TECHNICAL TIP

GAMMA STERILIZATION DOSE AUDITING FOR ANSI/AAMI/ ISO 11137-2: 2006 VD_{MAX25}

The Association for the Advancement of Medical Instrumentation (AAMI) generates numerous standards used by the professionals in the medical device industry. Occasionally, the AAMI Standards Board provides additional guidance to specific standards in the form of a Technical Information Report (TIR). The AAMI standards and TIR reflect common industry practices that evolve from an accumulated process knowledge base.

ANSI/AAMI/ISO 11137-1: 2006 and –2: 2006 address the issue of validation and Quarterly Dose Audits for product validated using the $VD_{max}25$ method. Once the sterilization dose has been established, periodic audits must be performed at a defined and documented frequency. The audits are performed to determine the continued validity of the sterilization dose. Additionally, an audit should be performed following any change that could significantly affect the level or nature of the bioburden. The changes in the way a product is made, in materials used, or a change in the manufacturing facilities may also require a dose audit. In the absence of any such changes, the audit must be performed at three-month intervals to detect any changes in the bioburden that could require an augmentation in the sterilization dose.

ANSI/AAMI/ISO 11137: 2006 sterilization dose auditing consists of three major steps.

- Environmental monitoring review
- Bioburden testing
- Verification dose experiment

Environmental Monitoring

The environmental monitoring of the manufacturing facility is essential for tracking and investigating any changes in the bioburden number or type. Air sampling, water samples, and swipe testing are all examples of environmental monitoring.

Bioburden Testing

The bioburden testing is the process of determining the population of viable microorganisms on a given sample (product). In this step of the dose audit, 10 samples are taken from a production batch (lot) to determine bioburden count, also known as the number of Colony Forming Units (CFU's). The results are then used for comparison with bioburden counts that were determined at the time of the initial validation. If for any reason the bioburden count is significantly higher than the initial bioburden, passing a sterilization dose audit may be unlikely. It is also recommended that a gram stain be performed at the time of the bioburden testing. This performance is helpful in identifying if the microorganisms have changed in type as well as in number.

Verification Dose Experiment

The verification dose experiment is performed to determine whether or not a change in the sterilization dose (SAL 10^{-6}) is needed. The verification dose experiment must be performed at the dose determined at the time of validation. If for any reason the dose established at initial validation was augmented, the verification dose experiment should be performed at that augmented dose.

NOTE: Each time the verification dose is augmented, the next sterilization dose audit must be performed at the newly established verification dose. Ten samples irradiated at the previously selected verification dose are tested for sterility.

Process Summary

The verification dose audits should be performed as follows:

1. Randomly select 20 samples from a production batch prior to the sterilization phase of production
2. Ten of these samples are used for bioburden testing. The bioburden testing of these samples are used for trending purposes only

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies
Web: www.steris-ast.com // Email: ast_info@steris.com
(EMEAA) +44 (0) 8456 88 99 70
(Americas) 877.783.7479

STERIS

TECHNICAL TIP

GAMMA STERILIZATION DOSE AUDITING FOR ANSI/AAMI/ ISO 11137-2: 2006 VD_{MAX25}

3. The remaining 10 samples are then used for the verification dose experiment. The samples are irradiated at the verification dose established at the time of initial validation or the verification dose from the last sterilization dose audit. The sterility testing is then performed on the irradiated samples to determine if viable microorganisms are still present

Acceptance Criteria

If after the completion of the sterility test, one or no positive sterility samples are obtained, the original sterilization dose is acceptable and no action is required. The positive sterility tests are sterility test samples, which exhibit detectable microbial growth after incubation. If after completion of the sterility test two or more positive sterility tests are obtained, the original sterilization dose is not acceptable and further action is required. Dose augmentation maybe appropriate see ANSI/ AAMI/ISO 11137: 2006.

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies
Web: www.steris-ast.com // Email: ast_info@steris.com
(EMEAA) +44 (0) 8456 88 99 70
(Americas) 877.783.7479

STERIS

TECHNICAL TIP

GAMMA STERILIZATION DOSE AUDITING FOR ANSI/AAMI/ ISO 11137-2: 2006 VD_{MAX25}

REFERENCES

1. ANSI/AAMI/ISO 11137-1: 2006. Sterilization of health care products-Radiation-Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices.

2. ANSI/AAMI/ISO 11137-2: 2006. Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose.

3. ANSI/AAMI/ISO 11137-3: 2006. Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects.

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies
Web: www.steris-ast.com // Email: ast_info@steris.com
(EMEAA) +44 (0) 8456 88 99 70
(Americas) 877.783.7479

STERIS

GAMMA STERILIZATION DOSE AUDITING FOR ANSI/AAMI/ ISO 11137-2: 2006 VD_{MAX25}