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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

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English version

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

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

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 204.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (prEN ISO 11137-1:2004) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

This document is currently submitted to the parallel Enquiry.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

Endorsement notice

The text of ISO/DIS 11137-1:2004 has been approved by CEN as prEN ISO 11137-1:2004 without any modifications.

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

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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

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

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ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received 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 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition, which has been technically revised.

ISO 11137 consists of the following parts, under the general title *Sterilization of health care products — Radiation*:

— *Part 1: Requirements for the development, validation and routine control of a sterilization process for medical products*

— *Part 2: Establishing the sterilization dose*

— *Part 3: Guidance on dosimetric aspects*

Introduction

A sterile medical device is one which is free of viable microorganisms. International standards, which specify requirements for validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimised. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one product in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a product item.

This standard describes requirements which will enable the demonstration that a radiation sterilization process intended to sterilize medical devices has appropriate microbicidal activity, and that this activity is both reliable and reproducible, such that the relationship for the inactivation of microorganisms can be extrapolated with reasonable confidence to low levels of probability of there being a viable microorganism present on a product after sterilization. This standard does not specify the maximal value to be taken by this probability; specification of this probability is a matter for Regulatory Authorities and may vary from country to country (see, for example, EN 556-1 and ANSI/AAMI ST67).

Generic requirements of the quality management system for design/development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognise that, for certain sterilization processes used in manufacturing or reprocessing, the effectiveness of the sterilization process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely and the equipment maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of factors including:

a) the microbiological status of incoming raw materials and/or components,

b) the validation and routine control of any cleaning and disinfection procedures used on the product,

c) the control of the environment in which the product is manufactured, assembled and packaged,

d) the control of equipment and processes,

e) the control of personnel and their hygiene,

f) the manner and materials in which the product is packaged, and,

g) the conditions under which product is stored.

This International Standard describes the requirements for ensuring that the activities associated with the process of radiation sterilization are performed properly. These activities are described in documented work programmes designed to demonstrate that the radiation process will consistently yield products treated with doses falling within predetermined limits.

The requirements are the normative parts of this standard with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a check list for auditors. The guidance provides explanations as well as methods that are accepted as being suitable means for complying with the requirements. Approaches other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of this International Standard.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities, for example calibration, maintenance, product definition, process definition, installation qualification, operational qualification, and performance qualification. While the activities required by this standard have been grouped together and are presented in a particular order; this International Standard does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the programs of development and validation may be iterative. It is possible that performing these different activities will involve a number of separate individuals and/or organizations, each of whom undertake one or more of these activities. This International Standard does not specify the particular individuals or organizations to carry out the activities.

Sterilization of health care products — Radiation —

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

1 Scope

1.1 Inclusions

1.1.1 This International Standard specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

NOTE Although the scope of this standard is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

1.1.2 Radiation sterilization processes covered by this standard employ,

a) irradiators, using the radionuclides ^{60}Co and ^{137}Cs,

b) irradiators using a beam from an electron generator, or

c) irradiators using a beam from an x-ray generator.

1.2 Exclusions

1.2.1 Sterilization processes validated and controlled in accordance with the requirements of this standard should not be assumed to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jacob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

NOTE (See, for example, EN 12442-1, -2 and -3).

1.2.2 This standard does not detail a specified requirement for designating a medical device as sterile.

NOTE Attention is drawn to national or regional requirements for designating medical devices as “sterile.” See, for example, EN 556-1 or ANSI/AAMI ST67.

1.2.3 This standard does not specify a quality management system for the control of all stages of production of medical devices.

NOTE It is not a requirement of this standard to have a full quality management system during manufacture, but the elements of a quality management system that are the minimum necessary to control the sterilization process are normatively referenced at appropriate places in the text (see, in particular, clause 4). Attention is drawn to the standards for quality management systems (see ISO 13485) that control all stages of production or reprocessing of medical devices, including the sterilization process. National and/or regional regulations for the provision of medical devices might require a complete the implementation of a full quality management system and the assessment of that system by a third party.

1.2.4 This standard does not require that biological indicators are used for validation or monitoring of radiation sterilization, nor that a pharmacopoeial test for sterility is carried out for product release.

1.2.5 This standard does not specify requirements for occupational safety associated with the design and operation of irradiation facilities**.**

NOTE Attention is also drawn to the existence in some countries of regulations laying down safety requirements for occupational safety related to radiation.

1.2.6 This standard is not applicable to the sterilization of used and reprocessed medical devices.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 13485 *Medical devices - Quality management systems – Requirements for regulatory purposes*

ISO 10012-1 *Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation system for measuring equipment*

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

ISO 11737-1 Sterilization of health care products – Microbiological methods – Part 1: Estimation of the population of microorganisms on products

ISO 11737-2 Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1
absorbed dose
quantity of absorbed energy imparted per unit mass of matter

NOTE The unit of absorbed dose is the gray (Gy) where 1 gray is equivalent to absorption of 1 joule per kilogram.

3.2
bioburden
population of viable microorganisms on or in product and/or a package

3.3
biological indicator
microbiological test system providing a defined resistance to a specified sterilization process

[ISO TS 11139:2001]

3.4
calibration
set of operations which establish, under specified conditions, the relationship between values indicated by a measuring system, or values represented by a material measure or a reference material, and the corresponding values of a quantity obtained from a reference standard

[ISO TS 11139:2001]

3.5
change control
formal assessment and determination of the appropriateness of a proposed alteration to product or procedure

[ISO TS 11139:2001]

3.6
correction
action to eliminate a detected nonconformity

NOTE a correction can be made in conjunction with corrective action. [ISO 9000:2000]