



TECHNICAL TIP

RADIATION VERIFICATION DOSE TRANSFER

Industrial radiation facilities are designed to achieve a dose uniformity inside a process load between the sterilization (minimum) dose and the maximal acceptable dose established during the validation process.

To demonstrate continued effectiveness of the established sterilization dose, a dose audit is required to be performed at defined frequencies. This audit requires the treatment of samples at a dose specific to the medical device. In performing such studies, lower dose must be performed at verification levels on SAL 10⁻¹ or 10⁻², typically at doses less than 10kGy.

This verification dose range (i.e. dose audit) is lower than the routine processing dose range to verify sterility assurance. To achieve this tighter dose range, the product configuration and/or irradiator processing parameters may need to be adjusted and qualified.

According to ISO 11137, the sterilization dose qualification and dose audit do not need to be performed at the same facility as the site used for routine product processing, provided:

- both routine processing and the associated dose audits are performed using the same technology (E-beam, gamma or X-ray) and
- product does not contain water in the liquid state

To meet the needs of our Customers, STERIS has consolidated dose verification work into our dedicated Radiation Technology Centers (RTC), which specialize in the high precision-processing of non-routine samples with a rapid turnaround.

Our Radiation Technology Centers are dedicated to providing high precision irradiation dose delivery for validation, dose audit, and research purposes. The following information details the requirements for transferring radiation verification dose work from a production processing facility to a STERIS RTC.

ISO 11137-1 defines the requirements necessary to transfer doses from one plant to another and must be complied with to warrant any transfer of dose. The requirements are detailed below:

8.4.2 Transference of verification dose or sterilization dose

8.4.2.1 Transference of a verification dose or a sterilization dose to a radiation source different from that on which the dose was originally established shall not be permitted unless:

- a) data are available to demonstrate that differences in operating conditions of the two radiation sources have no effect on microbicidal effectiveness
- or
- b) 8.4.2.2 or 8.4.2.3 applies.

8.4.2.2 For product that does not contain water in the liquid state, transference of the verification dose or sterilization dose is permitted between:

- a) one gamma irradiator and another gamma irradiator,
 - b) one electron beam generator and another electron beam generator
- or
- c) one X-ray generator and another X-ray generator.

8.4.2.3 For product that contains water in the liquid state, transference of the verification dose or sterilization dose is permitted between:

- a) one gamma irradiator and another gamma irradiator,
 - b) two electron radiation sources operating under identical operating conditions
- or
- c) two X-ray radiation sources operating under identical operating conditions.

FOR MORE INFORMATION

STERIS Applied Sterilization Technologies
Web: www.steris-ast.com // Email: ast_info@steris.com
(EMEA-APAC) +44 (0) 8456 88 99 70
(Americas) 877.783.7479

