# Ohio Administrative Code

## Rule 3745-570-203 Autoclaving.

Effective: April 6, 2025

(A) For the purposes of this rule, the following definitions apply:

(1) "Treatment cycle" means the combination of the minimum time, temperature, and pressure necessary to achieve the performance standard for treatment. Treatment cycle does not include the time needed to bring the autoclave up to the operating temperature or pressure or the time it takes for the autoclave to exhaust and allow opening of the chamber.

(2) "Total treatable volume" means the total volume of infectious waste that can be treated per treatment cycle. The total treatable volume of infectious waste is calculated using one of the following:

(a) The manufacturer's specification for the total volume of the autoclave.

(b) An estimate that is less than, but based upon, the manufacturer's specification for the total volume of the autoclave.

(c) The total treatable volume at each validation or biological challenge test calculated by listing the number of bags, boxes, bins, and sharps containers of infectious waste used during the testing and adding the volumes of those containers, provided the total treatable volume does not exceed the manufacturer's specifications.

(B) Methodology. The owner or operator shall operate an autoclave in such a manner that every load achieves the performance standard for treatment and in accordance with the following:

(1) Maintain a minimum gauge pressure of fifteen pounds per square inch and a minimum temperature of either one hundred twenty-one degrees Centigrade or two hundred fifty degrees Fahrenheit for a minimum of sixty minutes during a treatment cycle, provided the performance standard for treatment is achieved.

(2) Maintain a different combination of time, temperature, and pressure for the duration of the treatment cycle for which the owner or operator has demonstrated achievement of the performance standard for treatment through validation testing in accordance with paragraph (D) of this rule prior to use for the treatment of infectious waste.

(C) Operational criteria. The owner or operator shall operate an autoclave treating infectious waste in accordance with the following:

(1) Continuously record the temperatures, pressures, and time using recording devices with a real-time display that are permanently connected to the autoclave and produces an instant paper or electronic record.

(2) If the autoclave temperature and pressure readings are below what is specified in the gauge pressure versus temperature of saturated steam table in the appendix to this rule, or are not within two degrees over or two pounds per square inch over the corresponding reading specified in the gauge pressure versus temperature of saturated steam table in the appendix to this rule, do one of the following:

(a) Discontinue use of the autoclave until the autoclave is repaired or calibrated in accordance with paragraph (C)(4) of this rule.

(b) Perform biological challenge testing at a minimum weekly in accordance with paragraph (E) of this rule. If at any time biological challenge testing fails, the owner or operator shall discontinue use of the autoclave until the autoclave is repaired or calibrated in accordance with paragraph (C)(4) of this rule.

(3) If a recording device becomes inoperable, provide proof that repair parts have been ordered if requested by Ohio EPA or the approved health district and do either of the following until repairs are made:

(a) Manually record the data no longer available from the recording device at intervals that do not exceed five minutes until the exhaust cycle is initiated.

(b) Discontinue use of the autoclave until repaired if failure or malfunction occurs in any recording device.

(4) Use an independent person to calibrate, repair, or replace temperature recording devices or temperature measuring devices in accordance with either of the following:

(a) The manufacturer's maintenance schedule, specifications, or recommendations.

(b) If the manufacturer's maintenance schedule, specifications, or recommendations are not available, a calibration schedule as determined by the owner or operator that at a minimum includes annual calibrations.

(5) Evacuate the air from the autoclave chamber before each treatment cycle is started.

(6) Ensure that the autoclave is not loaded beyond the total treatable volume.

(7) Ensure that pathological waste is treated only after receipt of written concurrence from Ohio EPA in accordance with paragraph (D)(3)(c) of this rule.

(D) Validation testing. The owner or operator shall perform validation testing in accordance with paragraph (G) of rule 3745-570-200 of the Administrative Code and the following:

(1) Except as provided in paragraph (D)(3) of this rule, demonstrate the capability of the autoclave to achieve the performance standard for treatment as follows:

(a) Use a challenge population of spores as spore strips with a population of at least $1.0 \times 10^6$ Geobacillus stearothermophilus spores, ampules containing at least $1.0 \times 10^6$ Geobacillus stearothermophilus spores per milliliter, or commercially available steam packs that contain a population of at least $1.0 \times 10^6$ Geobacillus stearothermophilus spores.

(b) Ensure that the Geobacillus stearothermophilus spore testing methodology does not result in the denaturation of the proteins within the inoculating media.

(c) Compose the validation testing waste load in a manner that stimulates the most challenging waste load for the autoclave.

(d) Place the challenge population of spores into three test containers composed of material such as treated infectious waste, newspaper, plastic backed absorbent pads, or general refuse that has been placed into either boxes, bags, or sharps containers.

(e) Place the challenge population of spores into three test containers composed of material such as already treated infectious waste, newspaper, plastic backed absorbent pads, or general refuse that has been placed into either boxes, bags, or sharps containers in the center of each waste load.

(f) Place the test containers with the challenge population of spores in the location that poses the greatest challenge to the technology. If the autoclave will not hold three containers of waste, then each test container shall contain a spore strip or ampule. Commercially available steam packs may be placed into the three test containers instead of treated infectious waste, newspaper, plastic backed absorbent pads, or general refuse.

(g) Treat the waste load containing the challenge population of spores in a manner consistent with the daily operation of the autoclave for the treatment of infectious waste.

(h) Record the following information:

(i) The autoclave pressure, temperature, and treatment cycle time that the owner or operator is attempting to validate for the treatment of infectious waste.

(ii) The date and time the treatment cycle started.

(iii) The date and time the treatment cycle ended.

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

(v) A diagram depicting the pattern of infectious waste loading and location of the challenge population of spores during the validation testing. Those units that have rotating treatment chambers do not need to be diagrammed.

(vi) The total treatable volume of infectious waste used during the validation testing. Once a total treatable volume of infectious waste 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.

(vii) The autoclave chamber temperature and pressure during the treatment cycle, as recorded by the permanently connected recording devices.

(viii) The daily results of spore growth during an incubation period not less than the time specified by the manufacturer of the spore strip or ampule, 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.

(i) Remove and incubate the challenge population of spores used in validation testing for not less than the period of time specified by the manufacturer of the spore strip or ampule.

(j) Upon request by Ohio EPA or the approved health district, perform validation testing in the presence of Ohio EPA or the approved health district to verify that the written operating procedures in the facility management plan are sufficient to meet the performance standard for treatment.

(k) If directed by Ohio EPA or the approved health district, perform validation testing using twice as many spore strips or ampules in the same locations in the autoclave and allow Ohio EPA or the approved health district to remove and separately incubate one-half of the spore strips or ampules.

(2) If any of the challenge population of spores used to perform the testing are positive for growth at any time during the incubation period, do the following:

(a) Conclude that the autoclave has failed to achieve the performance standard for treatment.

(b) Manage the infectious waste placed within the autoclave during and after the failed validation testing as infectious waste.

(c) Not use the autoclave to treat infectious waste until a successful validation test has been performed.

(3) Demonstrate the capability of the autoclave to achieve the performance standard for treatment of pathological waste as defined in this chapter as follows:

(a) Submit a protocol to Ohio EPA for validation testing that is consistent with this rule and specifically addresses the density of pathological waste.

(b) Conduct the validation testing in accordance with the approved protocol only after receipt of written approval of the protocol from Ohio EPA.

(c) Submit results of the validation testing to Ohio EPA for concurrence.

(4) Repeat validation testing if there is a change to the physical structure of the treatment unit.

(E) Biological challenge testing. The owner or operator shall perform biological challenge testing on an autoclave treating infectious waste at a minimum monthly in accordance with the following:

(1) As follows to determine the capability of the autoclave to achieve the performance standard for treatment:

(a) Using a challenge population of spores as spore strips with a population of at least $1.0 \times 10^6$ Geobacillus stearothermophilus spores, ampules containing at least $1.0 \times 10^6$ Geobacillus stearothermophilus spores per milliliter, or commercially available steam packs that contain a population of at least $1.0 \times 10^6$ Geobacillus stearothermophilus spores.

(b) Ensure that the Geobacillus stearothermophilus spore testing methodology does not result in the denaturation of the proteins within the inoculating media.

(c) Place the challenge population of spores into the center of each of three test containers composed of material such as treated infectious waste, newspaper, plastic backed absorbent pads, or general refuse that has been placed into either boxes, bags, or sharps containers representative of the normal or anticipated use for that autoclave unit.

(d) Place the test containers with the challenge population of spores in the location that poses the greatest challenge to the technology. If the autoclave will not hold three containers of waste, then each test container shall contain a spore strip or ampule. Commercially available steam packs may be placed into the three test containers instead of newspaper, plastic backed absorbent pads, or general refuse.

(e) Treat the waste load containing the challenge population of spores in a manner consistent with the daily operation of the autoclave for the treatment of infectious waste including the same temperature, pressure, time, and total treatable volume.

(f) Perform the biological challenge testing at the same combinations of temperature, pressure, and time, as the validation testing.

(g) Record the following information for each treatment cycle:

(i) The date and time the treatment style started.

(ii) The date and time the treatment cycle ended.

(iii) The temperature and pressure recorded during the treatment cycle.

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

(v) A diagram depicting the pattern of infectious waste loading and location of the challenge population of spores during the testing. Those units that have rotating treatment chambers do not need to be diagrammed.

(vi) The total treatable volume.

(vii) The duration, in days, and temperature used for the incubation of the challenge population of spores, in accordance with the manufacturer's recommendation for optimal growth.

(viii) The results of spore growth during an incubation period not less than the time specified by the manufacturer of the spore strip or ampule, 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.

(h) Remove and incubate the challenge population of spores used in the biological challenge testing for not less than the period of time specified by the manufacturer of the spore strip or ampule.

(i) Upon request by Ohio EPA or the approved health district, perform biological challenge testing in the presence of Ohio EPA or the approved health district to verify that the written operating procedures in the facility management plan are sufficient to meet the performance standard for treatment.

(j) If directed by Ohio EPA or the approved health district, perform biological challenge testing using twice as many spore strips or ampules in the same locations in the autoclave and allow Ohio EPA or the approved health district to remove and separately incubate one-half of the spore strips or ampules.

(2) If any of the challenge population of spores used to perform the testing are positive for growth at any time during the incubation period, do the following:

(a) Conclude that the autoclave has failed to achieve the performance standard for treatment.

(b) Manage the infectious waste placed within the autoclave during and after the failed biological challenge testing as infectious waste.

(c) Not use the autoclave to treat infectious waste until a successful biological challenge test has been performed.