



Ohio Administrative Code Rule 3745-570-02 Definitions.

Effective: April 6, 2025

If a term used in this chapter is defined in rule 3745-500-02 of the Administrative Code, the definition of the term used in rule 3745-500-02 of the Administrative Code is applicable to this chapter unless the term is defined in this rule. As used in this chapter:

(A) "Alternative infectious waste treatment technology" or "alternative treatment technology" means any combination of methods, techniques, practices, designs, constructions, operations, processes, parameters, or equipment designed to treat infectious waste that is not specified in paragraphs (A) to (D) of rule 3745-570-201 of the Administrative Code.

(B)

(1) "Biological challenge testing" means periodic monitoring or testing of an infectious waste treatment unit or technology that employs the use of biological indicators to demonstrate achievement of the performance standard for treatment by the treatment unit or technology.

(2) "Biological indicator" means a specific microorganism used to evaluate the capability of a process to decontaminate or treat infectious waste. For the purposes of this definition, biological indicators include bacterial spores inoculated on carriers, suspensions, and self-contained indicators.

(C) [Reserved.]

(D) [Reserved.]

(E) "Efficacy testing" means testing of an autoclave, incinerator, or alternative infectious waste treatment technology conducted by a laboratory, independent of the system manufacturer, in conformance with generally recognized scientific principles and practices, including microbiologic examinations and other pertinent assessments of waste material to establish operating parameters for effective treatment of infectious waste.



(F) [Reserved.]

(G) [Reserved.]

(H) [Reserved.]

(I)

(1) "Infectious agent" has the same meaning as in section 3734.01 of the Revised Code.

(2) "Infectious waste storage area" or "storage area" means any portion of the infectious waste handling area used to collect, accumulate, or store any infectious wastes prior to treatment.

(3) "Infectious waste treatment unit" or "treatment unit" means the apparatus responsible for the attainment of the performance standard for treatment and for the reduction in microorganisms that is part of the treatment process. A free standing shredder or grinder is not considered a treatment unit.

[Comment: If the treatment process is completed within a single enclosed piece of equipment, then the treatment unit and treatment process are considered one and the same.]

(J) [Reserved.]

(K) [Reserved.]

(L) "Large generator of infectious waste" or "large generator" means the following:

(1) Any person who generates fifty pounds or more of infectious waste in any one month at any premises owned or operated by the person.

(2) Any person holding a registration certificate issued in accordance with rules adopted under Chapter 3734. of the Revised Code, including all generators listed on the infectious waste registration certificate.



(3) Any person who, as part of their business activities, engages in the designation and segregation of infectious waste at places including but not limited to crime or accident scenes and who generates fifty pounds or more of infectious waste per month.

(M) "Modify" or "modification" means an infectious waste treatment facility undergoing any of the following:

(1) A substantial change in waste handling at the infectious waste treatment facility including but not limited to any change to the following:

(a) Type of waste received.

(b) Any change in the infectious waste treatment facility's treatment technology or process.

(2) An increase in the treatment capacity. For the purposes of this definition, "treatment capacity" means the maximum amount of waste permitted by Ohio EPA to be loaded into the treatment unit per hour, or the engineered throughput capacity per hour if no such permitted capacity is authorized.

(3) Any other substantial change that may endanger human health or the environment.

(N) [Reserved.]

(O) [Reserved.]

(P)

(1) "Performance standard for treatment" means the following:

(a) For purposes of autoclaving and treatment by ozone, a six \log_{10} reduction of *Geobacillus stearothermophilus* spores.

(b) For purposes of incineration, a six \log_{10} reduction of *Bacillus subtilis* spores.



(c) For purposes of alternative infectious waste treatment technologies, a six \log_{10} reduction in the appropriate bacterial spores.

(2) "Primary container" means the inner packaging or containment system that is in direct contact with, holding, and securing infectious waste. A primary container includes but is not limited to a red bag or sharps container.

(Q) [Reserved.]

(R) [Reserved.]

(S)

(1) "Sample" means portions of previously inoculated wastes or portions of previously inoculated carriers.

(2) "Secondary container" means the non-bulk outer packaging or containment system used to hold and secure a primary container. A secondary container is a disposable or reusable rigid pail, carton, drum or portable bin that is, under normal conditions of use, leak-resistant, strong enough to prevent tearing or bursting, puncture resistant, impervious to moisture, has leak-proof sides and bottom, has a tight-fitting cover or is otherwise closeable, and is in good repair.

(3) "Select agent" means an infectious agent, zoonotic agent, or toxin determined to have the potential to pose a severe threat to public health or safety or the environment as specified in 42 C.F.R. Part 73, 7 C.F.R. part 331, or 9 C.F.R. part 121, as amended through July 2023.

(4) "Sharp infectious waste" or "sharps" means any instrument designed to cut, pierce, or lacerate that was or is likely to have been exposed to or contaminated with, or is likely to transmit, an infectious waste or zoonotic agent or has come in contact with blood or other body fluids including but not limited to needles, syringes with an attached needle, or any other type of instrument designed for the purpose to cut, pierce, or lacerate.



(5) "Small generator of infectious waste" or "small generator" means any person who generates less than fifty pounds of infectious waste in any one month at each premises owned or operated by the person.

(T)

(1) "Treat" or "treatment" means any method, technique, or process that renders the wastes noninfectious including but not limited to steam sterilization and incineration. Treat or treatment of wastes identified in division (R)(7) of section 3734.01 of the Revised Code includes methods, techniques, or processes to substantially reduce or eliminate the potential for the wastes to cause lacerations or puncture wounds.

(2) "Treatment cycle" means the timeframe from when the treatment unit attains the approved treatment parameters until achievement of the performance standard for treatment that has been demonstrated through the use of a biological indicator or parametric monitoring.