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Cleanrooms and associated controlled environments

Part 3: Test methods



AS ISO 14644.3:2021

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Cleanrooms and associated controlled environments

Part 3: Test methods

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Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee ME-060, Controlled Environment, to supersede AS/NZS 14644.3:2009, *Cleanrooms and associated controlled environments, Part 3: Test methods (ISO 14644-3:2005, MOD).*

The objective of this document is to provide test methods in support of the operation for cleanrooms and clean zones to meet air cleanliness classification, other cleanliness attributes and related controlled conditions.

This document specifies performance tests for two types of cleanrooms and clean zones: those with unidirectional airflow and those with non-unidirectional airflow, in three possible occupancy states: as-built, at-rest and operational.

This document provides test methods, recommended test apparatus and test procedures for determining performance parameters.

This document is not applicable to the measurement of products or of processes in cleanrooms, clean zones or separative devices.

This document does not address safety considerations associated with its use (for example, when using hazardous materials, operations and equipment). It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

This document is identical with, and has been reproduced from, ISO 14644-3:2019, *Cleanrooms and associated controlled environments — Part 3: Test methods.*

This document is intended to be used in conjunction with the following:

(a) AS ISO 14644.1:2017, *Cleanrooms and associated controlled environments, Part 1: Classification of air cleanliness by particle concentration.*

(b) AS 1807:2021, *Separative devices — Biological and cytotoxic drug safety cabinets, clean workstations and pharmaceutical isolators — Methods of test.*

(c) Other current test methods in the AS 1807 series (Test Methods 4, 16 and 17).

Test methods in this document replace test methods in specific parts of the AS 1807 series of test methods. The remaining AS 1807 series test methods are —

(i) consolidated into AS 1807:2021;

(ii) current (i.e. not replaced); or

(iii) withdrawn.

A summary of changes is set out in the table below.

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Relocation of AS 1807 series test methods

AS 1807 series test method number	Document status				AS 1807 series test method title
	To remain current	New location of superseded test methods			
		Replaced by AS ISO 14644 (series)	Not replaced	Superseded by AS 1807:2021	
AS 1807.0:2000				Clause 3	Determination of test apparatus used in the testing of separative devices, workstations, safety cabinets and pharmaceutical isolators
AS 1807.1:2000				Clause 4.1	Determination of air velocity and uniformity of air velocity in clean workstations, laminar flow safety cabinets and pharmaceutical isolators
AS 1807.2:2000				Clause 4.2	Determination of performance of clean workstations, laminar flow safety cabinets and pharmaceutical isolators under loaded filter conditions
AS 1807.3:2000		Part 3 Methods B.2 and B.3			Determination of air velocity and uniformity of air velocity in laminar flow cleanrooms
AS 1807.4:2000			Not replaced		Determination of performance of laminar flow cleanrooms under loaded filter conditions
AS 1807.5:2000				Clause 4.3	Determination of work zone integrity
AS 1807.6:2000				Clause 4.4	Determination of integrity of terminally mounted HEPA filter installations
AS 1807.7:2000	See Note 1				Determination of integrity of HEPA filter installations not terminally mounted
AS 1807.8:2000		Part 1 Appendix A			Particle counting in work zone by automatic particle counter

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Relocation of *(continued)*

AS 1807 series test method number	Document status				AS 1807 series test method title
	To remain current	New location of superseded test methods			
		Replaced by AS ISO 14644 (series)	Not replaced	Superseded by AS 1807:2021	
AS 1807.9:2000			See Note 2		Particle counting in cleanrooms by microscopic sizing and counting
AS 1807.10:2000		Part 3 Method B.1			Determination of air pressure of cleanrooms and pharmaceutical isolators
AS 1807.11:2000		Part 3 Method B.3			Determination of airflow parallelism in laminar flow cleanrooms
AS 1807.12:2000		Part 3 Method B.5			Determination of temperature in work zones
AS1807.13—2000		Part 3 Method B.6			Determination of relative humidity in cleanrooms
AS 1807.15:2000				Clause 4.5	Determination of illuminance
AS 1807.16:2000			Not replaced		Determination of sound level in cleanrooms
AS 1807.17:2000			Not replaced		Determination of vibration in cleanrooms
AS 1807.18:2000				Clause 4.6	Determination of vibration in workstations, safety cabinets and pharmaceutical isolators
AS 1807.19:2000			Withdrawn in 2006		Sizing and counting of particulate contaminants in and on cleanroom garments
AS 1807.20:2000				Clause 4.7	Determination of sound level at installed workstations, safety cabinets and pharmaceutical isolators
AS 1807.21:2000				Clause 4.8	Determination of inward air velocity of Class I biological safety cabinets

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Relocation of *(continued)*

AS 1807 series test method number	Document status				AS 1807 series test method title
	To remain current	New location of superseded test methods			
		Replaced by AS ISO 14644 (series)	Not replaced	Superseded by AS 1807:2021	
AS 1807.22:2000				Clause 4.9	Determination of air barrier containment of laminar flow safety cabinets
AS 1807.23:2000				Clause 4.10	Determination of intensity of radiation from germicidal ultraviolet lamps
AS 1807.24:2000		Part 3 Method B.4			Determination of recovery times of cleanrooms
AS 1807.25:2004				Clause 4.11	Determination of gas tightness of outer shell of biological safety cabinets
AS 1807.26:2004				Clause 4.12	Determination of air barrier containment of laminar flow safety cabinets — Potassium iodide discus test
NOTE 1: This document will remain in the short term. The intention will be to incorporate it into a future document. NOTE 2: This document is no longer used and has been withdrawn.					

As this document has been reproduced from an International Standard, a full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 209, *Cleanrooms and associated controlled environments*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This second edition of ISO 14644-3 cancels and replaces the first edition (ISO 14644-3:2005), which has been technically revised. The main changes compared to the previous edition are as follows:

— Clause B.7 has been simplified and corrected to address concerns over its complexity and noted errors;

— guidance concerning classification of air cleanliness by airborne particle concentration has been moved to 14644-1[1]

— the text of the whole document has been revised or clarified to aid in application.

A list of all parts in the ISO 14644 series can be found on the ISO website.

This corrected version of ISO 14644-3:2019 incorporates the following corrections:

— cross-references have been corrected in Table A.1, B.4.4, C.1, C.4.2 and C.4.3;

— the wording has been changed in B.2.1 a), Table B.2;

— old Figure B.2 has been removed.

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Introduction

Cleanrooms and associated controlled environments provide control of 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, healthcare and food.

This document sets out appropriate test methods for measuring the performance of a cleanroom, a clean zone or an associated controlled environment, including separative devices and controlled zones, together with all associated structures, air treatment systems, services and utilities.

NOTE Not all cleanroom parameter test procedures are shown in this document. The procedure and apparatus for the test carried out for the air cleanliness classes by particle concentration and for macroparticles are provided in ISO 14644-1,[1] and specifications for monitoring air cleanliness by nanoscale particle concentrations are provided in ISO 14644-12.[8] The procedures and apparatus to characterize other parameters, of concern in cleanrooms and clean zones used for specific products or processes, are discussed elsewhere in other documents prepared by ISO/TC 209 [for example, procedures for control and measurement of viable materials (ISO 14698 series), testing cleanroom functionality (ISO 14644-4[3]), and testing of separative devices (ISO 14644-7[4])]. In addition, other standards can be considered to be applicable. Other cleanliness attribute levels can be determined using ISO 14644-8[5] (levels of air cleanliness by chemicals), ISO 14644-9[6] (levels of surface cleanliness by particle concentration) and ISO 14644-10[7] (levels of surface cleanliness by chemical concentration).

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Cleanrooms and associated controlled environments

Part 3: Test methods

1 Scope

This document provides test methods in support of the operation for cleanrooms and clean zones to meet air cleanliness classification, other cleanliness attributes and related controlled conditions.

Performance tests are specified for two types of cleanrooms and clean zones: those with unidirectional airflow and those with non-unidirectional airflow, in three possible occupancy states: as-built, at-rest and operational.

The test methods, recommended test apparatus and test procedures for determining performance parameters are provided. Where the test method is affected by the type of cleanroom or clean zone, alternative procedures are suggested.

For some of the tests, several different methods and apparatus are recommended to accommodate different end-use considerations. Alternative methods not included in this document can be used by agreement between customer and supplier. Alternative methods do not necessarily provide equivalent measurements.

This document is not applicable to the measurement of products or of processes in cleanrooms, clean zones or separative devices.

NOTE This document does not purport to address safety considerations associated with its use (for example, when using hazardous materials, operations and equipment). It is the responsibility of the user of this document to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1 General terms

3.1.1
cleanroom
room within which the number concentration of *airborne particles* (3.2.1) is controlled and classified, and which is designed, constructed and operated in a manner to control the introduction, generation and retention of particles inside the room

Note 1 to entry: The class of airborne *particle concentration* (3.2.4) is specified.

Note 2 to entry: Levels of other cleanliness attributes such as chemical, viable or nanoscale concentrations in the air, and also surface cleanliness in terms of particle, nanoscale, chemical and viable concentrations might also be specified and controlled.

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