SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 11137-4:2023

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Sterilizacija izdelkov za zdravstveno oskrbo - Sevanje - 4. del: Navodila za nadzor procesov (ISO/TS 11137-4:2020)

Sterilization of health care products - Radiation - Part 4: Guidance on process control (ISO/TS 11137-4:2020)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 4: Leitfaden zur Verfahrenssteuerung (ISO/TS 11137-4:2020)

Stérilisation des produits de santé - Irradiation - Partie 4: Recommandations sur le contrôle de processus (ISO/TS 11137-4:2020)

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11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

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CEN ISO/TS 11137-4

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English Version

Sterilization of health care products - Radiation - Part 4: Guidance on process control (ISO/TS 11137-4:2020)

Stérilisation des produits de santé - Irradiation - Partie 4: Recommandations sur le contrôle de processus (ISO/TS 11137-4:2020)

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This Technical Specification (CEN/TS) was approved by CEN on 28 May 2023 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

The text of ISO/TS 11137-4:2020 has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TS 11137-4:2023 by Technical Committee CEN/TC 204 "Sterilization of medical devices" the secretariat of which is held by BSI.

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Endorsement notice

The text of ISO/TS 11137-4:2020 has been approved by CEN as CEN ISO/TS 11137-4:2023 without any modification.

TECHNICAL SPECIFICATION

ISO/TS 11137-4

First edition
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Sterilization of health care products — Radiation —

Part 4: Guidance on process control

Stérilisation des produits de santé — Irradiation —

Partie 4: Recommandations sur le contrôle de processus

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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).

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

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.

Introduction

ISO 11137-1 describes the requirements for the development, validation and routine control of a radiation sterilization process, and ISO 11137-3 gives guidance on dosimetric requirements in all stages of this development, validation and control. The purpose of ISO/TS 11137-4 is to provide additional guidance on the establishment and control of the irradiation process, including setting process target doses and verifying that the process is in a state of control.

This document addresses the establishment of methods to set process target doses and verify the process is in a state of control. Dosimetry is used during the validation of a radiation sterilization process to measure doses, and the interpretation of dosimetry results from operational and performance qualification studies is critical in establishing a process that will meet the requirements specified for minimum and maximum dose as outlined in ISO 11137-1, ISO 11137-2 and ISO/TS 13004.

Routine dosimetry is used to monitor that the process is in a state of control and dose specifications have been met. One purpose of this technical specification is to provide guidance on the application of a dose measurement as a tool used for monitoring an irradiation process using statistical techniques.

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 achieving conformity with the minimum and maximum dose specifications. Methods other than those given in the guidance may be used, if they are effective in achieving conformity with the requirements of ISO 11137-1, ISO 11137-2 and ISO/TS 13004.

Sterilization of health care products — Radiation —

Part 4: Guidance on process control

1 Scope

This document provides additional guidance to that given in ISO 11137-3 on meeting the requirements specified in ISO 11137-1, ISO 11137-2 and ISO/TS 13004 for the establishment and control of a radiation sterilization process using gamma, electron beam, and X-irradiation.

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 11137-1:2006, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-3:2017, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control*

3 Terms, definitions and symbols

For the purposes of this document, the terms and definitions given in ISO 11137-1, ISO 11137-3 and the following apply.

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

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1 General

3.1.1
acceptance range
range within which the statistic under consideration lies with a specified probability when the process is in a state of control

3.1.2
action level
value from monitoring that necessitates immediate intervention

[SOURCE: ISO 11139:2018, 3.5]

3.1.3
alert level
value from monitoring providing early warning of deviation from specified conditions

Note 1 to entry: An alert level value provides early warning of a potential deviation for a process under control. Although further action is not required, increased supervision of the process is recommended.

[SOURCE: ISO 11139:2018, 3.11, modified — Note 1 to entry has been added.]

3.1.4
cycle time
period of time an irradiation container spends in each dwell position in a gamma process, used as a control parameter for dose

Note 1 to entry: Cycle time can also apply to x-ray and could also include the time required to move between dwell positions.

[SOURCE: ISO 11139:2018, 3.73, modified — Note 1 to entry has been added.]

3.1.5
influence quantity
quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result

Note 1 to entry: In radiation processing dosimetry, this term includes temperature, relative humidity, time intervals, light, radiation energy, absorbed-dose rate, and other factors that might affect dosimeter response, as well as quantities associated with the measurement instrument.

[SOURCE: VIM 2012, 2.52, modified — Note 1 to entry added from ISO/ASTM 52701:2013.]

3.1.6
measurement uncertainty
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

3.1.7
process control
specific activities to ensure process requirements are achieved

[SOURCE: ISO 11139:2018, 3.209]

3.1.8
process load
volume of material with a specified product loading configuration irradiated as a single entity

Note 1 to entry: The process load consists of one or more irradiation containers.

[SOURCE: ISO/ASTM 52303:2015, 3.1.10]

3.1.9
process target dose
D_{target}
dose, at a specified monitoring location, which the irradiation process parameters are set to deliver

3.1.10
process variability
measure of factors that result in a random distribution of data around the average that provides information on how well the process can perform when all special cause variation is removed

3.1.11
Statistical Process Control
SPC
set of techniques for improving the quality of process output by reducing variability through the use of one or more control charts and a corrective action strategy used to bring the process back into a state of statistical control

[SOURCE: ASTM E2587-16]

3.1.12
targeting buffer
standard factor or factors used to determine process target doses which has been demonstrated to be more conservative calculated values of UF_{lower} and UF_{upper} during historical routine processing

3.2 Symbols

Symbol	Meaning
D_{min}	direct measurement of minimum dose in a given irradiation container
D_{max}	direct measurement of maximum dose in a given irradiation container
D_{mon}	direct measurement of dose at the routine monitoring position
D_{ster}	Sterilization dose determined in accordance with ISO 11137-1:2006, 8.2
$D_{max,acc}$	maximum acceptable dose determined in accordance with ISO 11137-1:2006, 8.1
$D_{min}^{limit} = D_{ster} * UF_{lower}$	calculated dose at the minimum dose position used for establishing process parameters that ensures at a specified level of confidence that D_{ster} is met or exceeded during routine processing
$D_{max}^{limit} = D_{max,acc} * UF_{upper}$	calculated dose at the maximum dose position used for establishing process parameters that ensures at a specified level of confidence that $D_{max,acc}$ is not exceeded during routine processing
$UF_{lower} = 1/(1 - k * \sigma_{process}^{min}/100)$	process factor used to calculate D_{target}^{lower} and D_{min}^{limit} (where $\sigma_{process}^{min}$ is expressed as a percentage)
$UF_{upper} = 1/(1 + k * \sigma_{process}^{max}/100)$	process factor used to calculate D_{target}^{upper} and D_{max}^{limit} (where $\sigma_{process}^{max}$ is expressed as a percentage)
$R_{min/mon} = D_{min} / D_{mon}$	ratio of minimum to monitor dose determined by dose mapping
$R_{max/mon} = D_{max} / D_{mon}$	ratio of maximum to monitor dose determined by dose mapping
$D_{mon}^{ster} = D_{ster}/R_{min/mon}$	dose at the monitoring position that correlates to the sterilization dose specification
$D_{mon}^{max,acc} = D_{max,acc}/R_{max/mon}$	dose at the monitoring position that correlates to maximum acceptable dose specification
$D_{target}^{lower} = D_{min}^{limit} / R_{min/mon}$	calculated dose at the routine monitoring position used for establishing process parameters that ensures at a specified level of confidence that D_{ster} is met or exceeded during routine processing
$D_{target}^{upper} = D_{max}^{limit} / R_{max/mon}$	calculated dose at the routine monitoring position used for establishing process parameters that ensures at a specified level of confidence that $D_{max,acc}$ is not exceeded during routine processing
σ_{cal}	component of uncertainty related to the calibration of the dosimetry system including the uncertainty reported by the calibration laboratory, uncertainty in the mathematical fit of the calibration function, and uncertainties due to influence quantities, but excluding components due to the reproducibility of the dosimeter measurement (see σ_{rep})
σ_{mach}	component of variability related to the radiation source and conveyor system
σ_{map}	component of variability measured during a dose mapping exercise
$\sigma_{process}$	standard deviation associated with the irradiation process used for setting process target doses $\sigma_{process}^{max}$ — The standard deviation associated with the process maximum dose $\sigma_{process}^{min}$ — The standard deviation associated with the process minimum dose
σ_{rep}	component of variability associated with the reproducibility of the dosimeter measurement