ANSI/AAMI/ISO 11137-2 METHOD to SUBSTANTIATE 25 kGy for GAMMA STERILIZATION

If you are routinely using 25 kGy as your sterilization dose and your product's bioburden level is <1000 CFU, VDmax may be an option worth looking into.

This method is not limited by batch size or production frequency, and, like method 1, is based on the standard distribution of resistance. Determination of the average bioburden and a verification dose experiment is required. The main difference between VDmax and Method 1 is that the verification is performed at a sterility assurance level (SAL) of 10^{-1} using only 10 product units opposed to 100 product units required by Method 1.

To initiate VDmax, determine the average bioburden level by randomly selecting 10 product units from each of three production batches. Using Table 9, the average bioburden value is used to establish the verification dose. 10 product units are then exposed to the indicated dose level and a test of sterility is performed. If no more than one positive response is observed, 25 kGy is substantiated as the sterilization dose.

Audits are performed to reaffirm the sterilization dose on a quarterly basis. These audits provide assurance that original manufacturing conditions have not changed and the bioburden level is under control.

Reference: ANSI/AAMI/ISO 11137-2; Sterilization of health care products – Radiation sterilization – Substantiation of 25 kGy as a sterilization dose – Method VDmax

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