AS/NZS ISO 11137.1:2006
ISO 11137-1:2006
Reconfirmed 2017

Australian/New Zealand Standard™

Sterilization of health care products—Radiation

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

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.
This Standard was published on 19 December 2006.

The following are represented on Committee HE-023:

Australian Association of Practice Managers
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Dental Association
Australian Dental Industry Association
Australian General Practice Accreditation
Australian Infection Control Association
Australian Nursing Federation
Bio Innovation SA
Commonwealth Dept of Health and Ageing
Dental Assistants Association of Australia
Department of Health, South Australia
Department of Human Services, Victoria
Federation of Sterilization Research and Advisory Councils of Australia
Gastroenterological Nurses Organization
Medical Industry Association of Australia
Ministry of Health, New Zealand
New Zealand Nurses Organization
New Zealand Sterile Services Association
N.S.W Health Department
Queensland Health
Royal Australian College of General Practitioners
Rural Doctors Association of Australia

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued. Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments which may have been published since the Standard was purchased.

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.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

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 06397.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

RECONFIRMATION

OF

AS/NZS 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

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.

Approved for reconfirmation in accordance with Standards Australia procedures for reconfirmation on 06 December 2016.

Approved for reconfirmation in New Zealand on behalf of the Standards Council of New Zealand on 10 August 2017.

The following are represented on Technical Committee HE-023:

Australasian College for Infection Prevention and Control
Australian Chamber of Commerce and Industry
Australian College of Perioperative Nurses
Australian Dental Association
Australian Dental Industry Association
Australian Industry Group
Australian Institute of Packaging
Australian Nursing and Midwifery Federation
Day Hospitals Australia
Department of Health (WA)
Department of Health and Human Services (VIC)
Federal Sterilizing Research and Advisory Council of Australia
Gastroenterological Nurses College of Australia
Institute of Hospital Engineering Australia
Medical Technology Association of Australia
New Zealand Nurses Organisation
New Zealand Sterile Services Association
NSW Health
Queensland Health
Royal Australian College of General Practitioners
Royal College of Pathologists of Australasia
SA Health
Therapeutic Goods Administration

NOTES

Australian/New Zealand Standard™

Sterilization of health care products—Radiation

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

Originated as part of AS ISO 11137—2002.
Jointly revised in part and redesignated as AS/NZS ISO 11137.1:2006.

Jointly published by Standards Australia, GPO Box 476, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 7917 4

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 fromISO 11137-1:2006, ISO 11137-1:2006ISO 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.*

The objective of this Standard is to specify requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

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
11137-2	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.

CONTENTS

Page

INTRODUCTION

A sterile medical device is one that is free of viable microorganisms. International Standards, which specify requirements for validation and routine control of sterilization processes, require, when it is necessary to supply a sterile medical device, that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such medical devices are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile medical devices into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent; inevitably this means that there is always a finite probability that a microorganism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one medical device in a population subjected to sterilization processing cannot be guaranteed and the sterility of a processed population is defined in terms of the probability of there being a viable microorganism present on a medical device.

This part of ISO 11137 describes requirements that, if met, will provide a radiation sterilization process intended to sterilize medical devices, that has appropriate microbicidal activity. Furthermore, compliance with the requirements ensures 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. Specification of this probability is a matter for regulatory authorities and may vary from country to country (see, for example, EN 556-1 and ANSI/AAMI ST67).

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 recognise that, for certain processes used in manufacturing, 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 is monitored routinely and the equipment is maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the products are sterile and, in this regard, suitable for its intended use. Attention is therefore given to a number of considerations including:

a) the microbiological status of incoming raw materials and/or components;

b) the validation and routine control of any cleaning and disinfection procedures used on the product;

c) the control of the environment in which the product is manufactured, assembled and packaged;

d) the control of equipment and processes;

e) the control of personnel and their hygiene;

f) the manner and materials in which the product is packaged;

g) the conditions under which product is stored.

This part of ISO 11137 describes the requirements for ensuring that the activities associated with the process of radiation sterilization are performed properly. These activities are described in documented work programmes designed to demonstrate that the radiation process will consistently yield sterile products on treatment with doses falling within the predetermined limits.

The requirements are the normative parts of this part of ISO 11137 with which compliance is claimed. The guidance given in the informative annexes is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being a 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 this part of ISO 11137.

The development, validation and routine control of a sterilization process comprise a number of discrete but interrelated activities; e.g. calibration, maintenance, product definition, process definition, installation qualification, operational qualification and performance qualification. While the activities required by this part of ISO 11137 have been grouped together and are presented in a particular order, this part of ISO 11137 does not require that the activities be performed in the order that they are presented. The activities required are not necessarily sequential, as the programme of development and validation may be iterative. It is possible that performing these different activities will involve a number of separate individuals and/or organizations, each of whom undertake one or more of these activities. This part of ISO 11137 does not specify the particular individuals or organizations to carry out the activities.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Sterilization of health care products — Radiation —

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

1 Scope

1.1 This part of ISO 11137 specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

NOTE Although the scope of this part of ISO 11137 is limited to medical devices, it specifies requirements and provides guidance that may be applicable to other products and equipment.

This part of ISO 11137 covers radiation processes employing irradiators using,

a) the radionuclide ^{60}Co or ^{137}Cs,

b) a beam from an electron generator

or

c) a beam from an X-ray generator.

1.2 This part of ISO 11137 does not specify requirements for development, validation and routine control of a process for inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

NOTE See, for example, ISO 22442-1, ISO 22442-2 and ISO 22442-3.

1.2.1 This part of ISO 11137 does not detail specified requirements for designating a medical device as sterile.

NOTE Attention is drawn to regional and national requirements for designating medical devices as “sterile.” See, for example, EN 556-1 or ANSI/AAMI ST67.

1.2.2 This part of ISO 11137 does not specify a quality management system for the control of all stages of production of medical devices.

NOTE It is not a requirement of this part of ISO 11137 to have a complete quality management system during manufacture, but the elements of a quality management system that are the minimum necessary to control the sterilization process are normatively referenced at appropriate places in the text (see, in particular, Clause 4). Attention is drawn to the standards for quality management systems (see ISO 13485) that control all stages of production of medical devices, including the sterilization process. Regional and national regulations for the provision of medical devices might require implementation of a complete quality management system and the assessment of that system by a third party.

1.2.3 This part of ISO 11137 does not require that biological indicators be used for validation or monitoring of radiation sterilization, nor does it require that a pharmacopoeial test for sterility be carried out for product release.