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Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1

Stérilisation des produits de santé — Irradiation — Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux

AMENDEMENT 1

Reference number
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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 11137-1:2013 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1

Page 2, Normative references

Replace the reference to ISO 11137-2:2006 with the following:

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

Page 6, Terms and definitions

Replace entry 3.29 with the following:

3.29
processing category
collection of different product or product families that can be sterilized together

NOTE Processing categories can be based on, for instance, composition, density or dose requirements.

Replace entry 3.31 with the following:

3.31
product family
group of product possessing characteristics that allow them to be sterilized using given defined process conditions

NOTE Bioburden on members of a product family destined for radiation sterilization has to comprise similar numbers and types of microorganisms.

Page 11, 6.2.5

Add the following item to the list:

m) the means of ceasing irradiation if failure of the target cooling system occurs.

Page 12, 7.4

Replace the reference “ISO 11137-2:2006, Clause 4” with “ISO 11137-2”.

Page 12, 8.2.2, NOTE to a)

Replace the reference “6.1 of ISO 11137-2:2006” with “ISO 11137-2”.

Page 12, 8.2.2, NOTE to b)

Replace the reference “6.2 of ISO 11137-2:2006” with “ISO 11137-2”.

Page 17, 12.1.1 a)

Replace a) with:

a) determinations of bioburden to monitor the number of microorganisms present on product in relation to a specified bioburden limit, and

Page 18, 12.1.2.5

Replace the first paragraph up to and including b) 1) with the following:

If the outcome of determinations of bioburden exceeds the specified bioburden limit, an investigation in accordance with ISO 11737-1 shall be performed. If the outcome of the investigation indicates that the bioburden determination is a true result, procedures specified in 4.4 shall be implemented and a sterilization dose audit shall be performed immediately. Depending on the outcome of the sterilization dose audit, a) or b) below shall be followed.

a) If the sterilization dose audit is unsuccessful, action shall be taken in accordance with 12.1.3.5.

b) If the outcome of the sterilization dose audit is successful and the bioburden continues to exceed the specified bioburden limit, sterilization shall continue using the dose used prior to the sterilization dose audit. Also

1) if the sterilization dose has been established using Method 1 (see ISO 11137-2), a three-month interval for the sterilization dose audit shall be used until either the bioburden is returned to the specified bioburden limit or the sterilization dose is re-established;

Page 19, 12.1.3.1

Replace b) 1) with the following:

1) the specified bioburden limit;

Page 19, 12.1.3.2

Replace b) 1) with the following:

1) bioburden determinations performed at least every three months or every month in the case of product of average bioburden less than 1,5 for which the sterilization dose has been set using Method 1 or a sterilization dose of 15 kGy has been selected and substantiated and

Page 20, 12.1.3.5

Replace the reference “ISO 11137-2:2006, Clause 10” with “ISO 11137-2”.

Add “and” at the end of b).

Page 24, A.7.4

Replace the reference “ISO 11137-2:2006, Clause 4” with “ISO 11137-2”.

Page 26, A.8.2.2

In the third line of 1), replace reference “ISO 11137-2:2006, Clause 7” with “Method 1 of ISO 11137-2”.

In the third line of 2), replace reference “ISO 11137-2:2006, Clause 8” with “Method 2 of ISO 11137-2”.

In the last line of the subclause, replace “≤” with “less than or equal to” and replace reference “ISO 11137-2:2006, Clause 9” with “ISO 11137-2”.

Page 26, A.8.4.1

Replace the first paragraph with the following paragraphs:

The assessment of the validity of the maximum acceptable dose for a radiation source other than that on which the dose was originally established should take into consideration dose rate and product temperature during irradiation. For example, the higher the dose rate, the less likely are unwanted effects upon product.

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 high dose rate (electron-beam). Conversely, a material qualified at a high dose rate may require more substantial qualification in the low or intermediate dose rate application.

Page 26, A.8.4.2.1

Replace the entire subclause with the following:

There is a concern in transferring between types of radiation source with widely differing dose rates that can provide different microbicidal effects. Demonstrating that the microbicidal effectiveness is not affected by changes in dose rate provides the necessary data for the transference to be permitted. A demonstration that transference does not alter microbicidal effectiveness can be accomplished by the performance of a successful verification dose experiment (see ISO 11137-2) using the radiation source to which transfer is being considered.

Page 27, A.8.4.2.2

Delete the second paragraph.

Page 27, A.8.4.2.3

Replace the entire subclause with the following:

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 the restrictions on permission being granted.

Page 30, A.12.1.2.5

Replace the entire subclause with the following:

Setting the specified bioburden limit for the purpose of demonstrating the continued effectiveness of the sterilization dose should be based on the consequences of exceeding the specified bioburden limit on the achievement of the specified requirements for sterility.