TECHNICAL TIP

TRANSFER OF STERILIZATION DOSE, VERIFICATION DOSE AND MAXIMUM ACCEPTABLE DOSE BETWEEN RADIATION SOURCES

Radiation source transfers can include either a change of location using the same technology, or a technology transfer such as gamma to E-beam or X-ray. This document answers many of the frequently asked questions posed during discussions regarding radiation source transfers, and addresses possible transfer types and areas for consideration. The information provided is based primarily on directives in the ISO 11137 international standards series.

1. As part of a transfer, will my minimum dose specification change?

NO. The minimum dose [or sterilization dose (D_{ster}) as defined in ISO11137] is the minimum dose defined to achieve the desired sterility assurance level, typically SAL 10^{-6}. The minimum dose is established to be in accordance with with ISO 11137-2.

2. Do I need to establish/verify my minimum dose in a transfer?

MAYBE. Minimum dose is a factor of the product bioburden and the resistance of the microorganisms comprising the bioburden. Sterilization dose is established or substantiated through a verification dose experiment per ISO 11137-2. ISO 11137-1 states the following regarding transfer of the defined verification dose (based on product bioburden):

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 as 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 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 additional information on E-beam to E-beam and products containing liquid water, please consult sections A8.4.2.2 and A8.4.2.3 ISO11137-1.

FOR MORE INFORMATION

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In summary, the following table details when a dose verification experiment must be performed.

Product transfer between same technology, No liquid water present	Verification dose experiment does not need to be repeated
Product transfer between same technology, Liquid water is present	Processes shall be demonstrated as identical If not identical, verification dose experiment must be performed
Product transfer to alternative technology	Verification dose experiment shall be performed

3. As part of transfer, will my maximum dose specification change?

MAYBE. The maximum dose ($D_{max, acc}$) specification is the dose that has been qualified as a maximum for product functionality and, like the minimum dose, is product specific. In some rare occasions, upon performance of dose mapping in a new radiation source, a higher measured maximum dose (D_{max}) may be observed. In such circumstances, two options become available:

1) Adjust product presentation and re-map to stay within the pre-defined dose range ($D_{ster} - D_{max, acc}$)

2) Qualify product to a new maximum dose specification ($D_{max, acc}$) aligned to higher maximum dose (D_{max}) measured in new radiation source product dose maps

11137-1, section 8.4.1 provides additional guidance.

4. Do I need to re-establish my maximum dose?

MAYBE. As previously stated, the maximum dose specification is determined by the product. However, the impact of the change of radiation source at that maximum dose level needs to be considered. The following scenarios should be considered:

Product transfer between same technology	*If dose rate and product temperature are equivalent, transfer between the same type of radiation source is appropriate. (ISO 11137)*
High dose rate to low dose rate (e.g. E-beam to gamma)	Consideration must be shown to the potential impact of dose rate on product residence time at the new radiation source and potential temperature impact on the product
Low dose rate to high dose rate	*A product qualified at a low dose rate (gamma rays) or intermediate dose rate (X-rays) will typically require minimal qualification to demonstrate material compatibility at a higher dose rate (E-beam). (ISO 11137)*

5. As part of a transfer, will a dose map need to be performed?

YES. As much as two radiation sources may be described as equivalent, often there will be variances. For example, with gamma, the cobalt loading, source geometry and facility design (e.g. distance product to source) can contribute to variances. In E-beam, power and subsequent conveyor speed, scan geometry, and E-beam configuration can create differences between sources. Hence, dose mapping at each site is required to establish that the minimum and maximum dose requirements are achieved with the established process settings.

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6. Are there any specific cases that need further scrutiny?

YES. In transferring radiation processes, ISO 11137 does draw particular attention to liquid water stating, 'Available experimental evidence indicates that when irradiation occurs in the presence of liquid water, microbicidal effectiveness can be affected by the operating characteristics of the radiation sources.' Hence, specific guidance is provided regarding transfer of verification dose (see section 2).

For product where temperature impacts product functionality, care should be taken, as temperature during process can change from one irradiator to another or one technology to the other.

Glossary of Terms (ISO 11137)

Symbol	Definition
$D_{max,acc}$	Maximum acceptable dose determined in accordance with ISO 11137-1
D_{ster}	Sterilization dose determined in accordance with ISO 11137-1
D_{max}	Direct measurement of maximum dose in a given irradiation container

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