**Section 1422.124 Initial Efficacy Test**

a) The manufacturer, owner, or operator of a treatment unit must conduct an Initial Efficacy Test, under Appendix A, for each model prior to its operation. If significant mechanical changes are made to a treatment unit, the Initial Efficacy Test must be repeated. Treatment units are the same model if they:

1) Are manufactured by the same company;

2) Have the same capacity; and

3) Have no significant mechanical changes.

b) The Initial Efficacy Test must be conducted using Option 1, 2, or 3 (see Appendix A), and the challenge loads as described in Appendix A, Table C. If any of the challenge loads fails the Initial Efficacy Test, the operating conditions must be revised and the Initial Efficacy Test must be repeated for all challenge loads.

1) A treatment unit that does not maintain the integrity of the container of test microorganisms (e.g., grinding followed by chemical disinfection) must use Option 1. This option is a two phase test.

A) The first phase is to determine the dilution of each test microorganism from the operation of the treatment unit for each challenge load. The log of the number of viable test microorganisms in the processed residue must be greater than or equal to six.

B) The second phase is to determine the effectiveness of the treatment unit. The log kill for each test microorganism after treatment must be greater than or equal to six.

2) A treatment unit that maintains the integrity of the container of test microorganisms (e.g., autoclaving) must use Option 2. The log kill for each test microorganism after treatment must be greater than or equal to six.

3) Option 3 can only be used for a thermal treatment unit that maintains the integrity of the container of indicator microorganism spores (e.g., autoclaving, incinerating). The log kill of indicator microorganism spores after treatment must be greater than or equal to six.

c) Composition of Challenge Loads.

1) For treatment units designed to treat all types of PIMW:

A) Conduct the Initial Efficacy Test using all three types of challenge loads in Appendix A, Table C. The three types of challenge loads represent PIMW with a high moisture content, low moisture content, and high organic content. Appendix A, Table C contains the moisture and organic content requirements that must be met in each type of challenge load.

B) The quantity of each challenge load must equal 100% of the maximum capacity of the treatment unit.

C) Each challenge load must include 5% of each of the following categories: blood/broth cultures, fibers, metals, sharps, plastics, pathological waste, glass, non-woven fibers, and bottles of liquids.

2) For treatment units designed to treat only select categories of PIMW (e.g., a sharps treatment unit), a modification in the composition of the challenge loads may be used if approved by the Agency in writing.

d) The Initial Efficacy Test must be conducted under the same operating conditions the treatment unit operates on a day-to-day basis. The feed rate for the treatment unit must remain constant throughout the Initial Efficacy Test. This feed rate must never be exceeded during the operation of the treatment unit.

e) The Initial Efficacy Test must be performed so that:

1) Each container of test microorganisms or indicator microorganism spores is placed in the load to simulate the worst case scenario (i.e., that part of the load that is the most difficult to treat). For example, the worst case scenario for an autoclave would be to place the container of test microorganisms or indicator microorganism spores within a sharps container that is deposited in a plastic biohazard bag that is then located centrally within each of the challenge loads.

2) Test microorganisms or indicator microorganisms must be cultured and enumerated following instructions provided by the supplier of the microorganisms and Standard Methods for the Examination of Water and Wastewater (see 35 Ill. Adm. Code 1420.103).

f) A Document of Initial Efficacy Demonstration must be kept at the treatment facility and made available at the treatment facility during normal business hours for inspection and photocopying by the Agency. The Document of Initial Efficacy Demonstration must include:

1) A detailed description of the test procedures used, including all test data generated, with descriptions of data handling, and a presentation and interpretation of final test results;

2) A detailed description and verification of the operating parameters (e.g., temperatures, pressures, retention times, chemical concentrations, irradiation doses, and feed rates);

3) A description of quality assurance and quality control procedures and practices for the culture, storage, and preparation of test or indicator microorganisms (including organism history, source, stock culture maintenance, and enumeration procedures). The purity of the test microorganisms or indicator microorganism spores must be certified by a commercial or clinical laboratory;

4) A description of microorganism preparation and packaging, challenge load weight and composition, unit testing scheme (numbers of test rows), and sampling strategy (e.g., number and weight of solid and liquid samples);

5) A description and demonstration of microorganism recovery, including sample processing, incubation and effective neutralization, and absence of toxic compounds due to neutralization (as applicable);

6) Appendices containing raw data and assumptions in tabular form;

7) The name, date, signature, title, and qualifications of the person or persons conducting the Initial Efficacy Test; and

8) A list of references used to evaluate the data and obtain the conclusion.

(Source: Amended at 43 Ill. Reg. 10072, effective August 30, 2019)