

3745-27-38

Alternative infectious waste treatment technology approval process.

(A) This rule sets forth the procedures and criteria for approval of an alternative infectious waste treatment technology. An alternative infectious waste treatment technology is any combination of methods, techniques, practices, designs, constructions, operations, process, or equipment, intended to treat infectious waste that is not specified in rule 3745-27-32 of the Administrative Code. Nothing in this rule relieves the owner or operator seeking such approval from the requirement to obtain any applicable permits or licenses including those pursuant to sections 3734.02 and 3734.05 of the Revised Code.

(B) The applicant may request either a statewide approval or a site-specific approval in accordance with paragraphs (C), (D), and (E) of this rule. An alternative treatment technology with statewide approval may be used at any facility throughout the state of Ohio without the operator first performing initial validation testing. An alternative treatment technology with site-specific approval shall have initial validation testing performed by the operator prior to use. The following demonstrations shall accompany any such approval request:

[Comment: Validation testing is performed prior to use to ensure that the alternative treatment technology will be able to achieve the performance standard for treatment. Quality assurance testing is an on-going monitor of the treatment technology's ability to attain the performance standard for treatment.]

(1) Statewide approval performance standard. The achievement of a minimum four \log_{10} reduction of bacterial spores and a minimum five \log_{10} reduction of mycobacteria as specified in table 1 of paragraph (E)(1) of this rule immediately upon exit of the wastes from the treatment unit.

(2) Site-specific approval performance standard. The achievement of a minimum four \log_{10} reduction of bacterial spores specified in table 2 of paragraph (E)(1) of this rule immediately upon exit of the wastes from the treatment unit.

(C) The applicant shall ensure that sound and accepted scientific microbial techniques were used to develop all data submitted during the approval process including but not limited to the following:

(1) Enumeration of all stock suspensions or a representative sampling of carriers.

(2) Placement of all samples and controls into buffered diluent.

(3) Performance of three test runs for each microorganism and control.

- (4) Collection of all samples and controls upon exiting the treatment unit.
- (5) Neutralization of the collected samples and applicable controls immediately upon exiting the treatment unit, if the technology utilizes chemical treatment.
- (6) Homogenation of each dilution immediately prior to withdrawing an aliquot for plating or continued dilution.
- (7) Inoculation of the growth media immediately with the dilutions of processed waste samples and applicable controls. If immediate inoculation is not possible, then the samples shall be placed in ice for a period of time not to exceed sixty minutes, unless an alternative timeframe for holding the samples has been approved by the director.

If there is documentation to support the use of longer time periods for holding the samples prior to plating, or prior to placing inoculant into growth media, or further handling for dilution of a particular technology that does not comply with this rule, Ohio EPA may accept the use of longer time periods prior to plating, or to placing into growth media, or further handling for dilution that demonstrates achievement of the performance standard for the treatment technology. The applicant shall demonstrate to Ohio EPA's satisfaction through the use of sound scientific microbial technique and peer-reviewed journal reference, or equivalent documentation, that an alternate time period is appropriate. The applicant shall submit the documentation for approval by Ohio EPA prior to use in testing.

- (8) Plating of dilutions in triplicate.
- (9) Utilization of those microbial plates that contain between thirty and three-hundred colonies.
- (10) Utilization of only those plate counts that demonstrate a margin of error no greater than five per cent difference between the replicate plates and no greater than a ten per cent difference in individual test runs. If one of the three replicate plates has a quantitative difference of greater than five per cent, then that replicate plate shall not be utilized and the calculation shall be formulated utilizing two replicate plates.
- (11) Performance of subsequent test runs. If all three of the plate counts have a quantitative difference of greater than five per cent between them, the test run is considered invalid and another test load for that particular microorganism or spore shall be prepared and processed through the unit.

- (12) Performance of subsequent test loads. If any one of the three test run plate dilution series has a quantitative difference of greater than ten per cent between them, the test run shall be considered invalid and another test load for that particular series shall be prepared and processed through the unit.

[Comment: "Samples" as used in this paragraph refers to either portions of previously inoculated wastes or inoculated carriers.]

(D) The applicant shall submit to Ohio EPA the following items:

- (1) A written request for approval of the infectious waste treatment technology. The request shall specify whether the applicant is seeking a statewide or site specific approval.
- (2) A completed "Evaluation Of An Infectious Waste Treatment Technology Information Request Form" as prescribed by Ohio EPA.

[Comment: Upon receipt of the written request and evaluation form, Ohio EPA will public notice the receipt of the application in the weekly review.]

- (3) An operating manual or other treatment unit program logic which describes in detail the operations of the unit and the critical factors influencing the treatment capability of the equipment. This description shall include, but is not limited to, the waste feed rate, maximum hourly capacity, residence time, pH, temperature reading, treatment chemical concentration, and sequence of treatment events.
- (4) The microbial testing protocol designed and used to evaluate the capability of the alternative infectious waste treatment unit to achieve the performance standard as specified in paragraph (B) of this rule.
- (5) A microbial testing report containing the microbial testing results using an appropriate protocol. The microbial testing results shall comply with paragraphs (C) and (E) of this rule and demonstrate the achievement of the performance standard upon exiting the treatment unit, as follows:
 - (a) For statewide approval, the request shall demonstrate the achievement of a minimum four \log_{10} reduction of bacterial spores and a minimum five \log_{10} reduction of mycobacteria as specified in table 1 in this rule.
 - (b) For site-specific approval, the request shall demonstrate the achievement of a minimum four \log_{10} reduction of bacterial spores specified in table

2 in this rule.

(E) The applicant shall ensure that the microbial testing and protocol are designed to evaluate the capability of the treatment unit to achieve the performance standard and comply with the following requirements. For the purposes of this rule, "samples" means either a representative portion of previously inoculated waste or an inoculated carrier:

[Comment: It is strongly recommended that the applicant submit the proposed microbial testing protocol to Ohio EPA prior to testing. Upon request, Ohio EPA will review and provide written comment on the protocol. This service is offered to provide guidance intended to help the applicant's efforts in documenting effective treatment of infectious wastes.]

(1) Selection of challenge microorganisms. The applicant shall use the appropriate microorganisms to test the effectiveness of a particular treatment technology in accordance with the following:

(a) Those applicants who request statewide approval shall select microorganisms from table 1 as follows:

(i) Use a mycobacteria species which is the most resistant to any aspect of the treatment technology.

(ii) Use a bacterial spore species which is the most resistant to any aspect of the treatment technology.

[Comment: Particular mycobacteria and bacterial spores are more resistant to various treatment conditions that each technology presents ; therefore, the selection of the appropriate species is a valuable test for challenging that alternative treatment technology. The applicant should consider the "D" value when selecting the appropriate species.]

Table 1

Mycobacteria	
•	Mycobacterium terrae
•	Mycobacterium phlei
•	Mycobacterium bovis
Bacterial spores	

•	Geobacillus stearothermophilus
•	Bacillus subtilis

- (b) Those applicants who request site-specific approval shall select one microorganism from the bacterial spore species which is the most resistant to all aspects of the treatment technology, listed in table 2.

[Comment: Particular bacterial spores are more resistant to various treatment conditions that each technology presents; therefore, the selection of the appropriate bacterial spores is a valuable test for challenging that alternative treatment technology. The applicant should consider the "D" value when selecting the appropriate species.]

Table 2

Bacterial spores	
•	Geobacillus stearothermophilus
•	Bacillus subtilis

- (c) Applicants for either type of approval may select and use other microorganism not listed in either table 1 or table 2, provided the applicant demonstrates to the satisfaction of the director that the alternative microorganism is of equal resistance as the listed indicator microorganism of that particular category.

- (d) Applicants for either type of approval shall select the most resistant microorganisms to their treatment technology for use in the testing process.

[Comment: All microorganisms used during testing for either type of request shall be reduced in number to the levels stated in paragraph (D)(5) of this rule.]

- (2) Sufficient number of challenge microorganisms. The applicant shall use and be able to retrieve a sufficient number of challenge microorganisms to quantify the results for each test waste load, and for each type of inoculation. Prior to \log_{10} reduction efficacy testing of the treatment unit, the applicant shall determine the number of recoverable microorganisms. The recoverable number of microorganisms will determine the number of challenge microorganisms sufficient to start with for all subsequent testing for \log_{10} reductions. The applicant shall perform one of the following:

[Comment: The percent number of recoverable microorganisms (%R) is in the appendix to this rule.]

- (a) Applicants may directly inoculate the waste load using the appropriate microbial suspension, to implement the following:
 - (i) Inoculation with enough liquid suspension of the appropriate mycobacteria to give an adjusted theoretical challenge, as defined in the appendix to this rule, of at least 1.0×10^6 microorganisms per gram of waste, or per milliliter of waste if the technology is designed to treat liquid infectious wastes, for the mycobacteria specified in table 1 of paragraph (E)(1) of this rule.
 - (ii) Inoculation with enough liquid suspension to give an adjusted theoretical challenge, as defined in the appendix to this rule, of at least 1.0×10^5 bacterial spores per gram of waste, or per milliliter of waste if the technology is designed to treat liquid infectious waste.
- (b) Applicants may choose to use a carrier system. Each individual carrier shall maintain a sufficient recoverable inoculum to allow the applicant to inoculate, retrieve, and calculate the adjusted theoretical challenge population. The applicant shall implement the following:
 - (i) Inoculation with enough recoverable carriers of the appropriate mycobacteria to give an adjusted theoretical challenge, as defined in the appendix to this rule, of at least 1.0×10^6 microorganisms.
 - (ii) Inoculation with enough recoverable carriers, such as bacterial spore strips, of the appropriate bacterial spores to give an adjusted theoretical challenge, as defined in the appendix to this rule, of at least 1.0×10^5 bacterial spores.
- (3) Selection of test waste loads. The applicant shall use test waste loads that are representative of the waste stream that the treatment technology is designed to treat. The amount of waste used to comprise an individual test run shall be sufficient to simulate operation of the unit at full capacity. The applicant shall utilize test waste loads that pose the greatest challenge to the treatment technology being tested in accordance with the following:
 - (a) Determine which categories of infectious wastes, as defined in rule 3745-27-01 of the Administrative Code, the treatment technology will

and will not be capable of treating.

(b) Use full-scale production units for all testing.

(c) Select infectious waste test loads using one of the following criteria:

(i) For those treatment technologies that are designed to treat any and all categories of infectious wastes, as defined in rule 3745-27-01 of the Administrative Code, the applicant shall use test waste loads comprised, at a minimum, of the following:

(a) Thirty per cent organic materials such as blood or other products derived from blood, and culture media.

(b) Forty per cent absorbent material.

(c) Thirty per cent non-absorbent material.

[Comment: Waste loads used for testing should contain at least thirty per cent organic material to simulate the possibility of processing laboratory waste. Absorbent material means those waste items such as surgical drapes and sponges and patient gowns that will readily absorb liquids. Non-absorbent material means waste items such as exam gloves, tubing, and plastic containers that do not readily absorb liquids.]

(ii) For those treatment technologies that are designed to treat a specific category of infectious waste, as defined in rule 3745-27-01 of the Administrative Code, the applicant shall use test waste loads composed of one hundred per cent of the specific infectious waste category that the treatment technology is designed to treat.

(iii) For those treatment technologies that are designed to treat any category of infectious wastes as defined in rule 3745-27-01 of the Administrative Code, but are sensitive to particular combinations or individual items contained in a waste stream, the applicant shall use test waste loads composed of one hundred per cent of the combination or individual item of that specific infectious waste category, as defined in rule 3745-27-01 of the Administrative Code, which poses the greatest challenge to that treatment technology.

[Comment: An example of a treatment technology that would have to use a test waste load as outlined in paragraph (E)(3)(c)(iii) of this rule would be a chemical treatment technology whose active ingredient is a chemical that is "bound" or "consumed" by large quantities of organics that may be present in a waste load. Therefore, the treatment technology would be required to use test waste loads composed of one hundred per cent of organics. This testing would challenge the treatment technology in a "worse case" scenario.]

- (iv) For those treatment technologies that are designed to treat any category of infectious wastes, as defined in rule 3745-27-01 of the Administrative Code, but the applicant intends to request approval for treating only specific waste loads at specific volumes, the applicant may use test waste loads comprised of combinations other than those listed in paragraph (E)(3) of this rule. The director's approval letter will reflect these specific conditions.

[Comment: An example of a treatment technology that may elect to use a test waste load as outlined in paragraph (E)(3)(c)(iv) of this rule would be a chemical treatment technology whose active ingredient is a chemical that is "bound" or "consumed" by large quantities of organics that may be present in a waste load. Therefore, the applicant may use test waste loads composed of combinations or volumes other than those listed above. The director's approval letter will reflect the applicants selection of test waste load for use during actual infectious waste treatment activities.]

- (v) For those treatment technologies that are designed to treat any and all categories of infectious wastes as defined in rule 3745-27-01 of the Administrative Code, the applicant may use alternative test waste loads comprised of materials or volumes other than those outlined in paragraph (E)(3)(c)(i) of this rule, provided that the applicant demonstrates to Ohio EPA's satisfaction that an alternative test waste load provides a greater challenge to the technology.

- (4) Preparation of the test waste loads. The applicant shall prepare and inoculate test waste loads selected in accordance with paragraph (E)(3) of this rule in the following manner:

- (a) Prepare the test waste load by doing any of the following:

- (i) Autoclaving infectious wastes to achieve sterility and then cooling the treated infectious wastes prior to inoculation with the challenge microbial suspensions or carrier.
- (ii) Preparing test waste loads using new/unused representative materials.

[Comment: An applicant who chooses to use test waste loads of noninfectious materials may do so either by using infectious wastes that have been autoclaved or materials that contain clean, unused, new, and/or previously packaged materials. It is the applicant's responsibility to ensure that the test waste load materials are representative of the waste stream.]

- (b) Inoculate the test waste loads ensuring that all preparations are accomplished in a manner that will distribute the inoculum evenly throughout the waste load. The ratio of the volume of inoculum to the amount of waste shall not be less than one to twenty (not less than five per cent). Inoculation shall be accomplished by doing any of the following:
 - (i) Using a microbial suspension, seed the test waste load with a sufficient number of challenge microorganisms as specified in paragraph (E)(2) of this rule.
 - (ii) Using a carrier system, introduce one carrier with the appropriate inoculum for each ten pounds of waste in the test load. If the test load consists of less than ten pounds of waste, then a minimum of three carriers shall be used in each test load. The carriers shall be evenly distributed throughout the waste load.
- (5) Enumeration of the original inoculum. The applicant shall perform the enumeration of either the initial inoculum in the stock suspension or a representative sampling of carriers as follows:
 - (a) For a stock suspension, do the following:
 - (i) Enumerate all initial stock suspensions of microorganisms and control immediately prior to introduction into the test waste load used.
 - (ii) Inoculate the test waste load immediately prior to introduction into

the treatment unit.

(iii) Use the stock suspension number obtained above to determine the theoretical challenge (TC) and subsequently the adjusted theoretical challenge (ATC) for each test run as described in the appendix to this rule.

(b) For a carrier system, do the following:

(i) Verify through prior enumeration the inoculum contained on a representative sampling of carriers.

(ii) Determine the theoretical challenge (TC) for each microorganism and subsequently the adjusted theoretical challenge (ATC) for each test run as described in the appendix to this rule.

(6) Performing the treatment test runs. The applicant shall evaluate the treatment unit utilizing microorganisms or carriers in accordance with the following:

(a) Use full-scale production units for all testing.

(b) Conduct a recovery test run, using sound and accepted scientific microbial techniques, as specified in paragraph (C) of this rule, for each microorganism to determine the percentage of microorganisms that can be recovered from the waste loads used for testing, as specified in the appendix of this rule. The applicant shall perform at least one recovery test run absent of the aspect of the treatment technology that is responsible for the microbial kill.

[Comment: One recovery test run must be performed for each *Mycobacterium* spp., *Geobacillus stearothermophilus* or *Bacillus subtilis* spore. The recovery test run is necessary to determine the amount of loss of microorganisms or spores that is due to the physical aspects of the treatment unit and therefore to determine the ability to retrieve the microorganisms or spores from the waste or carrier.]

(c) Utilize a minimum of three treatment test runs per microorganism or spore.

(d) Demonstrate the attainment of the applicable performance standard as specified in paragraph (B) of this rule at the completion of all three test

runs.

(7) Recording data during testing. The applicant shall produce a permanent record of the following observations or recordings:

- (a) The date of testing.
- (b) The time of day that each test load is placed into the treatment unit.
- (c) The time of day that each sample is retrieved from the treatment unit.
- (d) The applicable observed or recorded operational parameters at which the treatment unit was operated.

[Comment: The applicant is expected to record the operational parameters for the treatment unit which any operator would use to ensure that the treatment unit was operating properly. Such operational parameters would include any preset or permanent settings or parameters that would affect the function of the unit.]

(8) Determining the sample number. The applicant shall ensure that a sufficient number of samples are collected in order to demonstrate compliance with the applicable performance standard as specified in paragraph (B) of this rule by evaluating the following factors:

- (a) The total treatment capacity.
- (b) The throughput process, such as a batch or continuous treatment process.
- (c) The physical state of the processed waste, such as loose or conglomerated.
- (d) The categories of infectious waste as defined in rule 3745-27-01 of the Administrative Code that the technology is designed to treat.

[Comment: More processed waste samples should be collected from larger test loads to ensure that samples are representative. As a general guideline, Ohio EPA would recommend that at least nine samples be collected. The nine collected samples may be used to make three composite samples.]

(9) Collection of test samples. The applicant shall use a sufficient number of

samples collected from each test run as the waste exits the treatment unit or shall collect all carriers as they exit the treatment unit to determine the number of surviving microorganisms or spores in accordance with the following:

- (a) Neutralize, if applicable, all controls and samples immediately upon exiting the treatment unit using a documented or prior tested neutralizer that will not affect the viable number of microorganisms being tested.
- (b) Cool all samples and controls to room/ambient temperature upon exiting the treatment unit and prior to preparation of the dilutions.

[Comment: The use of a buffered diluent to place all samples and controls into will satisfy the requirement of cooling and preparation of the dilutions. This requirement need not be a two step process.]

- (c) Prepare dilutions from each collected sample or composite sample.
- (10) Plating of test samples and calculation of test results. The applicant shall ensure that samples are plated and the results shall be calculated as follows:
- (a) The dilutions that are chosen for plating must be plated in triplicate.
 - (b) Utilize only those microbial plates that contain between thirty and three hundred colonies or plaques for the demonstration of the attainment of the performance standard as specified in paragraph (B) of this rule.
 - (c) Do not use any plate count if one of the three replicate plates has a quantitative difference of greater than five per cent. That replicate plate shall not be used and the calculation shall be formulated utilizing two replicate plates. If all three of the plate counts have a quantitative difference of greater than five per cent between them, the test run is considered invalid and another test load for that particular microorganism or spore shall be prepared and processed through the unit.
 - (d) Do not use any dilution series from a test run if any one of the three test run plate dilution series has a quantitative difference of greater than ten per cent with either of the other two. The test run shall be considered invalid and another test load for that particular series shall be prepared and processed through the unit.

- (11) Preparing the microbial testing report. The microbial testing report shall be prepared by the test manager responsible for conducting the microbial testing and shall present the raw data and results gathered in accordance with the protocol, as specified in paragraph (E) of this rule. The report shall contain, at a minimum, the following information:
 - (a) Testing parameters and results based upon a protocol which follows the standards specified in paragraph (E) of this rule.
 - (b) Enough detailed information so that the reported results and procedures could be reproduced by an independent laboratory.
 - (c) An introduction describing the intent of the testing. The introduction shall also contain the name, address, and telephone number of the laboratory and the name of the test manager.
 - (d) A separate section describing all materials and methods used to perform the testing and subsequent incubation of dilution of samples.
 - (e) A results section which contains, but is not limited to, the following:
 - (i) All raw data including all individual microbial counts.
 - (ii) Log reduction levels achieved for each test microorganism or spore obtained from the microbial testing of the three test loads that achieved the performance standard.
 - (iii) At least one example of each calculation used to determine the \log_{10} reduction levels through the utilization of the formulas found in the appendix to this rule.
 - (f) A conclusion section documenting the ability of the treatment technology to achieve the applicable performance standard as specified in paragraph (B) of this rule.
- (12) When, in the judgement of Ohio EPA, the protocol or testing method of a particular technology can not be designed in accordance with this rule, the director may accept an alternate protocol or testing method that does demonstrate achievement of the performance standard for the treatment technology. The applicant shall demonstrate to the director's satisfaction through the use of sound scientific microbial technique and peer-reviewed

journal reference or equivalent documentation that an alternate is of equal or greater challenge.

[Comment: Ohio EPA anticipates requests for approval of technologies that will not have enough residual material available for microbial testing.]

(F) Approval criteria. The director shall not approve an application for an alternative infectious waste treatment technology unless the director determines all of the following:

- (1) The use of the technology will be protective of human health and the environment.
- (2) The application conforms with the applicable requirements of paragraphs (B), (C), (D) and (E) of this rule.
- (3) The treatment technology is, at a minimum, capable of attaining the performance standards in accordance with paragraph (B) of this rule.
- (4) The testing performed as a part of the application was performed on full-scale production units.
- (5) For a site-specific approval, the applicant shall produce published, scientific, peer reviewed literature which indicates that results included in the application are repeatable and will be able to attain the performance standard as specified in paragraph (B) of this rule.
- (6) In determining whether an alternative technology will be capable of attaining the applicable performance standard, the director may consider the actual performance history of a technology that has been used or approved for use outside of Ohio.

(G) Contents of the director's authorization. Those alternative infectious waste treatment technologies that are approved by the director shall receive an authorization which at a minimum, shall contain the following:

- (1) A description of the technology.
- (2) The parameters at which the technology shall be operated during the treatment of infectious wastes.

- (3) A condition that the applicant include a copy of the approval letter in the front of each operating manual distributed with the treatment units.
 - (4) The operational procedures to be followed during the use of the alternative technology including any prohibitions of specific categories of infectious wastes.
 - (5) A quality assurance testing program to ensure that the treatment technology is achieving a minimum four \log_{10} reduction in bacterial spores. When determining the frequency of biological quality assurance testing, the director may consider the use of reliable parametric monitoring that is available with that technology at the time of approval.
 - (6) Quality assurance record keeping requirements.
 - (7) The measures the operator shall take to manage infectious wastes in the event that the treatment technology fails to achieve the applicable performance standard.
 - (8) For those technologies that receive a site specific approval, a condition that infectious wastes may not be treated using that treatment technology until the owner or operator demonstrates through validation testing as specified in the director's approval letter that the treatment unit is capable of achieving the performance standard specified in paragraph (B) of this rule.
 - (9) Any other conditions or requirements that the director deems appropriate in order to ensure that the approved alternative technology will be capable of achieving the performance standard specified in paragraph (B) of this rule and that the technology will be capable of being operated in a manner that is protective of human health and the environment.
 - (10) The director's authorization for the treatment technology shall reflect the types and volumes of waste streams that the treatment technology has been tested against.
- (H) The director may deny an application for an alternative infectious waste treatment technology if, within one hundred and eighty days of receipt of notification, the application is incomplete or, the applicant has not corrected noted deficiencies and resubmitted the application, or has not notified Ohio EPA that the application is being withdrawn.

- (I) Changes to an authorized alternative treatment technology. Changes to an authorized alternative treatment technology shall be submitted in writing to Ohio EPA for the director's authorization and shall include the information required by this rule.

- (J) Revocation. The director may revoke any approval of an alternative infectious waste treatment technology when any of the following has occurred:
 - (1) Any applicable laws have been or are likely to be violated.

 - (2) The application contained false or incorrect information such that the application would not have been approved if the correct information had been submitted.

 - (3) Under actual operation, the technology consistently fails to attain the applicable performance standard as specified in paragraph (B) of this rule.

 - (4) The use of the technology causes or threatens to cause harm to human health or the environment.