TECHNICAL TIP

GAMMA STERILIZATION DOSE AUDITING FOR ANSI/AAMI/ISO

The Association for the Advancement of Medical Instrumentation (AAMI) generates numerous standards used by 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 the TIR reflect common industry practices that evolve from an accumulated process knowledge base.

ANSI/AAMI/ISO 11137: 2006 addresses the issue of Quarterly Dose Audits for product validated by ANSI/AAMI/ISO 11137: 2006. An audit must be performed at a defined and documented frequency. The audits are performed to determine the continued validity of the sterilization dose. An audit should be performed following any change that could significantly affect the level or nature of the bioburden. 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/SIO 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 to track and investigate any changes in bioburden number or type. Air sampling, water samples, and swipe testing are all examples of environmental monitoring. This is an on-going program to verify the production system is in control.

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 the bioburden count, also known as the number of Colony Forming Units (CFU's). The results are then used for comparison with the bioburden counts that were determined at time of 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 recommended that a gram stain be performed at the time of bioburden testing. This performance is helpful in identifying if the microorganisms have changed.

Verification Dose Experiment

The verification dose experiment is performed to determine whether or not a change in the sterilization dose 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 verification dose audit must be performed at the newly established verification dose. One hundred samples are irradiated at the previously determined verification dose and tested for sterility.

Process Summary

The verification dose audits should be performed as followed:

1. Randomly select 110 samples from a production batch prior to the sterilization phase of production
2. 10 of these samples are used for bioburden testing. The bioburden testing of these samples are used for trending purposes only
3. The remaining 100 samples are then used for the verification dose experiment. The 100 samples are

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TECHNICAL TIP

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irradiated at the verification dose established at the time of the initial validation or the verification dose from the last sterilization dose audit

4. Sterility testing is then performed on the irradiated samples to determine if viable microorganisms are still present on samples after samples have been irradiated

Acceptance Criteria

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

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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.

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