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ISO 11137:1995

Australian Standard™

Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization

Standards Australia

This Australian Standard was prepared by Committee HE-023, Processing of medical and surgical instruments. It was approved on behalf of the Council of Standards Australia on 26 June 2002 and published on 28 June 2002.

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PREFACE

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

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian, rather than an Australian/New Zealand Standard, through the Joint Standards Australia/Standards New Zealand Committee HE-023 on Processing of medical and surgical instruments.

This Standard is identical with and has been reproduced from ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization.*

The objective of this Standard is to specify requirements for validation, process control and routine monitoring in the radiation sterilization of health care products.

At the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems — Requirements,* but will remain available as superseded standards until December 2003. The use of the superseded standards beyond that date is endorsed for applications covered by the Australian Medical Device legislation.

This Standard provides for the use of the following Australian/New Zealand Standards as equivalents to the ISO Standards referenced herein:

Reference to International Standard or other publication		*Equivalent Australian/New Zealand Standard*
ISO		AS/NZS ISO
9001	Quality management systems — Requirements	Quality management systems — Requirements

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 International Standard’ should read ‘this Australian Standard’.

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CONTENTS

1 Scope **1**

2 Normative references **1**

3 Definitions **1**

4 Documentation **4**

5 Personnel **4**

6 Sterilization process validation **4**

6.1 General **4**

6.2 Product qualification **5**

6.2.1 Product and packaging materials evaluation **5**

6.2.2 Sterilization dose selection **5**

6.2.3 Transfer of sterilization dose **6**

6.3 Installation qualification **6**

6.3.1 Equipment documentation **6**

6.3.2 Equipment testing **7**

6.3.3 Equipment calibration **7**

6.3.4 Irradiator dose mapping **7**

6.4 Process qualification **7**

6.4.1 Determination of product loading pattern **7**

6.4.2 Product dose mapping **8**

6.5 Certification **8**

6.6 Maintenance of validation **8**

6.6.1 Calibration programme **8**

6.6.2 Irradiator requalification **8**

6.6.3 Sterilization dose auditing **8**

7 Routine process control **8**

CONTENTS

7.1 Process specification **8**

7.2 Product handling **9**

7.2.1 Product shipment and receipt **9**

7.2.2 Pre- and post-irradiation product storage **9**

7.3 Routine and preventive maintenance **9**

7.4 Product irradiation **9**

7.4.1 Process control **9**

7.4.2 Process interruption **9**

7.4.3 Dose monitoring **9**

7.5 Process documentation **10**

7.6 Sterilization acceptance **10**

8 Management and control **11**

Annexes

A Device and packaging materials qualification **12**

B Dose setting methods for radiation sterilization **17**

C Dosimeters, dosimetry and associated equipment **46**

D Bibliography **59**

INTRODUCTION

This International Standard describes the requirements for ensuring that the activities associated with the process of radiation sterilization are performed properly. These activities comprise documented work programmes designed to demonstrate that the radiation process, operating within specified limits, will consistently yield products treated with doses that fall between predetermined limits.

The radiation process is a physical one, involving the exposure of a product to ionizing radiation. The product is exposed in specially designed equipment to gamma rays from cobalt 60 (60 Co) radionuclides or cesium 137 (137 Cs) radionuclides, or to an electron or x-ray beam from an electron beam generator. When properly applied, radiation sterilization is a safe and reliable industrial process.

Sterilization is an example of a process for which efficacy cannot be verified by retrospective inspection and testing of the product. It is important to be aware that exposure to a validated and accurately controlled sterilization process is not the only factor associated with ensuring that the product is sterile and suitable for its intended use. Attention has to be given to the microbiological status of raw materials and/or components, the microbiological barrier properties of the packaging, and to the control of the environment in which the product is manufactured, assembled, packaged and stored.

A sterile product is one that is free of viable microorganisms. Items produced under controlled manufacturing conditions can, prior to sterilization, have microorganisms on them, although ordinarily in low numbers. Such products are, by definition, non-sterile. The purpose of sterilization processing is to destroy the microbiological contaminants on these non-sterile products. The destruction of microorganisms by physical and chemical agents follows an exponential law. Accordingly, one can calculate a finite probability of a surviving microorganism regardless of the magnitude of the delivered sterilization dose or treatment. The probability of survival is a function of the number and types (species) of microorganisms present on the product (bioburden), the sterilization process lethality, and, in some instances, the environment in which the organisms exist during treatment. It follows that the sterility of individual items in a population of products sterilized cannot be ensured in the absolute sense. A sterility assurance level (SAL) is derived mathematically and it defines the probability of a viable microorganism on an individual product unit.

The primary manufacturer has ultimate responsability for ensuring that all sterilization operations and quality assurance checks used for the product are appropriate, adequate and correctly performed. However, the irradiator operator is responsible for delivering the required dose within the validated process specifications.

NOTES

AUSTRALIAN STANDARD

Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization

1 Scope

This International Standard specifies requirements for validation, process control and routine monitoring in the radiation sterilization of health care products. It applies to continuous and batch type gamma irradiators using the radionuclides 60 Co and 137 Cs, and to irradiators using a beam from an electron or x-ray generator.

Annexes are also included to provide supplementary information.

Facility design, licensing, operator training and factors related to radiation safety are outside the scope of this International Standard. It does not cover the assessment of the suitability of the product for its intended use. The use of biological indicators for validation or process monitoring, or the use of sterility testing for product release, are also not covered, as they are not recommended practices for radiation sterilization.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

ISO 9002:1994, *Quality systems — Model for quality assurance in production, installation and servicing.*

ISO 11737-1:—[1], *Sterilization of medical devices — Microbiological methods — Part 1: Estimation of population of microorganisms on products.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 "Health care product" and related terms

3.1.1 batch: Defined quantity of bulk, intermediate or finished product that is intended or purported to be uniform in character and quality, and which has been produced during a defined cycle of manufacture.

3.1.2 health care product: Term encompassing medical devices, medicinal products (pharmaceuticals and biologics) and *in vitro* diagnostics.

3.1.3 primary manufacturer: Company or body responsible for the fabrication, performance and safety of a health care product.

1) To be published.