AS/NZS ISO 14644.1:2002 ISO 14644-1:1999

Australian/New Zealand Standard[™]

Cleanrooms and associated controlled environments

Part 1: Classification and air cleanliness





AS/NZS ISO 14644.1:2002

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.

The following interests are represented on Committee ME-060:

Auckland Regional Chamber of Commerce Australian Chamber of Commerce and Industry Australian Contamination Control Society Australian Industry Group Australian Institute of Refrigeration Air Conditioning and Heating Australian Pharmaceutical Manufacturers Association Australian Society for Microbiology Commonwealth Department of Health and Aged Care CSIRO—Division of Animal Health Medical Industry Association of Australia National Association of Testing Authorities, Australia N.S.W. Health Department Society of Hospital Pharmacists of Australia

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This Standard was issued in draft form for comment as DR 01303.

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Originated as part of AS 1386—1976 and AS 1387—1976. Previous edition AS 1386.1—1989. Jointly revised and redesignated in part as AS/NZS ISO 14644.1:2002.

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Jointly published by Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 4375 7

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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 Practise 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.
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- (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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