DRAFT AMENDMENT ISO 11137-1:2006/DAM 1

ISO/TC **198** Secretariat: **ANSI**

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INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

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

ICS 11.080.01

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the European Committee for Standardization (CEN), and processed under the **CEN-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as r eceived from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

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

This amendment modifies subclauses in the International Standard.

Sterilization of health care products — Radiation —

Part 1:
Requirements for development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1

***Change normative reference to undated reference*:**

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

***Change the definitions for processing category and product family per ISO/TC 198/WG 5, Terminology*:**

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.

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.

Add an additional item to be specified

6.2.5 For X-ray irradiators, the specification shall at least describe:

…

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

Change reference to ISO 11137-2 to an undated reference.

7.4 If a sterilization dose is to be established for a product family, requirements for defining a product family in ISO 11137-2 shall be met.

8.2.2 One of two approaches, as described in a) and b) below, shall be taken in establishing the sterilization dose:

a knowledge of the number and/or resistance to radiation of the bioburden is obtained and used to set the sterilization dose

NOTE Methods of setting the sterilization dose and circumstances under which these methods may be applied are detailed in ISO 11137-2.

or

a sterilization dose of 25 kGy or 15 kGy is selected and substantiated; in substantiating a sterilization dose of 25 kGy or 15 kGy, the primary manufacturer shall have evidence that the selected sterilization dose is capable of achieving the specified requirements for sterility (see 1.2.2).

NOTE Methods VD_{max}^{25} and VD_{max}^{15} for substantiation of the sterilization dose and circumstances under which these methods may be applied are detailed in ISO 11137-2. Methods VD_{max}^{25} and VD_{max}^{15} are linked to achievement of a sterility assurance level of 10^{-6}.

Replace "defined bioburden specification" with "specified bioburden limit" throughout ISO 11137-1 for consistency with ISO 11737-1.

Delete "action shall be taken in accordance with 4.4" with "procedures specified in 4.4 shall be implemented" for accuracy.

12.1.1 General

The continued effectiveness of the established sterilization dose shall be demonstrated through the conduct of

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

12.1.2.5 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.

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

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

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;

12.1.3.1 One of two possible approaches, described in a) and b) below, shall be made in initially determining the interval of time between the performance of sterilization dose audits:

an interval of time of three months between sterilization dose audits is selected

or

a rationale is prepared and documented for the selection of the initial interval of time between the performance of sterilization dose audits; in preparing the rationale, account shall be taken, and records made, of a review and conclusions reached with respect to, at least:

the specified bioburden limit;

Add text for clarity.

12.1.3.2 An increase in the interval of time between the performance of sterilization dose audits shall only be permitted if:

at least four consecutive sterilization dose audits, whose outcomes have required neither dose augmentation nor sterilization dose re-establishment, have been performed at the previously selected interval of time;

data are available that demonstrate the stability of bioburden within the bioburden specification over the same period of time as item a) above; these include

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

Change references to ISO 11137-2 to undated references.

12.1.3.5 If a sterilization dose audit is unsuccessful, action shall be taken in accordance with ISO 11137-2. The frequency of performance of sterilization dose audits shall be an interval of time of not greater than three months until:

the cause of the sterilization dose audit failure or the increase in bioburden has been investigated and correction and/or corrective action implemented;

the rationale (see 12.1.3.1) for the interval of time between the performance of sterilization dose audits has been reviewed and, if necessary, a new interval of time specified; and

the criteria for increasing the interval of time between the performance of sterilization dose audits in 12.1.3.2 have been met.

A.7.4 See ISO 11137-2.

Text changed for consistent use of text rather than symbols.

A.8.2.2 With regard to 8.2.2 a), in order to establish the sterilization dose with this approach, the following can apply:

a knowledge of the number and resistance of microorganisms comprising the bioburden may be used in establishing the sterilization dose for product having an average bioburden greater than or equal to 0,1 (see ISO 11137-2);

a knowledge of the resistance of microorganisms comprising the bioburden may be used in establishing the sterilization dose for product having any level of average bioburden (see ISO 11137-2).

With regard to 8.2.2 b), an appropriate method for substantiation of 25 kGy for product having an average bioburden less than or equal to 1 000 or substantiation of 15 kGy for product having an average bioburden less than or equal to 1.5 is given in ISO 11137-2.

Change text to clarify that X-rays should not be regarded as low dose radiation.

A.8.4.1 Transference of maximum acceptable dose

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.

If dose rate and product temperature are equivalent, transfer between the same type of radiation sources is appropriate.

Change text to align correctly with requirement clauses.

A.8.4.2.1 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.

A.8.4.2.2 Experimental evidence indicates that when irradiation occurs under ‘dry’ conditions, microbicidal effectiveness is independent of the operating condition; hence the granting of this permission.

A.8.4.2.3 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.

Consistent use of term "specified bioburden limit."

A.12.1.2.5 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.

Annex ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC

By agreement between ISO and CEN, this CEN annex is included in the DIS and the FDIS but will not appear in the published ISO standard.

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the relevant Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.