

AS/NZS ISO 14644.5:2006
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Reconfirmed 2016

Australian/New Zealand Standard™

Cleanrooms and associated controlled environments

Part 5: Operations



AS/NZS ISO 14644.5:2006

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee ME-060, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 12 December 2005 and on behalf of the Council of Standards New Zealand on 21 December 2005.

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The following are represented on Committee ME-060:

Airconditioning & Refrigeration Equipment Manufacturers Association of Australia
Auckland regional Chamber of Commerce
Australian Chamber of Commerce and Industry
Australian Institute of Refrigeration Air Conditioning and Heating (Inc)
Australian Pharmaceutical Manufacturers Association
Commonwealth Department of Health and Ageing
Ergonomics Society of Australia
Medical Industry Association of Australia Inc
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This Standard was issued in draft form for comment as DR 05305.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

RECONFIRMATION
OF
AS/NZS ISO 14644.5:2006
Cleanrooms and associated controlled environments
Part 5: Operations

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Technical Committee ME-060 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.

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National Association of Testing Authorities Australia
NSW Health
Society of Hospital Pharmacists of Australia
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NOTES

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee ME-060, Controlled Environment to supersede AS 1386.6—1989, *Cleanrooms and clean workstations*, Part 6: *Operations and inspection of cleanrooms*.

The objective of this Standard is to specify basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom.

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

- (a) Its number appears on the cover and title page while the international standard number appears only on the cover.
- (b) In the source text ‘this part of ISO 14644’ 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:

<i>Reference to International Standard*</i>	<i>Australian/New Zealand Standard</i>
ISO	AS/NZS ISO
14644 Cleanrooms and associated controlled environments	14644 Cleanrooms and associated controlled environments
14644-1 Part 1: Classification of air cleanliness	14644.1 Part 1: Classification of air cleanliness
14644-2 Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1	14644.2 Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000, MOD)
14644-4 Part 4: Design construction and start-up	14644.4 Part 4: Design construction and start-up

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.

* Only referenced international Standards that have been adopted as an Australian/New Zealand Standard have been listed.

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INTRODUCTION

Industries and organizations of all kinds utilize cleanrooms. Operational procedures have a profound effect on the cleanliness levels achieved during the operation of the cleanroom and equipment. Consistent quality is cleanliness dependent. Operational cleanliness can only be attained and maintained through a deliberate programme established to specify, measure and enforce defined operational procedures. Regulatory agencies that have authority over processes and products produced in the cleanroom may require additional procedures and measures of cleanliness not covered in this general operating standard.

This part of ISO 14644 addresses normative and informative operational requirements related to:

- a) providing a system that defines policies and operational procedures;
- b) clothing used to isolate human-generated contamination from the cleanroom environment;
- c) training of personnel inside the cleanroom and monitoring their compliance to specified procedures and disciplines;
- d) transfer, installation and maintenance of stationary equipment (selection criteria is not discussed);
- e) selection and use of materials and portable equipment in the cleanroom;
- f) maintaining the cleanliness of the cleanroom through systematic cleaning and monitoring procedures.

AUSTRALIAN/NEW ZEALAND STANDARD

Cleanroom and associated controlled environments**Part 5:
Operations****1 Scope**

This part of ISO 14644 specifies basic requirements for cleanroom operations. It is intended for those planning to use and operate a cleanroom. Aspects of safety that have no direct bearing on contamination control are not considered in this part of ISO 14644 and national and local safety regulations must be observed. This document considers all classes of cleanrooms used to produce all types of products. Therefore, it is broad in application and does not address specific requirements for individual industries. Methods and programmes for routine monitoring within cleanrooms are not covered in detail in this part of ISO 14644 but reference is made to ISO 14644-2 and ISO 14644-3 for monitoring particles and ISO 14698-1 and ISO 14698-2 for monitoring micro-organisms.

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 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 14644-2:2000, *Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1*

ISO 14644-3:—¹⁾, *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 14644-4:2001, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start-up*

ISO 14698-1:2003, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods*

ISO 14698-2:2003, *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data*

1) To be published.