AS 1807:2021

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Separative devices — Biological and cytotoxic drug safety cabinets, clean workstations and pharmaceutical isolators — Methods of test

AS 1807:2021

This Australian Standard ® was prepared by ME-060, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 01 March 2021.

This Standard was published on 1 April 2021.

The following are represented on Committee ME-060:

Airconditioning and Refrigeration Equipment Manufacturers Association of Australia
Association of Biosafety for Australia and New Zealand
Australian Chamber of Commerce and Industry
Australian Industry Group
Australian Institute of Refrigeration Air Conditioning and Heating
CSIRO
Engineers Australia
Human Factors and Ergonomics Society of Australia
Institute of Healthcare Engineering Australia
International Society for Pharmaceutical Engineering
Medical Technology Association of Australia
National Association of Testing Authorities Australia
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Therapeutic Goods Administration

This Standard was issued in draft form for comment as DR AS 1807:202

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ISBN 978 1 76113 252 0

Separative devices — Biological and cytotoxic drug safety cabinets, clean workstations and pharmaceutical isolators — Methods of test

Originates AS 1807.0—1989, AS 1807.1—1976, AS 1807.2—1976, AS 1807.5—1976, AS 1807.6—1976, AS 1807.15—1976, AS 1807.18—1976, AS 1807—1989, AS 1807.21—1989, AS 1807.22—1989, AS 1807.23—1989, AS 1807.25—1990 and AS 1807.26—2004.
Previous editions AS 1807.0—2000, AS 1807.1—2000, AS 1807.2—2000, AS 1807.5—2000, AS 1807.6—2000, AS 1807.15—2000, AS 1807.18—2000, AS 1807—2000, AS 1807.21—2000, AS 1807.22—2000, AS 1807.23—2000, AS 1807.25—2004 and AS 1807.26—2004.

Preface

This Standard was prepared by the Australian members of Joint Standards Australia/Standards New Zealand Committee ME-060, Controlled Environments, to supersede AS 1807.0—2000, AS 1807.1—2000, AS 1807.2—2000, AS 1807.5—2000, AS 1807.6—2000, AS 1807.15—2000, AS 1807.18—2000, AS 1807.20—2000, AS 1807.21—2000, AS 1807.22—2000, AS 1807.23—2000, AS 1807.25—2004 and AS 1807.26—2004 and amalgamate them into a single standard.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this document as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this document is to specify the apparatus and test methods for the on-site testing of separative devices, as per the equipment described in AS 4273, *Design, installation and use of pharmaceutical isolators*, and the AS 2252, *Controlled environments*, series of standards. This document offers users and mechanical certifying groups consistent methods of testing based on proven engineering principles.

The objective of the revision is to amalgamate into one Standard, the test methods listed above from the AS 1807 series.

The remaining documents in the AS 1807 series, Methods 3, 4, 8 to 13, 16, 17 and 24, will be withdrawn; either because they are no longer used, or because they will be replaced by key test methods in AS ISO 14644.3:2021, *Cleanrooms and associated controlled environments — Part 3: Test methods.* AS 1807.7 *Determination of integrity of HEPA filter installations not terminally mounted* – will remain current until replaced at a later date. See Table A for a summary of these details.

Table A — Relocation of superseded AS 1807 series test methods

AS 1807 series test method number	Document status				Superseded test method title
	To remain current	New location of superseded test methods			
		Replaced by AS ISO 14644 (series)	Not replaced	Superseded by this document	
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

Table A *(continued)*

AS 1807 series test method number	Document status				Superseded test method title
	To remain current	New location of superseded test methods			
		Replaced by AS ISO 14644 (series)	Not replaced	Superseded by this document	
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
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
AS 1807.13—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

Table A *(continued)*

AS 1807 series test method number	Document status				Superseded test method title
	To remain current	New location of superseded test methods			
		Replaced by AS ISO 14644 (series)	Not replaced	Superseded by this document	
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
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 1807.2[illegible]—20[illegible]				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.

Conformance to an Australian Standard does not in itself confer immunity from legal obligations. Reference to or the application of an Australian Standard does not diminish the user's obligation or risk under WHS regulations when selecting, purchasing and maintaining safety cabinets.

In using an international or regional overseas standard as an alternative to this document, manufacturers need to consider the separative device's suitability in the intended workplace environment.

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

Contents

Introduction

Laboratory Acquired Infections (LAIs) are a concern for the community, and user groups engaged in the laboratory, research, pathology, and life science, industry sectors. The management and safe handling control of pathological samples and in particular those samples that may contain radioactive or cytotoxic residue obtained from human or animal samples remains an on-going concern for risk assessment programs.

Similarly, many clean air devices are used for the containment of toxic materials such as chemotherapy preparations. The implications of contamination may not be immediately apparent and symptoms tend to develop later. It remains important that user groups working and handling the samples described above use equipment that can be serviced and maintained on a regular basis and to an independently recognized level of safety.

Safe Work Australia published in 2015 a list of diseases deemed work related. This list was substantially increased from the few asbestos diseases, previously listed. A worker with the disease who has been exposed to the relevant exposure in the course of their work is assumed to have developed that disease because of the exposure, unless there is strong evidence to the contrary. In addition, the effects of this disease may not occur until many years after the worker has left the place of employment.

It is of critical importance that clean workstations used within the education sector conform to this document and all relevant safety requirements for the protection of students and staff members.

Finally, and most importantly, many of these devices are used for the preparation of life-saving treatments and in the discovery of new drugs, or the analysis of existing ones. They provide an aseptic or low bioburden environment to ensure the processes can be completed safely and effectively without the risk of adulteration.

NOTES

Australian Standard®

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Section 1 Scope and general

1.1 Scope

This document specifies requirements and test methods for the testing of separative devices, comprising biological and cytotoxic drug safety cabinets, clean workstations and pharmaceutical isolators.

The testing methods can be applied on any manufactured product that meets the requirements of AS 2252 Parts 1 to 6 and AS 4273. This document can also be used for other items of equipment that are used as a separative device in critical applications.

NOTE For testing of cleanrooms, see AS ISO 14644.3.

1.2 Application

The methods of test can be applied to separative devices within any work place environment.

Where separative devices are not manufactured in accordance with this document (e.g. imported products), testing to this document may be suitable for the purposes of claims of conformance to an Australian Standard.

1.3 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document:

NOTE Documents referenced for informative purposes are listed in the Bibliography.

AS 1259.1, *Acoustics—Sound level meters, Part 1: Non-integrating*

AS 2252 (series), *Controlled environments*

AS 4260, *High efficiency particulate air (HEPA) filters—Classification, construction and performance*

AS 4273, *Design, installation and use of pharmaceutical isolators*

AS ISO 14644-1, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*

AS ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

IEC 60051-1, *Direct acting indicating analogue electrical measuring instruments and their accessories, Part 1: Definitions and general requirements common to all parts*

IEC 60051-2, *Direct acting indicating analogue electrical measuring instruments and their accessories, Part 2: Special requirements for ammeters and voltmeters*

1.4 Terms and definitions

1.4.1
aerosol challenge
challenging an installed HEPA filter by test aerosol