

Australian Standard<sup>®</sup>

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**Cleanrooms and clean workstations**

**Part 1: Principles of clean space control**

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This Australian Standard was prepared by Committee ME/60, Controlled Environments. It was approved on behalf of the Council of Standards Australia on 7 April 1989 and published on 19 June 1989.

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The following interests are represented on Committee ME/60:

Australian Institute of Refrigeration, Air Conditioning and Heating  
Australian Medical Association  
Australian Pharmaceutical Manufacturers Association  
Commonwealth Serum Laboratories  
Confederation of Australian Industry  
CSIRO, Australian Animal Health Laboratory  
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## PREFACE

This Standard was prepared by the Standards Australia's Committee on Controlled Environments.

It is Part 1 of a series of seven Standards published simultaneously as a revision and amalgamation of—

AS 1386—1976 *Cleanrooms and work-stations*; and

AS 1387—1976 *Code of practice for cleanrooms and work-stations*.

The series consists of the following Standards:

AS 1386 *Cleanrooms and clean workstations*

*Part 1: Principles of clean space control* (this Standard, AS 1386.1)

*Part 2: Laminar flow cleanrooms* (AS 1386.2)

*Part 3: Non-laminar flow cleanrooms—Class 350 and cleaner* (AS 1386.3)

*Part 4: Non-laminar flow cleanrooms—Class 3500* (AS 1386.4)

*Part 5: Clean workstations* (AS 1386.5)

*Part 6: Operation and inspection of cleanrooms* (AS 1386.6)

*Part 7: Installation and use of clean workstations* (AS 1386.7)

The above seven Standards supersede both AS 1386—1976 and AS 1387—1976.

This Standard deals with the classification of air cleanness and general principles of clean space control. It is based on Chapter 16 of the 1982 ASHRAE *Handbook of the American Society of Heating, Refrigeration and Air-conditioning Engineers*. It also takes account of the latest British and American draft documents on the subject. Six classes of air cleanness are now specified for the work zone of clean spaces under operational conditions, instead of the three classes specified in AS 1386—1976.

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## FOREWORD

Our environment contains large amounts of contamination, both gaseous and particulate. However, the application of cleanrooms pertains primarily to the problem of particulate contamination.

Increased contamination not only poses a threat to health, it finds its way into sophisticated manufacturing and assembly plants, laboratories, hospitals, and other critical areas requiring clean atmospheres. This applies to the fabrication of minute subassemblies, electronic devices, and instruments, and to the increasing demand for sterility and purity assurance in drugs and controlled atmospheres for biomedical and industrial applications.

Such operations are performed in clean spaces, wherein the following are controlled:

- (a) Viable and non-viable airborne particles.
- (b) Air flow patterns.
- (c) Temperature and humidity.
- (d) Barrier containment (for product and personnel protection).
- (e) Air pressure.
- (f) Operating procedures.

Achievement of these requirements necessitates special construction techniques, materials, and methods. The clean spaces may be rooms, or workstations or safety cabinets within a room.

Cleanrooms, clean workstations and safety cabinets are widely used in the medical, pharmaceutical, industrial and research fields in a number of areas such as the following:

*Medical and Biological*

Cell culturing  
 Critical infection-risk surgery  
 Genetic engineering  
 Infectious diseases  
 Intensive care wards  
 Media pouring  
 Pathology laboratories  
 Preparation of medical devices  
 Recombinant DNA research  
 Treatment of asthma and hay fever  
 Treatment of burns  
 Veterinary research

*Pharmaceutical*

Aseptic dispensing of therapeutic goods  
 Biological assays  
 Ophthalmic preparations  
 Production of parenteral solutions  
 Sterility testing

*Industrial*

Audio electronic  
 Avionics industry  
 Crystal growing  
 Gyroscopes  
 Hydraulic and fuel systems and components  
 Integrated circuits  
 Magnetic data storage  
 Miniature bearings  
 Optics  
 Photographic films  
 Precision measuring equipment  
 Semiconductors  
 Thin film processes

## STANDARDS AUSTRALIA

**Australian Standard**  
**Cleanrooms and clean workstations**

**Part 1: Principles of clean space control**

**1 SCOPE.** This Standard sets out the principles of clean space control. Six classes of air cleanness are specified and guidelines are given for the selection of airflow patterns, control of temperature and humidity, regulation of air pressure, materials and construction techniques, as well as operating procedures. The clean spaces may be achieved in rooms, or in workstations or safety cabinets within a room.

## NOTES:

1. The designs of cleanrooms illustrated in this Standard are typical of existing installations which consistently demonstrate satisfactory performance. However, the principle criterion for room design is the achievement of the desired class of air cleanness. Alternative designs, such as those of large dimensions or, those constructed to protect specialized equipment and processes but which attain the same level of air cleanness as specified in the Standard, are acceptable within the limits of AS 1386.2, AS 1386.3 or AS 1386.4, as applicable. The ultimate test of the performance of clean space systems is that components processed within the facilities they serve economically comply with the manufacturing standards imposed upon them.
2. Specific requirements for laminar flow cleanrooms, non-laminar flow cleanrooms, and clean workstations are specified in AS 1386.2, AS 1386.3, AS 1386.4 and AS 1386.5. Similarly, AS 1386.6 and AS 1386.7 specify requirements for operation and inspection of cleanrooms and installation and use of workstations. Requirements for safety cabinets are specified in AS 2252.1, AS 2252.2, AS 2567, AS 2639 and AS 2647. Separate specifications and related documents cater for certain vital components, e.g. air filters.

**2 REFERENCED DOCUMENTS.** The following documents are referred to in this Standard:

## AS

- 1132 Methods of test for air filters for use in air conditioning and general ventilation
- 1132.5 Method 5: Determination of arrestance efficiency, average arrestance efficiency, dust-holding capacity, and dust-holding capacity per unit of effective face area for test dusts nos 1, 2 and 3
- 1324 Air filters for use in air conditioning and general ventilation
- 1386 Cleanrooms and clean workstations
- 1386.2 Part 2: Laminar flow cleanrooms
- 1386.3 Part 3: Non-laminar flow cleanrooms—Class 350 and cleaner
- 1386.4 Part 4: Non-laminar flow cleanrooms—Class 3500
- 1386.5 Part 5: Clean workstations
- 1386.6 Part 6: Operation and inspection of cleanrooms
- 1386.7 Part 7: Installation and use of clean workstations
- 1668 SAA Mechanical Ventilation and Airconditioning Code
- 1668.2 Part 2: Ventilation requirements

- 2013 Cleanroom garments
- 2013.1 Part 1: Product requirements
- 2013.2 Part 2: Processing and use
- 2252 Biological safety cabinets
- 2252.1 Part 1: Biological safety cabinets (class I) for personnel protection
- 2252.2 Part 2: Laminar flow biological safety cabinets (class II) for personnel and product protection
- 2567 Cytotoxic drug safety cabinets
- 2639 Cytotoxic drug safety cabinets—Installation and use
- 2647 Biological safety cabinets—Installation and use

**3 DEFINITIONS.** For the purpose of this Standard, the definitions below apply.

**3.1 Anteroom**—a room attached to a cleanroom which provides access to the cleanroom for personnel, equipment, and operating components.

NOTE: An anteroom may also provide additional facilities like facilities for changing of clothes and storage (see Clause 5.12).

**3.2 Cleanroom**—a room or suite of rooms in which the concentration of airborne particulate matter is strictly controlled as specified in one of the classes of this Standard and where other factors may be controlled to within limits necessary to cater for particular needs.

**3.3 Clean space**—an area of controlled environment, with respect to airborne particulate matter as defined by the classification of cleanness desired.

NOTE: Clean spaces may be rooms, or workstations or safety cabinets or other enclosures within a room.

**3.4 Clean workstation**—an enclosure with a work zone which provides a controlled environment for protection of products from contamination but which does not provide personnel or environmental protection. It is characterized by having its own air filtration system and motor blowers which supply filtered, laminar flow air in the work zone.

Typical clean workstations are illustrated in Figure 1 and Figure 2.

## NOTES:

1. For a clean workstation manufactured in accordance with AS 1386.5 and incorporating a HEPA filter, and operated and maintained in accordance with AS 1386.7 in a Class 350 cleanroom (see Clause 4), Class 3.5 air is assumed in the work zone of the clean workstation. This *double barrier concept* is incorporated in FRED rooms (see Clause 3.9).
2. Throughout this Standard, clean workstations are also referred to as 'workstations'.
3. Safety cabinets designed primarily for personnel and environmental protection are covered by AS 2252.1, AS 2252.2, and AS 2567.



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