

Australian Standard[®]

Controlled environments

**Part 6: Clean workstations—Design,
installation and use**



This Australian Standard® was prepared by Committee ME-060, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 6 October 2011. This Standard was published on 31 October 2011.

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- Airconditioning & Refrigeration Equipment Manufacturers Association of Australia
 - Auckland Regional Chambers of Commerce
 - Australian Chamber of Commerce and Industry
 - Australian Industry Group
 - Australian Institute of Refrigeration Air Conditioning and Heating
 - Australian Society for Microbiology
 - CSIRO Australian Animal Health Laboratory
 - Engineers Australia
 - Human Factors and Ergonomics Society of Australia
 - International Society for Pharmaceutical Engineering
 - Ministry of Agriculture and Forestry New Zealand
 - NSW Health Department
 - National Association of Testing Authorities Australia
 - Office of the Gene Technology Regulator
 - Therapeutic Goods Administration
-

This Standard was issued in draft form for comment as DR AS 2252.6.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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Part 6: Clean workstations—Design, installation and use

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PREFACE

This Standard was prepared by Standards Australia Committee ME-060, Controlled Environment, to supersede AS 1386.5—1989, *Cleanrooms and clean workstations*, Part 5: *Clean workstations* and AS 1386.7—1989, *Cleanrooms and clean workstations*, Part 7: *Installation and use of clean workstations*.

This Standard provides design requirements and guidance for the construction of clean workstations, recommendations for the environment in which they are to be used, performance requirements and guidance on their installation and use. The air cleanliness requirements for clean workstations are specified in terms of the international classification system defined in AS/NZS ISO 14644.1, *Cleanrooms and associated controlled environments*, Part 1: *Classification of air cleanliness*. This new system of numerical classification for the concentration of particulates in controlled environments supersedes the Australian classification system used in preceding editions of Australian Standards for clean workstations.

This revision of the Standard incorporates significant changes and should be read in its entirety. In particular the following changes were made:

- (a) ISO 14644 series are referenced throughout the document for guidance along with internationally accepted standards for the manufacture and certification of unidirectional* airflow workstations.

Where these workstations are selected, certification for on-site commissioning and periodic test requirements are to be performed to comply with the requirements of the relevant Standard of manufacturer or AS 2252.6.

- (b) Factory test requirements have been introduced in addition to the existing test requirements.
- (c) Field test requirements have been amended.
- (d) Previous prescriptive requirements have been amended in favour of performance based requirements.

This Standard is Part 6 of a series which deals with separative devices. When complete the series will comprise the following:

AS

- 2252.1 Controlled environments—Part 1: Biological safety cabinets Class I—Design
- 2252.2 Controlled environments—Part 2: Biological safety cabinets Class II—Design
- 2252.3 Controlled environments—Part 3: Biological safety cabinets Class III—Design
- 2252.4 Controlled environments—Part 4: Biological safety cabinets Class I, II and III—Installation and use (BS 5726:2005, MOD)
- 2252.5 Controlled environments—Part 5: Cytotoxic cabinets—Design, installation and use
- 2252.6 Controlled environments—Part 6: Clean workstations—Design, installation and use
- 2252.7 Controlled environments—Part 7: Pharmaceutical isolators—Design, installation and use

The term 'informative' has been used in this Standard to define the application of the appendix to which it applies. An 'informative' appendix is only for information and guidance.

Compliance with an Australian or Australian/New Zealand Standard does not in itself confer immunity from legal obligations.

* In this Standard, the term 'unidirectional flow' has the same meaning as the term 'laminar flow'.

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STANDARDS AUSTRALIA

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Part 6: Clean workstations—Design, installation and use

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard specifies design, construction and performance requirements for clean workstations, together with requirements and guidance relating to their installation and use.

NOTE: Requirements for biological safety cabinets and cytotoxic drug safety cabinets are specified in AS 2252, Parts 1, 2, 3 and 4, and AS 2252.5 respectively.

1.2 APPLICATION

Clean workstations shall comply with the general requirements of Section 2 and the performance requirements of Section 3. Their performance shall be checked at specified intervals in accordance with the certification requirements of Clause 3.4. Workstations shall be installed and used as specified in Section 4. Due consideration should be given to the recommendations of Section 4 regarding the environment in which clean workstations are to be used.

1.3 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS

1807	Cleanrooms, workstations, safety cabinets and pharmaceutical isolators— Methods of test
1807.0	Part 0: List of methods and apparatus
1807.1	Method 1: Determination of air velocity and uniformity of air velocity in clean workstations, laminar flow safety cabinets and pharmaceutical isolators
1807.5	Method 5: Determination of work zone integrity
1807.6	Method 6: Determination of integrity of terminally mounted HEPA filter installations
1807.15	Method 15: Determination of illuminance
1807.18	Method 18: Determination of vibration in workstations, safety cabinets and pharmaceutical isolators
1807.20	Method 20: Determination of sound level at installed workstations, safety cabinets and pharmaceutical isolators
1807.23	Method 23: Determination of intensity of radiation from germicidal ultraviolet lamps
2252	Biological safety cabinets
2252.1	Part 1: Biological safety cabinets (Class I) for personnel and environment protection
2252.2	Part 2: Biological safety cabinets (Class II) Design
2252.3	Part 3: Biological safety cabinets (Class III) Design
2252.4	Part 4: Biological safety cabinets Class I, II and III—Installation and use