

GAMMA STERILIZATION VALIDATION: KEY STEPS TO DOSE SETTING



Applied Sterilization Technologies

TECHNICAL TIP #41

When gamma radiation is selected as sterilization method for a product, the dose at which a product will be irradiated is established and validated according to one of two methods:

- ANSI/AAMI/ISO 11137-2 Sterilization of Healthcare Products- Radiation Part 2: Establishing the sterilization dose, or
- ANSI/AAMI/ISO TIR13004. Sterilization of health care products - Radiation - Substantiation of a selected sterilization dose: Method VDmaxSD.

Selection of the dose setting method depends on the bioburden of the product and the maximum dose at which the product can retain its form, fit and functionality.

The following testing will be performed during a radiation sterilization validation:

Maximum Dose Testing: Maximum dose testing is performed to confirm product tolerance at the selected maximum dose. The number of units required for this test is based on the test performed by the manufacturer to assure safety and efficacy of product.

Bioburden Test Method Validation: A validation is performed prior to conducting bioburden testing, providing an assessment of the efficiency of the specified extraction technique to remove microorganisms from a product. A correction factor is derived based on the recovery efficiency and, typically, extraction efficiency is determined by using inoculation recovery. Five irradiated samples are required for this method, though the number of samples can vary if a different method is used to determine the recovery efficiency. This is a one-time test for a product unless there is a change in materials, supplier, product configuration, or other factors that may impact bioburden or dose absorption.

Bacteriostasis/Fungistasis (B/F) Test: The B/F test is performed with selected microorganisms to demonstrate the presence of substances that inhibit the multiplication of microorganisms. This is done prior to a sterility test to assure that the readings of the sterility test are true. This test will determine that the product is not leaching anything in the test media during the sterility test resulting in false negatives. Three irradiated samples are required for the B/F test. This is also a one-time test for a product unless there is a change in materials,

supplier, product configuration, or other factors that may impact bioburden or dose absorption.

Bioburden Testing: Bioburden testing is the process of determining the population of viable microorganisms on a given sample (product). For a full validation, a total of 30 non-sterile samples, 10 each from three different production lots, are selected for bioburden testing. Samples are tested for aerobic bioburden and an overall average bioburden is calculated. Depending upon the method used for the dose setting, a verification dose is selected using the appropriate table from ANSI/AAMI/ISO 11137-2 or ANSI/AAMI/ISO TIR13004:2013 based on the overall average bioburden of the three lots.

If three production lots are not available, then a single lot validation can be performed. For a single lot validation, 10 samples from the lot to be validated will be tested for bioburden. Based on the average bioburden, a verification dose will be determined.

Sterility Testing: The number of samples required for sterility testing depends on the test method used. A VDmax method requires 10 non-sterile samples from one production lot. Samples are irradiated at the calculated verification dose followed by the sterility test. For a single lot validation, 10 samples from the lot being validated will be irradiated and tested for sterility. This will give an SAL-1, which means that if one sample is positive out of 10 samples tested, sterility test passes.

If Method1 is used for dose setting, 100 samples will be tested for sterility. This will give a SAL-2, which means that if two samples are positive out of 100 samples tested, sterility test passes.

If the sterility test passes, the validation is considered successfully completed and the product can be irradiated at the production dose.

After the validation is completed, quarterly dose audits are required to substantiate the sterility claim. The number of samples required for dose audits will be based on the sterilization method chosen for dose setting. If the product production interval exceeds three months, the dose audit will be performed on the next production lot.

References

ANSI/AAMI/ISO 11137-2 Sterilization of Healthcare Products-
Radiation Part 2: Establishing the sterilization dose, or

ANSI/AAMI/ISO TIR13004. Sterilization of health care products
- Radiation - Substantiation of a selected sterilization dose:
Method V_{DmaxSD}.

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