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Australian/New Zealand Standard™

Sterilization of health care products—Radiation

Part 3: Guidance on dosimetric aspects

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-023, Processing of Medical and Surgical Instruments. It was approved on behalf of the Council of Standards Australia on 17 October 2006 and on behalf of the Council of Standards New Zealand on 17 November 2006.
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The following are represented on Committee HE-023:

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Australian Dental Association
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Australian General Practice Accreditation
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Detailed information about joint Australian/New Zealand Standards can be found by visiting the Standards Web Shop at www.standards.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR 06399.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

RECONFIRMATION

OF

AS/NZS ISO 11137.3:2006
Sterilization of health care products—Radiation
Part 3: Guidance on dosimetric aspects

RECONFIRMATION NOTICE

Technical Committee HE-023 has reviewed the content of this publication and in accordance with Standards Australia procedures for reconfirmation, it has been determined that the publication is still valid and does not require change.

Certain documents referenced in the publication may have been amended since the original date of publication. Users are advised to ensure that they are using the latest versions of such documents as appropriate, unless advised otherwise in this Reconfirmation Notice.

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NOTES

Australian/New Zealand Standard™

Sterilization of health care products—Radiation

Part 3: Guidance on dosimetric aspects

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments, to supersede (in part) AS ISO 11137:2002, *Sterilization of health care products—Requirements for validation and routine control—Radiation Sterilization.*

This Standard has been developed to assist in the process of implementation of the Australian Medical Device Legislation.

This Standard is identical with, and has been reproduced from IISO 11137-3:2006SO 11137-3:2006, *Sterilization of health care products—Radiation* —Part 3: *Guidance on dosimetric aspects.*

The objective of this Standard is to specify the dosimetric procedures related to the development, validation and routine control of a radiation sterilization process.

There are three parts in the series for AS/NZS 11137, *Sterilization of health care products—Radiation* as follows:

Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
Part 2: Establishing the sterilization dose
Part 3: Guidance on dosimetric aspects

As this Standard is reproduced from an international standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text ‘this part of ISO 11137’ should read ‘this Australian/New Zealand Standard’

(c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard ISO		*Australian or Australian/New Zealand Standard* AS/NZS ISO	
11137	Sterilization of health care products—Radiation	11137	Sterilization of health care products—Radiation
11137-1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	11137.1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
11137-2	Part 2: Establishing the sterilization dose	11137.2	Part 2: Establishing the sterilization dose
		AS ISO	
13485	Medical devices—Quality management systems—Requirements for regulatory purposes	13485	Medical devices—Quality management systems—Requirements for regulatory purposes

Only international references that have been adopted as Australian or Australian/New Zealand Standards have been listed.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

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CONTENTS

Page

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 application of dose measurements (dosimetry) during all stages of the sterilization process.

ISO 11137-1 describes requirements that, if met, will provide a radiation sterilization process, intended to sterilize medical devices, which has appropriate microbicidal activity. Furthermore, compliance with the requirements helps ensure 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.

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 recognize that, for certain processes used in manufacturing or reprocessing, 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 monitored routinely and the equipment maintained.

Requirements in regard to dosimetry are given in ISO 11137-1 and ISO 11137-2. 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.

AUSTRALIAN/NEW ZEALAND STANDARD

Sterilization of health care products — Radiation —

Part 3:
Guidance on dosimetric aspects

1 Scope

This part of ISO 11137 gives guidance on the requirements in ISO 11137 parts 1 and 2 relating to dosimetry. Dosimetry procedures related to the development, validation and routine control of a radiation sterilization process are described.

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 11137-2:2006, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

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
dosimetry system
interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards and procedures for their use

[ISO/TS 11139:2005]

4 Measurement of dose

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