
**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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Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms, definitions and symbols	1
3.1 General	1
3.2 Symbols	3
4 Principles applied in validating and controlling an irradiation process	4
4.1 General	4
4.2 Use of the dose measurement at the monitoring location	4
4.2.1 General	4
4.2.2 D_{mon} as an indirect measurement of dose to product	4
4.2.3 D_{mon} as a process monitor	4
4.2.4 D_{min} or D_{max} as a direct measurement of dose to product	5
4.3 Monitoring of critical process parameters	5
5 Establishing process target doses	6
5.1 Inputs and steps in establishing a process target dose	6
5.1.1 General	6
5.1.2 Process validation inputs (installation, operational and performance qualification)	7
5.1.3 Additional inputs	7
5.1.4 Determine σ_{process}	7
5.1.5 Product dose specifications	8
5.1.6 Select coverage factor k	8
5.1.7 Setting process target doses	8
5.1.8 Analyse process output	8
5.1.9 Review	8
5.2 Performance qualification outputs	8
5.2.1 General	8
5.2.2 Experimental design for PQ	9
5.2.3 Processing categories	9
5.3 Components of σ_{process}	10
5.3.1 General	10
5.3.2 Components related to measurement uncertainty	11
5.3.3 Components related to process variability	12
5.3.4 Combining components of uncertainty	13
5.3.5 Reducing σ_{process}	13
5.4 Establishing process target doses	16
5.4.1 Coverage factors	16
5.4.2 Process factors	17
5.4.3 Choice of target processing parameters	17
5.4.4 Assessing process capability	18
6 Routine monitoring and control	18
6.1 General	18
6.2 Product handling	19
6.2.1 Receipt of product	19
6.2.2 Loading	19
6.2.3 Unloading	19
6.2.4 Storage	20
6.2.5 Shipment	20
6.3 Processing of product	20
6.3.1 General	20

6.3.2	Processing parameters	20
6.3.3	Location of dosimeters	21
6.3.4	Partially filled containers	21
6.3.5	Process interruptions	21
6.3.6	Transitions between densities	22
6.4	Special processing conditions	22
6.4.1	Off-carrier processing	22
6.4.2	Irradiation of product under modified environmental conditions	22
6.5	Process output interpretation	24
6.5.1	General	24
6.5.2	Using an acceptance range based on $D_{\text{mon}}^{\text{ster}}$ and $D_{\text{mon}}^{\text{max,acc}}$	24
6.5.3	Using an acceptance range with alert and action levels	24
6.5.4	Using an acceptance range based on process monitoring	25
6.5.5	Investigation of a dose measurement outside of expectation	26
6.6	Collection and analysis of data	27
6.6.1	General	27
6.6.2	Dosimeter data trending	27
6.6.3	Parametric data trending	28
6.6.4	Statistical process control	29
7	Release of product from the irradiation process	30
8	Maintaining process effectiveness	31
8.1	General	31
8.2	Assessment of changes made to the product	31
8.3	Assessment of changes made to the equipment	31
Annex A (informative)	Examples of setting process target dose ranges and interpretation of process output	32
Bibliography		55

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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*.

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.

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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.