METHOD 1 QUARTERLY DOSE AUDITS: PART II INTERPRETATION OF RESULTS

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TECHNICAL TIP #07

Regular audits are used to confirm that the sterilization dose determined for your product is still the appropriate one. A dose audit for a product in regular production determines if any changes in bioburden have affected the sterilization dose. ANSI/AAMI/ISO 11137 in addition to giving guidance for setting the sterilization dose, also gives guidance on how to interpret the results of a quarterly dose audit. A dose audit includes bioburden and sterility testing (for details see Technical Tip #05). Interpretation of these results may require additional action of the part of the product manufacturer.

How do I Interpret the results of my Method 1 Audit?

1. If the results of the sterility test portion of the audit show **two or fewer** positives, the sterilization dose selected in the initial validation is still acceptable. **No further action is required**. Repeat audits as required.
2. If **three or four** positives are obtained, the sterilization dose is in question. The sterilization dose should be augmented immediately. The verification and sterilization doses are changed to the greater of:
    - Utilizing the average bioburden from the audit, determine a new verification and sterilization dose from Table 5 of AAMI 11137-2: 2006
    - Multiply the average bioburden from the initial validation by a factor of 10, then use this bioburden value to select a new verification and sterilization dose from Table 5
3. With **three to four positives**, a retest at the original verification dose can be performed to determine if return to the original dose is possible. On retest, the following acceptance rules apply:
    - With **two or less** positives, return to the original verification dose
    - With **three to four** positives, follow the audit action steps for **five to six** positives*
    - With **five or more positives**, follow the audit action steps for **seven or more** positives**
4. *If **five to six** positives are obtained, the original dose is not sufficient. If the bioburden has increased, the sterilization dose must be augmented immediately. A retest is not allowed unless evidence can support a compromised procedure or an improperly delivered dose. The next audit is performed at this newly established verification dose. If the bioburden has not increased, the radiation resistance of the bioburden has likely changed. The sterilization dose must be reestablished. No augmentation or retesting is permitted.
5. **If **seven or more** positives are obtained and there has been no significant change in bioburden, the radiation resistance of the bioburden has likely changed. The sterilization dose must be reestablished. No augmentation or retesting is permitted.

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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