SLOVENSKI STANDARD
oSIST prEN ISO 11137-3:2015

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Sterilizacija izdelkov za zdravstveno nego - Sevanje - 3. del: Smernice o dozimetričnih vidikih za razvoj, validacijo in rutinski nadzor (ISO/DIS 11137-3:2015)

Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO/DIS 11137-3:2015)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 3: Anleitung zu dosimetrischen Aspekten der Entwicklung, Validierung und Lenkung der Anwendung (ISO/DIS 11137-3:2015)

Stérilisation des produits de santé - Irradiation - Partie 3: Directives relatives aux aspects dosimétriques de développement, la validation et le contrôle de routine (ISO/DIS 11137-3:2015)

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11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

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Sterilization of health care products — Radiation —

Part 3:
Guidance on dosimetric aspects of development, validation and routine control

Stérilisation des produits de santé — Irradiation —

Partie 3: Directives relatives aux aspects dosimétriques de développement, la validation et le contrôle de routine

ICS: 11.080.01

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO 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 received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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 11137-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*,.

This second edition cancels and replaces the first edition and has been extensively revised.

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

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

— *Part 2: Part 2: Establishing the sterilization dose*

— *Part 3: Guidance on dosimetric aspects of development, validation and routine control*

Introduction

An integral part of radiation sterilization is the ability to measure dose. Dose is measured during all stages of development, validation and routine monitoring of the sterilization process. It has to be demonstrated that dose measurement is traceable to a national or International Standard, that the uncertainty of measurement is known, and that the influence of temperature, humidity and other environmental considerations on dosimeter response is known and taken into account. Process parameters are established and applied based on dose measurements. This part of ISO 11137 provides guidance on the use of dose measurements (dosimetry) during all stages in the development, validation and routine control of the radiation sterilization process.

Requirements in regard to dosimetry are given in ISO 11137 parts 1 and 2 and ISO TS 13004. This part of ISO 11137 gives guidance to these requirements. The guidance given is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being suitable means for complying with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of ISO 11137-1 and ISO 11137-2.

Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control

1 Scope

This part of ISO 11137 gives guidance on meeting the requirements in ISO 11137 parts 1 and 2 and in ISO TS 13004 relating to dosimetry and its use in development, validation and routine control of a radiation sterilization process.

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.

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

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11137-1, ISO 11137-2 and the following apply.

3.1 Definitions

3.1.1
combined standard measurement uncertainty
standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model. (VIM 2012)

3.1.2
coverage factor
number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

NOTE A coverage factor is usually symbolized k (see also GUM:1995, 2.3.6).

3.1.3
dose uniformity ratio
ratio of the maximum to the minimum absorbed dose within the irradiation container

3.1.4
dosimetry system
interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards and procedures for their use [ISO/TS 11139:2006]

3.1.5
expanded measurement uncertainty
product of a combined standard measurement uncertainty and a factor larger than one

NOTE 1 The factor depends upon the type of probability distribution of the output quantity in a measurement model and on the selected coverage probability.

NOTE 2 The term “factor” in this definition refers to a coverage factor.

3.1.6
scan length
dimension of the irradiation zone, perpendicular to the scan width and direction of the electron beam at a specified distance from the accelerator window.

NOTE ASTM standards use "beam length" to mean the same thing that "scan length" means in this document. This document uses "scan length" for consistency with ISO 11137-1.

3.1.7
scan width
dimension of the irradiation zone in the direction that the beam is scanned, perpendicular to the beam length and direction of the electron beam at a specified distance from the accelerator window

NOTE ASTM standards use "beam width" to mean the same thing that "scan width" means in this document. This document uses "scan width" for consistency with ISO 11137-1.

3.1.8
simulated product
material with attenuation and scattering properties similar to those of the product, material or substance to be irradiated

NOTE 1 Simulated product is used as a substitute for the actual product, material or substance to be irradiated. When used in routine production runs in order to compensate for the absence of product, simulated product is sometimes referred to as compensating dummy. When used for absorbed dose mapping, simulated product is sometimes referred to as phantom material.

NOTE 2 In this standard “dose mapping” is used for “absorbed dose mapping”

3.1.9
spatial resolution
resolution in two dimensions

NOTE Ability to detect change in dose in two dimensions

3.1.10
standard measurement uncertainty
uncertainty of the result of a measurement expressed as a standard deviation (VIM 2012)

3.1.11
uncertainty budget
statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination

NOTE An uncertainty budget should include the measurement model, estimates, and measurement uncertainties associated with the quantities in the measurement model, covariances, type of applied probability density functions, degrees of freedom, type of evaluation of measurement uncertainty, and any coverage factor.

3.2 Terms

3.2.1 Dose specification(s)

3.2.1.1
$D_{max,acc}$
maximum acceptable dose determined in accordance with ISO 11137-1, section 8.1

3.2.1.2
D_{ster}
sterilization dose determined in accordance with ISO 11137-1, section 8.2

3.2.2 Doses

3.2.2.1
D_{max}
measured maximum dose in a given irradiation container

3.2.2.2
D_{min}
measured minimum dose in a given irradiation container

3.2.2.3
D_{mon}
measured dose at the routine monitoring position

3.2.3 Dose mapping ratios and their associated uncertainties

3.2.3.1
$R_{max/min}$
ratio of maximum to minimum dose (D_{max}/D_{min}) determined by dose mapping

3.2.3.2
$R_{max/mon}$
ratio of maximum to monitor dose (D_{max}/D_{mon}) determined by dose mapping

3.2.3.3
$R_{min/mon}$
ratio of minimum to monitor dose (D_{min}/D_{mon}) determined by dose mapping

3.2.4 Doses at monitoring positions that correlate to dose specifications

3.2.4.1
$D_{mon}^{ster} = D_{ster}/R_{min/mon}$
dose value at the monitoring location that directly correlates, by means of the ratio $R_{min/mon}$, with D_{ster} in product

3.2.4.2
$D_{mon}^{max,acc} = D_{max,acc}/R_{max/mon}$
dose value at the monitoring location that directly correlates, by means of the ratio $R_{max/mon}$, with $D_{max,acc}$ in product

3.2.5 Dose targets

3.2.5.1
D_{target}^{lower}
calculated dose at the routine monitoring position used for establishing process control parameters that ensure D_{ster} is exceeded during routine processing.

3.2.5.2
D_{target}^{upper}
calculated dose at the routine monitoring position used for establishing process control parameters that ensure $D_{max,acc}$ is not exceeded during routine processing.

3.2.6 Uncertainty

3.2.6.1
σ_{total}
calculated term that appropriately accounts for all potentially significant sources of measurement uncertainty

3.2.6.2
σ_{cal}
component of uncertainty associated with dosimetry system calibration

3.2.6.3
σ_{map}
component of uncertainty associated with dose mapping

3.2.6.4
σ_{mach}
component of uncertainty associated with machine variability

3.2.6.5
σ_{rep}
component of uncertainty associated with dose monitor measurement reproducibility

4 Measurement of Dose

4.1 All aspects of the dosimetry system(s) used have to comply with the relevant requirements of ISO 10012-1 or ISO 13485, which are normative references in ISO 11137-1.The dosimetry system(s) need to be included in a formal measurement management system, as defined in ISO 10012-1, which sets out quality procedures to achieve metrological confirmation and continual control of the measurement processes. An important aspect of this is the competence and training of staff involved, both in the calibration and operation of the dosimetry system(s), and also in the performance and analysis of dose measurements. Activities such as the choice of location of dosimeters for dose mapping and the analysis of the resultant data require specific skills and training. Examples of general requirements for dosimetry in radiation processing are given in ISO/ASTM 52628 and further guidance on dose mapping can be found in ISO/ASTM 52303.

4.2 Measurement of absorbed dose in connection with the radiation sterilization of medical devices is expressed in terms of absorbed dose to water. Dosimetry systems should be calibrated in terms of absorbed dose to water.

NOTE In this part of ISO 11137, absorbed dose is referred to as dose.

4.3 With the completion of the calibration of the dosimetry system, establishment of measurement traceability, and the application of the total measurement uncertainty to set process target values, the result of a dosimeter measurement represents the best estimate of dose. Therefore, dose values from measured dosimeters should not be corrected by the associated measurement uncertainty when determining if irradiated product meets its dose specification.

5 Measurement of dose to product

5.1 Dosimetry system selection and calibration

5.1.1 General

Dosimetry systems used in the development, validation and routine control of a radiation sterilization process have to be capable of providing accurate and precise results over the entire dose range of interest and under the conditions of use.

5.1.2 Selection of dosimetry systems

5.1.2.1 Dose measurements are required in the development, validation and routine control of radiation sterilization; different dosimetry systems might be needed for these three different tasks. For example, in sterilization dose establishment, the range of doses required for a verification or an incremental dose experiment might be outside the calibrated range of the dosimetry system used for the measurement of sterilization dose and, in such circumstances, an alternative system would have to be employed.

5.1.2.2 Guidance on the selection of appropriate dosimetry systems used in the development, validation and routine control of radiation sterilization can be found in ISO/ASTM 52628. The properties of individual dosimetry systems are given in ICRU 80. Procedures for their use are given in the ISO/ASTM Practices listed in the Bibliography.

5.1.3 Calibration of dosimetry systems

5.1.3.1 Calibration of dosimetry systems for use in radiation sterilization is a significant activity. The response of most dosimeters is influenced by the conditions of irradiation and measurement (e.g. temperature, humidity, dose rate and interval of time between termination of irradiation and measurement). In addition, the effects of these conditions are often interrelated and they can vary from batch to batch of dosimeters, see ICRU 80 and ISO/ASTM 52701 for further details. Therefore, calibration should be carried out under conditions that match as closely as possible the actual conditions of use. This means that calibrations or calibration verifications might be needed for each irradiator pathway. It is inappropriate to apply the calibration curve supplied by the dosimeter manufacturer without verification of its validity. However, the supplier's curve might provide useful information about the expected response of the dosimetry system. Where practicable, the calibration should be based on irradiations carried out in the irradiator of intended use, rather than derived from irradiations carried out at a different irradiator.

5.1.3.2 In order to ensure traceability of dose measurements, calibration irradiations and reference standard dosimeters used as part of a calibration need to be supplied by a national metrology institute recognized by the International Committee for Weights and Measures (CIPM) or other calibration laboratory accredited to ISO/IEC 17025. A calibration certificate provided by a laboratory not having formal recognition or accreditation might not necessarily be proof of traceability to a national or International Standard and additional documentary evidence will be required.

5.1.3.3 The ability to make accurate dose measurements depends on the calibration and consistency of performance of the entire dosimetry system. This means that all of the equipment associated with the measurement procedure, not just the dosimeters, is controlled and calibrated or, if equipment cannot be calibrated, its perforance should be verified.

5.1.3.4 It is important that the validity of the calibration is maintained throughout the period of use of the calibration results. This might entail performing verification of the calibration using a reference dosimetry system (see ISO/ASTM 52628) at regular intervals and also when a significant change in irradiation conditions has occurred, for example following a source replenishment. Seasonal variations in temperature and humidity can potentially affect dosimeter response, and verification of the calibration at different times of the year might be necessary.

5.1.3.5 The response of some types of dosimeters is known to be influenced by the period of time between termination of irradiation and measurement; the magnitude of this effect can depend on storage