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Sterilization of health care products — Radiation

Part 4: Guidance on process control

bsi.

National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

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European foreword

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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.

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Foreword

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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*.

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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.

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