

Australian/New Zealand Standard™

**Cleanrooms and associated controlled environments**

**Part 1: Classification and air cleanliness**

## **AS/NZS ISO 14644.1:2002**

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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 15 February 2002 and on behalf of the Council of Standards New Zealand on 27 February 2002. It was published on 16 April 2002.

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The following interests are represented on Committee ME-060:

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Australian Industry Group  
Australian Institute of Refrigeration Air Conditioning and Heating  
Australian Pharmaceutical Manufacturers Association  
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# Australian/New Zealand Standard™

## **Cleanrooms and associated controlled environments**

### **Part 1: Classification and air cleanliness**

Originated as part of AS 1386—1976 and AS 1387—1976.  
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## PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee ME-060, Controlled Environment, to supersede those clauses of AS 1386.1—1989, *Cleanrooms and clean workstations*, Part 1: *Principles of clean space control* that address the classification of air cleanliness.

The objective of this Standard is to assign classification levels to be used for the specification of air cleanliness in cleanrooms and associated controlled environments. Classifications are defined exclusively in terms of concentration of airborne particles. This Standard also prescribes a method of testing and a procedure for determining the concentration of airborne particles.

This Standard is identical with and has been reproduced from ISO 14644-1:1999, *Cleanrooms and associated controlled environments*, Part 1: *Classification of air cleanliness*.

ISO 14644-1:1999 is the first Standard to be published in a series relating to cleanrooms and associated controlled environments. It is a core document which establishes a new system of numerical classification for the concentration of particulates in controlled environments. Various countries have published Standards with numerical classifications of particulate contamination in environmental air. It is anticipated that ISO 14644-1 will effectively supersede these Standards. To assist users in Australia and New Zealand in making the transition to the new classification system, further explanation is provided in Appendix ZA.

It should be noted that Annex B sets a reference standard for the determination of particulate levels. The existing Australian Standard method AS 1807.8 *Particle counting in work zone by automatic particle counter* is an acceptable equivalent (under Clause 4.2 of the Standard) as it delivers the same classification with greater precision.

It should also be noted that particulate levels are specified for certain pharmaceutical manufacturing applications under Therapeutic Goods legislation. The relevant Codes of Practice should be consulted.

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.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the annex or appendix to which they apply. A 'normative' annex or appendix is an integral part of a Standard, whereas an 'informative' annex or appendix is only for information and guidance.

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## INTRODUCTION

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include those in such industries as aerospace, microelectronics, pharmaceuticals, medical devices, food, and healthcare.

This part of ISO 14644 assigns ISO classification levels to be used for the specification of air cleanliness in cleanrooms and associated controlled environments. It also prescribes the standard method of testing as well as the procedure for determining the concentration of airborne particles.

For classification purposes, this part of ISO 14644 is limited to a designated range of considered particle sizes for determination of particle concentration limits. This part of ISO 14644 also provides standard protocols for the determination and designation of cleanliness levels that are based on airborne concentrations of particles smaller or larger than the size range designated for classification.

This part of ISO 14644 is one of a series of standards concerned with cleanrooms and contamination control. Many factors besides airborne particulate cleanliness must be considered in the design, specification, operation, and control of cleanrooms and other controlled environments. These are covered in some detail in other parts of the International Standards prepared by ISO/TC 209.

In some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures may be required.

# AUSTRALIAN/NEW ZEALAND STANDARD

## Cleanrooms and associated controlled environments —

### Part 1: Classification of air cleanliness

#### 1 Scope

This part of ISO 14644 covers the classification of air cleanliness in cleanrooms and associated controlled environments exclusively in terms of concentration of airborne particles. Only particle populations having cumulative distributions based on threshold (lower limit) sizes ranging from 0,1  $\mu\text{m}$  to 5  $\mu\text{m}$  are considered for classification purposes.

This part of ISO 14644 does not provide for classification of particle populations that are outside of the specified particle size range, 0,1  $\mu\text{m}$  to 5  $\mu\text{m}$ . Concentrations of ultrafine particles (particles smaller than 0,1  $\mu\text{m}$ ) and macroparticles (particles larger than 5  $\mu\text{m}$ ) may be used to quantify these populations in terms of U descriptors and M descriptors, respectively.

This part of ISO 14644 cannot be used to characterize the physical, chemical, radiological, or viable nature of airborne particles.

**NOTE** The actual distribution of particle concentrations within incremental size ranges normally is not predictable and typically is variable over time.

#### 2 Definitions

For the purposes of this part of ISO 14644, the following definitions apply.

##### 2.1 General

###### 2.1.1

###### **cleanroom**

room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of parti-

cles inside the room, and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary

###### 2.1.2

###### **clean zone**

dedicated space in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the zone, and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary

**NOTE** This zone may be open or enclosed and may or may not be located within a cleanroom.

###### 2.1.3

###### **installation**

cleanroom or one or more clean zones, together with all associated structures, air-treatment systems, services, and utilities

###### 2.1.4

###### **classification**

level (or the process of specifying or determining the level) of airborne particulate cleanliness applicable to a cleanroom or clean zone, expressed in terms of an ISO Class *N*, which represents maximum allowable concentrations (in particles per cubic metre of air) for considered sizes of particles

**NOTE 1** The concentrations are determined by using equation (1) in 3.2.

**NOTE 2** Classification in accordance with this International Standard is limited to the range extending from ISO Class 1 through ISO Class 9.

**NOTE 3** The considered particle sizes (lower threshold values) applicable for classification in accordance with this International