AS ISO 11134—2003
ISO 11134:1994

Australian Standard™

Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization

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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 28 May 2003 and published on 30 June 2003.

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/ Standards New Zealand Committee HE-023, Processing of Medical and Surgical Instruments. 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.

This Standard is identical with and has been reproduced from ISO 11134:1994, *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization.*

The objective of this Standard is to specify requirements for the use of moist heat in sterilization process development, validation of the sterilization process and control of routine sterilization. This Standard covers all moist heat processes, including saturated steam and air-steam mixtures, and applies to all industrial manufacturers and all others who perform contract moist heat sterilization. Although moist heat sterilization in non-industrial health care facilities is not specifically covered in this Standard, the principles outlined may be useful to the user of moist heat sterilization in these facilities.

The terms 'normative' and 'informative' are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

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'.

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

Users in Australia should be aware that, at the time of publication, the 1994 editions of AS/NZS ISO 9001, AS/NZS ISO 9002 and AS/NZS ISO 9003 have been superseded by AS/NZS ISO 9001:2000, *Quality management systems—Requirements*, but will remain available superseded standards until December 2003.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.

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INTRODUCTION

The manufacture of a safe and sterile health care product requires attention to product characteristics and to sterilization methods and controls. This International Standard provides the essential elements of good manufacturing practice for moist heat sterilization of health care products.

A sterile product is one that is free of viable microorganisms. Even items produced under controlled manufacturing conditions may, prior to sterilization, have microorganisms on them. 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, 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 guaranteed in the absolute sense. The probability of non-sterility of each individual product unit is derived mathematically. For example, with a probability of 10^{-6}, the likelihood of a non-sterile product unit is less than or equal to one in a million.

Requirements for the quality system for the design, development, production, supply, installation and servicing of health care products are given in the ISO 9000 series of Standards.

The ISO 9000 series of Standards designates certain processes used in the manufacture of health care products as "special" in that the result cannot be fully verified by subsequent inspection or testing of the product. Sterilization is an example of a special process because efficacy cannot be verified by inspection or testing of the product. For this reason, sterilization processes must be validated before use, the process routinely monitored and the equipment maintained.

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AUSTRALIAN STANDARD

Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization

1 Scope

This International Standard specifies requirements for the use of moist heat in sterilization process development, validation of the sterilization process and control of routine sterilization.

It covers all moist heat processes, including saturated steam and air-steam mixtures, and applies to all industrial manufacturers and all others who perform contract moist heat sterilization. Although moist heat sterilization in non-industrial health care facilities is not specifically covered in this International Standard, the principles outlined may be useful to the user of moist heat sterilization in these facilities.

NOTE 1 While the general requirements of this International Standard may apply to the sterilization of pharmaceuticals, other technical or regulatory requirements may also apply.

This International Standard does not cover the quality assurance system which is necessary to control all stages of manufacture, including the sterilization process.

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.

1) To be published.

ISO 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002:1987, *Quality systems — Model for quality assurance in production and installation.*

ISO 9003:1987, *Quality systems — Model for quality assurance in final inspection and test.*

ISO 11138-1:—[1], *Sterilization of health care products — Biological indicators — Part 1: General.*

IEC 1010-1:1990, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements.*

IEC 1010-2-041, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials and for laboratory purposes.*

3 Definitions

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

3.1 air-steam mixture: Uniform mixture of air and saturated steam used for sterilization.

NOTE 2 Air is used to compensate for pressures generated within sealed containers that exceed saturated steam pressures.

3.2 bioburden: Population of viable microorganisms on a raw material, component, a finished product and/or a package.

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