

Australian/New Zealand Standard™

**Cleanrooms and associated controlled environments**

**Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)**



## **AS/NZS ISO 14644.7:2006**

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 9 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 Industry Group  
Australian Institute of Refrigeration Air Conditioning and Heating (Inc)  
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*This Standard was issued in draft form for comment as DR 05277.*

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

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**RECONFIRMATION**

**OF**

**AS/NZS ISO 14644.7:2006**

**Cleanrooms and associated controlled environments**

**Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)**

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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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## NOTES

# Australian/New Zealand Standard™

## **Cleanrooms and associated controlled environments**

### **Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)**

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## PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee ME-060, Controlled Environment.

The objective of this Standard is to specify the minimum requirements for the design, construction installation, test and approval of separative devices.

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 environment	14644 Cleanrooms and associated controlled environment
14644-1 Part 1: Classification of air cleanliness	14644.1 Part 1: Classification of air cleanliness
14644-2 Part 2: Specification for testing and monitoring to prove continued compliance with ISO 14644-1	14644.2 Part 2: Specification 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.

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

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## INTRODUCTION

In the spirit of the generic requirements of an International Standard, the term “separative devices” was developed by Technical Committee ISO/TC 209 to encompass the wide continuum of configurations from open unrestricted air overspill to wholly contained systems. Common terms-of-trade, such as clean air hoods, gloveboxes, isolators and mini-environments, have different meanings depending on the specific industry.

Difficulties experienced in the manufacture and handling of certain products or materials have driven the development of separative devices. These difficulties include product sensitivity to particles, chemicals, gases or microorganisms; operator sensitivity to the process materials or byproducts; and both product and operator sensitivity.

Separative devices provide assured protection in varying levels by utilising physical or dynamic barriers, or both, to create separation between operation and operator. Certain processes may require special atmospheres to prevent degradation or explosions. Some systems may be capable of providing 100 % recirculation of the contained atmosphere to allow inert gas operation or biodecontamination with reactive gases.

Usually people do not work directly inside the separative-device environment during production. These separative devices may be movable or fixed, and used for transport, transfer and process. The product or process, or both, are manipulated remotely with access devices either manually, with protection by barrier technology such as wall-integrated personal interface systems (e.g. gloves, gauntlets, half-suits), or mechanically with robotic handling systems.

Air cleanliness definitions and test methods covered in ISO 14644-1, 14644-2 and 14644-3 generally apply within separative devices. In applications with biological contamination requirements, ISO 14698-1 and 14698-2 will apply. However, some applications can have special requirements for monitoring because of extreme conditions that may be encountered. These unique conditions are covered in this part of ISO 14644.

Transfer devices to move material in and out of separative devices form an important portion of this part of ISO 14644. In addition, material can be moved from one fixed separative device to another in transport containers.

Design and construction of cleanrooms, including generic aspects of clean zones, are covered in ISO 14644-4. ISO 14644-4:2001, Figure A.4, illustrates aerodynamic measures or air overspill often used in industry-specific separative devices called clean air hoods and mini-environments. Mini-environments are often used in the electronics industry with transport containers, called boxes or pods, to provide very clean process conditions. The application of barrier technology used in industry-specific separative devices called isolators is shown in ISO 14644-4:2001, Figure A.5. Separative devices, often called gloveboxes, containment enclosures or isolators, are used in the medical products and nuclear industries to provide protection to the operator as well as the process. Isolators may be rigid- or soft-walled depending on the application. The Bibliography contains industry-specific references. However, from a unifying conceptual standpoint, a continuum of separation exists between the operation and the operator, ranging from totally open to totally enclosed systems depending on the application. Similarly, a continuum exists for containment.

The concept of separative devices is not limited to one specific industry, as many industries use these technologies for different requirements. In that light, this part of ISO 14644 provides a generic overview of the requirements involved.

AUSTRALIAN/NEW ZEALAND STANDARD

## Cleanrooms and associated controlled environments —

Part 7:

### Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)

#### 1 Scope

This part of ISO 14644 specifies the minimum requirements for the design, construction, installation, test and approval of separative devices, in those respects where they differ from cleanrooms as described in ISO 14644-4 and 14644-5.

The application of this part of ISO 14644 takes into account the following limitations.

- User requirements are as agreed by customer and supplier.
- Application-specific requirements are not addressed.
- Specific processes to be accommodated in the separative-device installation are not specified.
- Fire, safety and other regulatory matters are not considered specifically; where appropriate, national and local regulations apply.

This part of ISO 14644 is not applicable to full-suits.

#### 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 10648-2:1994, *Containment enclosures — Part 2: Classification according to leak tightness and associated checking methods*

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:—<sup>1)</sup>, *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*

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1) To be published.