



Ohio Administrative Code

Rule 3745-570-205 Ozone exposure treatment.

Effective: April 6, 2025

(A) For the purposes of this rule, "treatment cycle" means the combination of the minimum time and minimum ozone concentration necessary for the ozone treatment unit to achieve the performance standard for treatment. Treatment cycle does not include the time needed to bring the unit up to the minimum ozone concentration necessary to achieve the performance standard for treatment.

(B) Methodology. The owner or operator shall operate an ozone treatment unit such that every load achieves the performance standard for treatment and as follows:

(1) Maintain a minimum concentration of ozone of one thousand five hundred parts per million for sixty minutes during a treatment cycle.

(2) Maintain a different combination of minimum concentration of ozone and time for which the owner or operator has demonstrated achievement of the performance standard for treatment through validation testing performed in accordance with paragraph (D) of this rule prior to use for the treatment of infectious wastes.

(C) The owner or operator shall operate an ozone treatment unit in accordance with the following:

(1) Continuously record the ozone concentration and time throughout the treatment unit using ozone recording devices that are capable of producing an instant paper or electronic record with a real-time display permanently connected to the ozone treatment unit that continuously displays the ozone concentration and time for visual monitoring. The owner or operator shall 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 a recording device become 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 ozone concentration at intervals that do not exceed five minutes.
- (b) Discontinue use of the ozone treatment unit for the treatment of infectious waste until repaired if failure or malfunction occurs in any ozone recording device.
- (3) Use an independent person to calibrate, repair, or replace ozone recording 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.
- (4) 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 of an ozone treatment unit 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 ozone treatment unit 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 1.0×10^6 *Geobacillus stearothermophilus* spores.
 - (b) Compose the validation testing waste load in a manner that simulates the most challenging waste load for the ozone treatment unit.
 - (c) Treat the waste load containing the challenge population of spores in a manner consistent with the daily operation for the ozone treatment unit for the treatment of infectious wastes.



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

(i) The ozone concentration and treatment cycle time that the owner or operator is attempting to validate for the treatment of infectious wastes.

(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 ozone treatment unit and the name of the person performing laboratory analysis of the challenge population of spores.

(v) The ozone concentration during the treatment cycle, as recorded by the permanently connected ozone recording device.

(vi) 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.

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

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

(f) 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.

(g) If directed by Ohio EPA or the approved health district, perform validation testing using twice as



many spore strips and allow Ohio EPA or the approved health district to remove and separately incubate one-half of the spore strips.

(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 ozone treatment unit has failed to achieve the performance standard for treatment.

(b) Manage the infectious waste placed in the ozone treatment unit during and after the failed validation testing as infectious waste.

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

(3) Demonstrate the capability of the ozone treatment unit 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 ozone treatment unit.

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

(1) As follows to demonstrate the capability of the ozone treatment unit to achieve the performance



standard for treatment:

- (a) Using a challenge population of spores as spore strips with a population of at least 1.0×10^6 *Geobacillus stearothermophilus* spores.
- (b) Treat the waste load containing the challenge population of spores in a manner consistent with the daily operation of the ozone treatment unit for the treatment of infectious wastes at the same combinations of ozone concentration and time as the validation testing.
- (c) Record the following information for each treatment cycle:
 - (i) The date and time the treatment cycle started.
 - (ii) The date and time the treatment cycle ended.
 - (iii) The ozone concentration recorded during the treatment cycle.
 - (iv) The name of the person who loaded the ozone treatment unit and the name of the person performing laboratory analysis of the challenge population of spores.
 - (v) 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.
 - (vi) The results of spore growth during an incubation period not less than the time specified by the manufacturer of the spore strip, 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.
- (d) 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.
- (e) 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.

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

(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 ozone treatment unit has failed to achieve the performance standard for treatment.

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

(c) Not use the ozone treatment unit to treat infectious wastes until a successful biological challenge test has been performed.