge population of spores used in the validation 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 are positive for growth at any time during the incubation period, the unit has failed to achieve the performance standard required for treatment of infectious wastes. In order to utilize the autoclave for the treatment of infectious wastes using combinations of temperature, pressure and time other than the minimums specified in paragraph (D)(1) of this rule, the operator shall either:

(i) Change the treatment cycle temperature, pressure, or time requirements and again perform the validation testing until the performance standard is achieved. Rectification may require the operator to increase the minimum treatment cycle temperature, pressure or time requirements; or

(ii) Operate the autoclave at the minimum operation parameters of one hundred twenty-one degrees Centigrade or two hundred fifty degrees Fahrenheit, fifteen pounds per square inch gauge pressure for sixty minutes.

(g) Perform validation testing, upon request by, and in the presence of, 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 log (base ten) 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 Ohio EPA or approved health department to remove and separately incubate one-half of the spore tests.

[Comment: Autoclave owners or operators treating infectious wastes in accordance with the specifications in this rule must maintain, for a three year period, the dated permanent recordings of autoclave chamber temperatures, documentation of the calibrations of the temperature measuring devices performed by an independent company, documentation of the monthly checks on the measuring device, and the results of the validation testing using a challenge population of spores.]

(5) Comply with paragraph (I) of this rule.

(E) Chemical treatment with sodium hypochlorite solution for cultures. The owner or operator of any infectious waste treatment facility utilizing chemical treatment with sodium hypochlorite solution for cultures shall comply with the following:

[Comment: The use of chemical treatment with sodium hypochlorite solution for cultures is intended for those cultures either with surface colonies or in suspension as the chemical must come in direct contact with the cultures to effectively treat the microorganisms.]

(1) Methodology. The owner or operator shall use methods, techniques, and practices for the treatment of infectious wastes in accordance with the following:

(a) The approved chemical treatment solution shall contain, volume per volume, fifteen per cent sodium hypochlorite (household grade bleach);

[Comment: The specific solutions stated in the rule are percent solutions of household bleach not per cent solutions of the active ingredient, sodium hypochlorite. The hypochlorite concentration of household bleaches ranges from 3.00 to 5.25 per cent. The resulting hypochlorite concentration of the treatment solution ranges from 0.45 to 0.79 per cent (or four thousand five hundred to seven thousand eight hundred seventy-five parts per million). To make one gallon of treatment solution,

mix 2.4 cups of household bleach and 3.4 quarts (13.6 cups) of water.]

(b) All cultures shall be submerged for a minimum of twenty minutes, in the chemical treatment solution specified in this rule;

(c) Cultures of infectious agents that are recommended by the centers for disease control to be handled in accordance with biosafety level 3 or 4 practices shall not be treated by a non-mechanical chemical treatment method;

(d) Mix the treatment solution immediately prior to use and discard after use; and

(e) Decant or absorb excess treatment solution from the cultures before disposal.

(2) Comply with paragraph (I) of this rule.

(F) Applied heat encapsulation for sharps. The owner or operator of any infectious waste treatment facility utilizing applied heat encapsulation for sharps shall comply with the following:

(1) Methodology. The owner or operator shall use methods, techniques, and practices for the treatment of infectious wastes in accordance with the following:

(a) Process only waste loads of sharps that consist of at least seventy per cent by weight of plastic material;

(b) Process only waste loads of sharps in a heating chamber within the treatment unit for a minimum treatment time of thirty minutes at a minimum temperature of three hundred thirty degrees Fahrenheit;

(c) Process sharps that are not totally encapsulated within a solid plastic mass as sharp infectious wastes;

(d) Treat only sharps as defined in rule 3745-27-01 of the Administrative Code and as specified in division (A)(1)(a) of section 3734.021 of the Revised Code. No other infectious wastes shall be

treated using this treatment technology; and

(e) Treat only sharps that contain no more than "residual liquid". "Residual liquid", for the purposes of this rule, is defined as that liquid which remains in the waste item after being emptied or in the case of a syringe after the plunger has been fully depressed.

(2) Specific operational criteria. The owner or operator shall design, construct, and operate the equipment for the treatment of infectious wastes in accordance with the following:

(a) Maintain the following documentation for a period of three years for each treatment unit:

(i) A quality assurance log as specified in this rule;

(ii) A daily operating log which permanently maintains a record of the following:

(a) The date of each treatment cycle;

(b) The time of day each treatment cycle was started and ended; and

(c) The name of the person operating the treatment unit for each treatment cycle.

(b) If the treatment of sharps is interrupted as a result of a malfunction of the treatment unit due to such occurrences as jamming, overloading, electrical, or mechanical reasons, all sharps contained within the unit shall be managed as infectious wastes. Infectious wastes may be maintained within the unit until the problem is corrected unless the wastes become putrescent or become a food source or breeding place for insects or rodents; and

(c) Treat only sharps that are not contaminated with chemicals that volatilize or are contaminated with antineoplastic agents.

(3) Quality assurance. The owner or operator shall perform quality assurance testing to demonstrate the capability of the applied heat encapsulation system to achieve the performance standard of a minimum four log (base ten) reduction of Bacillus subtilis spores. The owner or operator of the

applied heat encapsulation system shall perform quality assurance testing in accordance with the following provisions:

(a) Perform quality assurance testing semi-annually or after every fifty cycles whichever comes first to ensure that the applied heat encapsulation system is capable of achieving the performance standard of a minimum four log (base ten) reduction of Bacillus subtilis spores;

(b) Prepare a challenge population of spores using a spore strip, still within the glassine envelope, containing at least a minimum population of 1.0×10^4 Bacillus subtilis spores by:

(i) Wrapping the spore strip in aluminum foil and placing it at the bottom of the heating chamber, prior to adding sharps and initiation of the treatment cycle, so that the folded seams are placed on the outside of the resulting solid mass; or

(ii) Placing the aluminum foil wrapped spore strip directly into the heating chamber without the addition of any waste, for technologies that utilize a system where the foil wrapped strip would become part of the encapsulated material.

[Comment: For quality assurance testing, Ohio EPA has set the performance standard for the treatment of infectious wastes to be a four log (base ten) reduction of Bacillus subtilis spores. The quality assurance is designed to be a qualitative (growth or no growth) system. If the treatment unit owner or operator uses strips with a greater spore population, then the treatment unit must still achieve a complete kill of all spores.]

(c) Compose the waste load of sharp infectious wastes;

(d) Treat the sharp waste load containing the challenge population of spores in the same manner as the daily operation of the applied heat encapsulation system for the treatment of sharps as specified in paragraph (F) of this rule;

(e) Aseptically remove the spore strip from the wrapped foil and glassine envelope, upon completion of the treatment cycle;

(f) 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 strip. If any of the challenge population of spores used to perform the testing are 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 applied heat encapsulation system 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;

(g) Maintain a quality assurance log that provides a written record of the results of the quality assurance testing performed. Record the following information during the quality assurance testing:

(i) The date;

(ii) The time the treatment cycle started, as specified in paragraph (F) of this rule;

(iii) The time the treatment cycle ended, as specified in paragraph (F) of this rule;

(iv) The heating chamber temperature;

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

(vi) The challenge population of spores shall be incubated in accordance with the manufacturer's recommendation for optimal growth; and

(vii) 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.

(h) Perform the quality assurance testing, upon request by, and in the presence of, 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 log (base ten) reduction in Bacillus subtilis spores. If so directed, the owner or operator shall use twice as many spore strips in the same location in the heating chamber and permit Ohio EPA or approved health department to remove and separately incubate one-half of the spore strips.

(4) Comply with paragraph (I) of this rule.

(G) Chemical treatment with peracetic acid and grinding. The owner or operator of any infectious waste treatment facility utilizing chemical treatment with peracetic acid and grinding shall comply with the following:

(1) Methodology. The owner or operator shall use methods, techniques, and practices for the treatment of infectious wastes in accordance with the following:

(a) Process each waste load using the appropriate concentration of peracetic acid, as specified in paragraph (G)(1)(f) of this rule;

(b) Operate all treatment units at a minimum of ten minutes per treatment cycle using the following parameters: the grinding cycle shall operate for a minimum of three minutes at the beginning of the treatment cycle. The chemical soak portion of the treatment cycle shall operate for a minimum of seven minutes;

(c) Mark the canister to indicate the volume of blood present. The person(s) filling the canister with infectious wastes shall mark the canister to indicate that the canister contains less than one hundred milliliters of blood or that the canister contains at least one hundred milliliters but less than one thousand milliliters of blood. The generator shall also separately indicate the approximate volume of blood contained within the canister on the daily operating log as prescribed by Ohio EPA;

(d) Not process waste loads containing volumes of blood greater than one thousand milliliters or one liter;

(e) Not process wastes contaminated with non-incidental quantities of chemicals, body parts containing bone, organs, whole carcasses, quantities of gauze or rubber or latex that may become entangled around the rotors or blades, or heavy metal items;

(f) Use a minimum of 17.1 milliliters of thirty-five per cent peracetic acid when the infectious waste load contains less than or equal to one hundred milliliters of blood. Use a minimum of 79.8 milliliters of thirty-five per cent peracetic acid when the infectious waste load contains greater than one hundred milliliters but less than or equal to one thousand milliliters (one liter) of blood;

(g) Examine the specifically designed indicator disk upon completion of the treatment cycle and before the waste is dewatered and bagged. The entire indicator on the disk shall have a visible color change as an indication that peracetic acid was used during the process; and

(h) If there is not a complete color change, then the wastes are not considered treated and shall be treated again with either a new charge of the appropriate concentration of peracetic acid and a new indicator disk or using another approved treatment method in accordance with this rule.

(2) Specific operational criteria. The owner or operator shall design, construct, and operate the equipment for the treatment of infectious wastes in accordance with the following:

(a) Use rotating blades contained within the specialized canister to grind the infectious wastes;

(b) Operate all treatment units using a specially designed canister that sets down inside the machine cabinetry and contains internal grinding blades;

(c) Record the peracetic acid dosage used for each treatment cycle in a daily operating log. The unit operator shall complete the operating log as prescribed by Ohio EPA;

(d) Keep the cap on the canister when the canister is in use as an infectious waste receptacle. The cap shall not be removed prior to arrival at the treatment area. The collection cap is to be removed before treatment;

(e) Disinfect the canister cap after each use using any one of the following disinfectants:

(i) An U.S. EPA registered hospital disinfectant that is also tuberculocidal, for a contact time as specified by the manufacturer; or

(ii) A unexpired dated stabilized bleach product that is an U.S. EPA registered hospital disinfectant that is also tuberculocidal, for a contact time as specified by the manufacturer; or

(iii) A minimum ten per cent sodium hypochlorite solution prepared immediately prior to use with a minimum of thirty minutes of contact time.

(f) If treatment occurs outside the parameters as outlined in this rule, as a result of a malfunction of the unit due to such occurrences as jamming, overloading, electrical, or mechanical reasons, all wastes contained within the unit shall be managed as infectious wastes. Infectious wastes may be temporarily maintained within the unit unless the wastes becomes putrescent or becomes a food source or breeding ground for insects or rodents.

(3) Quality assurance. The owner or operator shall perform quality assurance testing to demonstrate the capability of the chemical treatment with peracetic acid and grinding unit to achieve the performance standard of a minimum four $\log_{10}$ reduction of Bacillus subtilis spores. The quality assurance testing for the chemical treatment with peracetic acid and grinding unit for the treatment of infectious wastes is specified as follows:

(a) Produce and maintain for a period of three years a permanent record of the daily operational and maintenance activities for the infectious waste treatment technology in the facility management plan as follows:

(i) Utilize a daily operating log form, as prescribed by Ohio EPA for each unit for each day that infectious wastes are treated in the unit. All daily operating logs for a treatment unit shall be grouped together and arranged by date within the grouping; and

(ii) Conduct preventative maintenance checks and services as stated in the operating manual.

(b) Repair the treatment unit in the event of a malfunction of the chemical treatment using peracetic

acid and grinding. The unit shall not be used for the treatment of infectious wastes until repaired; and

(c) Perform quality assurance testing, upon request of Ohio EPA, for each unit. This testing shall demonstrate the unit's capability to achieve a minimum four log (base ten) reduction of Bacillus subtilis spores.

(4) Comply with paragraph (I) of this rule; and

(5) Comply with requirements as specified in the director's approval letter issued in accordance with rule 3745-27-38 of the Administrative Code.

(H) Mobile treatment methods (reserved).

(I) General facility requirements. All owners and operators of a infectious waste treatment facility shall comply with the following:

(1) Retain all records for three years. Retention periods are extended during the course of any unresolved litigation, or when requested by Ohio EPA. The three-year period for records retention shall start from the date of recording, sample, or measurement and is applicable to all records included in the facility management plan;

(2) Develop and maintain in one area on the premises of the infectious waste treatment unit a facility management plan, excluding generators who utilize chemical treatment of cultures or applied heat encapsulation for sharps, in accordance with this rule:

[Comment: The facility management plan may be composed of several volumes, binders, or computer disks.]

(a) The facility management plan shall contain copies of the following information and documentation:

(i) Applicable environmental regulations regarding infectious wastes, solid wastes, surface water, and air pollution control;

(ii) Applicable infectious wastes, solid wastes, surface water, and air authorizing documents (such as licenses, registrations, or permits) for the treatment facility;

(iii) Manufacturer's equipment specifications, owner's manual for the treatment unit, and maintenance schedule;

(iv) Monitor and recording device calibration or replacement schedule;

(v) Maintenance and repair log for each treatment unit;

(vi) Facility contingency plan;

(vii) Results of quality assurance and applicable validation testing requirements;

(viii) Procedures for treatment unit start-up, loading, operating, shut down, and equipment malfunction;

(ix) Emergency telephone numbers including, at a minimum: the facility emergency coordinator, the fire department, any existing local emergency management office, the local health department, the police department, and Ohio EPA district office;

(x) The permanently recorded daily logs as specified in paragraph (I)(3) of this rule. A daily log shall be maintained for each treatment unit for a period of three years;

(xi) All strip charts, graphs, or manually produced temperature records. Each chart, graph, or record shall be dated and maintained for a period of three years;

(xii) Disposal shipping papers for the infectious wastes treated; and

(xiii) A training certification statement, as required in paragraph (I)(3) of this rule, shall be maintained for each employee who operates the infectious waste treatment unit or loads infectious wastes into the infectious wastes treatment unit. Each training certification statement shall be

maintained for the duration of such employment.

[Comment: The training certificate statement is not required to be maintained for an employee who no longer works for the organization or whose job responsibilities no longer include and will not include operating or loading the infectious waste treatment unit.]

(b) All of the current calendar year's information is to be located in this same area such as an office or work area. The two previous calendar year's information may be maintained in other accessible areas or multiple rooms depending on the amount of available space at the facility. A notation shall be made in the current year's facility management plan regarding the location of any past calendar year's information; and

(c) Documents and information contained in paragraph (I)(2)(a) of this rule of the facility management plan shall be accessible to employees during working hours.

[Comment: Nothing in this rule prohibits the facility management plan or parts thereof from being copied and located in other areas of the facility for the purpose of easy access for employees. However, there shall be only one official facility management plan that shall be located in one general area and accessible during working hours.]

(3) Provide training on the contents of the facility management plan for each employee who will operate the infectious waste treatment unit or load the infectious waste treatment unit before the employee is responsible for operating or loading the infectious waste treatment unit. A written certification statement attesting that the employee received the specified training shall be signed and dated by each employee and the owner or operator of the facility;

(4) Use a daily log of operation to record charging of the infectious waste treatment unit. A printout produced by the treatment unit may substitute for the daily log provided all the information required is present on the printout. Unless already required to keep a charging log in accordance with rule 3745-75-04 of the Administrative Code, permanently record in a daily log of operation the following, as applicable:

(a) The date;

(b) The time the first load or batch of infectious wastes was charged into each treatment unit;

(c) The time the last load or batch of infectious wastes were charged into each treatment unit for the day;

(d) Name(s) of the person(s) operating each infectious waste treatment unit and the time of day the operator started the unit;

(e) The time the treatment unit was unloaded;

(f) Whether the load was for validation, quality assurance or usual treatment; and

(g) The actual daily autoclave pressure and temperature reading.

[Comment: A printout containing partial information may be used when attached to a daily log containing the remaining required information.]

(5) Provide, in the immediate area of the infectious waste treatment unit and readily available to the personnel operating the treatment unit, the operating and loading procedures for the treatment unit;

(6) If the treatment of infectious wastes occurs outside the treatment parameters established in each methodology paragraph of this rule specific to the type of treatment technology in use and as a result of a malfunction of the unit due to such occurrences as jamming, overloading, electrical, or mechanical reasons, then all wastes contained within the unit shall be managed as infectious wastes. The infectious wastes may be maintained within the treatment unit until the problem is corrected unless the wastes become putrescent or become a food source or breeding place for insects or rodents;

(7) Conduct all construction and operations at the facility in strict compliance with the applicable authorizing document(s), including permit(s) to install issued under Chapter 3745-27 of the Administrative Code, plan approval(s), and alteration(s) concurred with in writing by Ohio EPA; the license issued under Chapter 3745-37 of the Administrative Code; court orders; and findings and

orders issued by the director;

(8) Construct and maintain all-weather access roads in such a manner as will withstand the anticipated degree of use and allow passage of vehicles with minimum erosion and dust generation;

(9) Construct and maintain non-absorbent floors in all infectious waste handling areas. Such areas shall not be overlaid with an absorbent covering;

[Comment: Nothing in this paragraph prohibits the overlaying of the concrete or asphalt floors with a cleanable non-absorbent covering.]

(10) Conduct loading operations into any treatment unit in such a manner as not to compact or puncture the containers of infectious wastes;

(11) Do not charge infectious wastes into the treatment unit during periods of precipitation unless the wastes to be loaded and the waste loading operations are protected from the elements of weather;

(12) Discharge into a disposal system in accordance with Chapter 6111. of the Revised Code or absorb and handle as infectious wastes, any wastewater resulting from a spill of infectious wastes or the cleanup of a spill of infectious wastes from all infectious waste handling areas. Such wastewater shall not be disposed into a storm sewer;

(13) Construct and maintain proper slopes and drainage to prevent the ponding of liquids in infectious waste handling areas;

[Comment: Methods of drainage are not limited to systems consisting of underground pipes.]

(14) Restrict infectious waste handling areas to authorized personnel, utilizing signs or a locking mechanism;

(15) Shall not treat wastes for which such treatment or disposal is prohibited by the Ohio department of health or the U.S. nuclear regulatory commission;

(16) Shall not accept wastes for which such storage, treatment or disposal is prohibited in the "hazardous wastes rules" as defined in paragraph (A) of rule 3745-50-10 of the Administrative Code;

[Comment: The "hazardous wastes rules" as defined in paragraph (A) of rule 3745-50-10 of the Administrative Code contain the regulations for the proper handling of hazardous wastes. For technical information regarding the designation, handling, treatment, and disposal of hazardous waste, please contact the division of hazardous waste management at the appropriate Ohio EPA district office.]

(17) The owner or operator of a licensed infectious waste treatment facility shall submit an annual report to Ohio EPA central office and the approved health district no later than february first of each year. The annual report shall consist, at a minimum, of the following:

(a) The name, address, telephone number, and contact person for the facility;

(b) Hours of operation for the facility;

(c) Monthly total of infectious wastes treated at the facility for each state or country of origin; and

(d) Any quality assurance results that do not demonstrate achievement of the performance standard.

(18) Infectious wastes that have been treated in accordance with the provisions of this rule shall be handled in the same manner as solid wastes. Such treated infectious wastes shall be disposed in a licensed solid waste disposal facility, or a facility in another state operating in compliance with state and federal regulations. Shipments of treated infectious wastes shall be accompanied by disposal papers as required by rule 3745-27-33 of the Administrative Code;

[Comment: Small generators of infectious wastes who treat the infectious wastes that they generate are not required to comply with the disposal shipping paper requirements of rule 3745-27-33 of the Administrative Code.]

(19) All "sharps" shall be managed in a manner to eliminate the potential of those wastes to cause lacerations or puncture wounds during handling and disposal;

(20) Perform quality assurance testing to demonstrate the ability of the treatment unit to achieve the performance standard if the unit has not been used for the treatment of infectious wastes for more than one year;

(21) Any large generator who treats infectious wastes on-site and any infectious waste treatment facility licensed to treat infectious wastes, who intends to discontinue treating infectious wastes at any facility or premise, shall comply with rules 3745-27-36 and 3745-27-39 of the Administrative Code;

(22) Apply for and obtain an operating license from the board of health of the health district where the facility will be located, or from the director if the director has assumed the licensing function, unless the facility currently holds an operating license; and

(23) The following infectious waste treatment facilities are exempt from the permitting and licensing requirements stated in division (C) of section 3734.02 and division (B) of section 3734.05 of the Revised Code:

(a) An infectious waste treatment facility that is owned or operated by the generator of the wastes and exclusively treats wastes that are produced by that generator at any premises owned or operated by that generator, by methods established under this rule; and

(b) Hospitals as defined in section 3727.01 of the Revised Code, that accept for treatment infectious wastes generated by any of the following:

(i) Generators who produce fewer than fifty pounds of infectious wastes during any one month and who are not listed on a registration certificate as a generator of infectious wastes and who have staff privileges at that hospital; or

(ii) An emergency medical service organization, as defined in section 4765.01 of the Revised Code, regardless of whether the wastes were generated in providing care to the patient at the scene of an emergency or during the transportation of the patient to the hospital; or

(iii) An individual for purposes of his own care or treatment.