



TECHNICAL TIP

VD_{MAX25} QUARTERLY DOSE AUDITS: PART II INTERPRETATION OF RESULTS

Regular audits are used to confirm that the sterilization dose determined for your product is still appropriate. A dose audit for a product in regular production determines if any changes in bioburden have affected the sterilization dose. ANSI/AAMI/ISO 11137: 2006 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 #06). Interpretation of these results may require additional action on the part of the product manufacturer.

How do I Interpret the results of my VD_{max25} Audit?

1. If zero or one positive is obtained on sterility test, the 25kGy sterilization dose is confirmed. No further action is required. Repeat audits as required. The typical audit schedule is once every three months. Guidance on reducing the frequency of the dose audits is included in AAMI 11137-1: 2006.
2. If two positives occur, a confirmatory test is required. The confirmatory test is a repeat of the sterility test at the same verification dose as the initial test. This test requires 10 more samples (same or a different product batch).
 - If no positives are seen on the confirmatory test, the 25 kGy dose is confirmed. This result represents two positives out of 20 total (10 tested in the first test, plus 10 more positives from the second test).
 - If one to four positives are obtained on this confirmatory test, the 25 kGy sterilization dose has not been confirmed. This method is treated as the equivalent of three to six positives on the initial audit test.* The sterilization dose should be augmented per the following equation:
3. *If three to six positives are obtained, the 25 kGy sterilization dose should be immediately augmented until an alternative method of dose setting is completed. The Augmented Dose is obtained per the following equation: Augmented Dose in kGy= 25 + Dose Augmentation Value from Table 9 AAMI 11137-2.
4. **If seven or more positives are obtained, no augmentation is allowed. An alternative method of dose setting must be used. The audit experiments cannot be repeated unless evidence is available to show incorrect procedure or dose was delivered in error (less than 90% of verification dose).

Augmented dose in kGy = 25 + Dose Augmentation Value from Table 9 11137-2:2006 VD_{max25}

- This augmented sterilization dose is meant to be used

FOR MORE INFORMATION

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REFERENCES

1. Technical Tip #06 Gamma Sterilization Dose Auditing for AAMI 11137-2:2006 VD_{max}25
2. Technical Tip #03 Gamma Sterilization Validations VD_{max} and Method 1: Frequently Asked Questions (FAQs)
3. 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
4. ANSI/AAMI/ISO 11137-2: 2006. Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose
5. ANSI/AAMI/ISO 11137-3: 2006. Sterilization of health care products-Radiation-Part 3: Guidance on dosimetric aspects

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