MediZap
Advanced Sterilization

Radiation Dose Uniformity: Validating Doses

The process of establishing radiation dose uniformity between the sterilization dose, or minimum dose, and the maximum dose deemed acceptable during the validation process is something every industrial radiation entity must do—and must get right. To do so, a dose audit is necessary at specific frequencies, ensuring consistency. Samples are tested to show verification levels on medical devices at SAL 10^{-1} or 10^{-2} and doses usually less than 10kGy.
The dose audit must be lower than the standard processing dose to certify sterility assurance. To get a more precise dose range, the guiding principles for irradiator processing and the product configuration may require fine-tuning and then be substantiated.

The governing standard (ISO 11137) states that the sterilization dose and the dose audit are not required to be done at the same site as the product processing, provided that a) the product in question does not consist of water in a liquid state and b) that the same X-Ray or E-Beam methods are used for both standard processing and the dose audit.

MediZap delivers precisely what our customers need: exact sample processing done efficiently and effectively. From irradiation dose identification and dose audits to the advancement of research, our commitment to quality work is unwavering.

Transferring The Radiation Verification Dose Between Facilities

The industry standard (ISO 11137-1) contains several requirements to safely transfer doses from one facility to another (8.4.2). For example, moving a verification dose or a sterilization dose to a radiation source different from the original will not be permitted (8.4.2.1) unless studies show differences in radiation sources (i.e., E-Beam or X-Ray) has no adverse consequences on microbial effectiveness.

Additionally, one of these can also be true:

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- The transference of the sterilization dose or verification dose for a product not comprised of water is allowed between either E-Beam generators or two X-Ray generators. (8.4.2.2)

- The transference of the sterilization dose or verification dose for products that is comprised of water in a liquid state is allowed between two electron radiation sources with the same operating conditions or two X-Ray radiation sources with the same operating conditions. (8.4.2.3)