



SLOVENSKI STANDARD
oSIST prEN ISO 11137-1:2023
01-junij-2023

Sterilizacija izdelkov za zdravstveno nego - Sevanje - 1. del: Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke (ISO/DIS 11137-1:2023)

Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO/DIS 11137-1:2023)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 1: Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO/DIS 11137-1:2023)

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 (ISO/DIS 11137-1:2023)

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Sterilization of health care products — Radiation —

Part 1:

Requirements for the development, validation and routine control of a sterilization process for medical devices

ICS: 11.080.01

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11137-1:2006 and its amendments), which has been technically revised.

The main changes compared to the previous edition are as follows:

- addition of ISO 13004 as a normative reference;
- addition of the ASTM standard practice for dosimetry in radiation processing as a normative reference and alignment of terminology across the document to ASTM standards terminology;
- replacement of [Clause 4](#) with the updated common [Clause 4](#) for ISO/TC 198 documents;
- increase of the allowable limits above which the potential induced radioactivity shall be assessed to 11 MeV for electrons and [7.5 MeV](#) for X-rays (see [5.1.2](#));
- addition of a requirement to ensure that failure of a control function does not lead to a failure in recording process parameters such that an ineffective process appears effective (see [6.1](#));
- simplification of content on transference of verification dose or sterilization dose based on published data that demonstrates that differences in operating conditions of the two radiation sources have no effect on microbicidal effectiveness for product that does not support microbial growth (see [8.4.2](#));
- addition of references to the Bibliography;
- removal of dosimeter placements and measurements as the means of routine monitoring control and elimination of specifying the method of measurement (see [10.6](#) and [10.7](#));
- clarification has been provided on the allowable interval of time for quarterly dose audits, allowing for an interval of 4 months provided there are 4 dose audits per year (see [12.1.2](#));

- addition of references for all VD_{\max}^{SD} dose levels contained in both ISO 11137-2 and ISO 13004 (see [8.2.2](#) and [12.1.2](#));
- addition of guidance related to new or modified normative content.

A list of all parts in the ISO 11137 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

A sterile medical device is one that 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 minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) can, prior to sterilization, have microorganisms on them. Such medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices 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 can 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 microorganisms exist during treatment. It follows that the sterility of any one medical device 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 medical device.

This document describes requirements that, if met, will provide a radiation sterilization process, intended to sterilize medical devices, that has appropriate microbicidal activity. Furthermore, conformance with the requirements ensures that this activity is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable microorganism present on product after sterilization. Specification of this probability is a matter for regulatory authorities and can vary from country to country (see, for example, EN 556-1 and ANSI/AAMI ST67).

Generic requirements of the quality management system for design and 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 processes used in manufacturing, the effectiveness of the 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 is monitored routinely and the equipment is maintained.

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

- a) the microbiological quality 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;
- g) the conditions under which product is stored.

This document 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 irradiation process will consistently yield sterile medical devices on treatment with doses falling within the predetermined limits.

The requirements are the normative parts of this document with which conformance is claimed. The guidance given in the informative annexes is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being a suitable means for conforming with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving conformance with the requirements of this document.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities; e.g. calibration, maintenance, product definition, process definition, installation qualification, operational qualification and performance qualification. While the activities required by this document have been grouped together and are presented in a particular order, this document does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the programme 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 document does not specify the particular individuals or organizations to carry out the activities.

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Sterilization of health care products — Radiation —

Part 1:

Requirements for the development, validation and routine control of a sterilization process for medical devices

1 Scope

1.1 This document specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

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

This document covers radiation processes employing irradiators using

- a) the radionuclide ^{60}Co or ^{137}Cs ;
- b) a beam from an electron generator; or
- c) a beam from an X-ray generator.

1.2 This document does not specify requirements for development, validation and routine control of a process for inactivating viruses or the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

NOTE See, for example, ISO 22442-1, ISO 22442-2 and ISO 22442-3.

1.2.1 This document does not detail specified requirements for designating a medical device as sterile.

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

1.2.2 This document 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 document to have a complete 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 of medical devices, including the sterilization process. Regional and national regulations for the provision of medical devices can require implementation of a complete quality management system and the assessment of that system by a third party.

1.2.3 This document does not require that biological indicators be used for validation or monitoring of radiation sterilization, nor does it require that a pharmacopoeial test for sterility be carried out for product release.

1.2.4 This document does not specify requirements for occupational safety associated with the design and operation of irradiation facilities.

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

1.2.5 This document does not specify requirements for the sterilization of used or reprocessed devices.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

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

ISO 13004, *Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VD_{max}^{SD}*

ISO 11737-1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

ISO/ASTM 52628, *Standard practice for dosimetry in radiation processing*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

absorbed dose **dose**

quantity of ionizing radiation energy imparted per unit mass of a specified material

Note 1 to entry: The unit of absorbed dose is the gray (Gy) where 1 Gy is equivalent to the absorption of 1 J/kg.

Note 2 to entry: For the purposes of this document, the term dose is used to mean “absorbed dose”.

[SOURCE: ISO 11139:2018, 3.3, modified — Dose has been added as an accepted term; notes to entry have been added.]

3.2

bioburden

population of viable microorganisms on or in a product and/or sterile barrier system

[SOURCE: ISO 11139:2018, 3.23]

3.3

biological indicator

test system containing viable microorganisms providing a specified resistance to a specified sterilization process

[SOURCE: ISO 11139:2018, 3.29]

3.4 calibration

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO 11139:2018, 3.31]

3.5 change control

assessment and determination of the appropriateness of a proposed alteration to product, process, or equipment

[SOURCE: ISO 11139:2018, 3.39]

3.6 correction

action to eliminate a detected nonconformity

Note 1 to entry: A correction can be made in conjunction with corrective action.

[SOURCE: ISO 9000:2015, 3.12.3, modified — Note 2 to entry has been deleted.]

3.7 corrective action

action to eliminate the cause of a nonconformity and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

[SOURCE: ISO 9000:2015, 3.12.2, modified — Note 3 to entry has been deleted.]

3.8 *D* value *D*₁₀ value

time or dose required under stated conditions to achieve inactivation of 90 % of a population of the test microorganisms

Note 1 to entry: For the purpose of the ISO 11137 series, the *D* value refers to the dose necessary to achieve the 90 % reduction.

[SOURCE: ISO 11139:2018, 3.75, modified — Note to entry has been added.]

3.9 development

act of elaborating a specification

[SOURCE: ISO 11139:2018, 3.79]

3.10 dose mapping

measurement of dose distribution and variability in material irradiated under specified conditions

[SOURCE: ISO 11139:2018, 3.87]

ISO/DIS 11137-1:2023(E)**3.11****dosimeter**

device having a reproducible, measurable response to radiation that can be used to measure the absorbed dose in a given system

[SOURCE: ISO 11139:2018, 3.89]

3.12**dosimetry**

measurement of absorbed dose by the use of dosimeters

[SOURCE: ISO 11139:2018, 3.90]

3.13**establish**

determine by theoretical evaluation and confirm by experimentation

[SOURCE: ISO 11139:2018, 3.107]

3.14**fault**

situation in which one or more of the process or cycle parameters is/are outside its/their specified tolerance(s)

[SOURCE: ISO 11139:2018, 3.116]

3.15**health care product**

medical device, including *in vitro* diagnostic medical device, or medicinal product, including biopharmaceutical

[SOURCE: ISO 11139:2018, 3.132]

3.16**installation qualification****IQ**

process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

3.17**irradiation container**

holder in which product is transported through the irradiator

Note 1 to entry: The holder can be a carrier, cart, tray, product carton, pallet or other container.

[SOURCE: ISO 11139:2018, 3.146]

3.18**irradiator operator**

company or body responsible for irradiation of product

[SOURCE: ISO 11139:2018, 3.147]

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3.19**maximum acceptable dose** **$D_{\max,acc}$**

dose given in the process specification as the highest dose that can be applied to a specified product without compromising safety, quality or performance

Note 1 to entry: The specification for maximum acceptable dose may apply to an entire product or a defined portion of a product.

[SOURCE: ISO 11139:2018, 3.161, modified — Note 1 to entry has been added.]

3.20**medical device**

instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, or software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- items specifically intended for cleaning or sterilization of medical devices;
- pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;
- disinfection substances;
- aids for persons with disabilities;
- devices incorporating animal and/or human tissues;
- devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added.]

3.21**microorganism**

entity of microscopic size, encompassing bacteria, fungi, protozoa and viruses

Note 1 to entry: A specific standard might not require demonstration of the effectiveness of the sterilization process in inactivating all types of microorganisms, identified in the definition above, for validation and/or routine control of the sterilization process.

[SOURCE: ISO 11139:2018, 3.176, modified — Note to entry has been added.]