AS 1807.0—2000
(Incorporating Amendment No. 1)

Australian Standard™

Cleanrooms, workstations, safety cabinets and pharmaceutical isolators—Methods of test

Part 0: List of methods and apparatus

Standards Australia

This Australian Standard was prepared by Committee ME-060, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 15 January 2000 and published on 15 February 2000.

The following interests are represented on Committee ME-060:

Air-Conditioning & Refrigeration Equipment Manufacturers

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

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee ME/60, Controlled Environment to supersede AS 1807.0—1989. This Standard is the result of a consensus among representatives on the Joint Committee to produce it as an Australian Standard.

*This Standard incorporates Amendment No. 1 (*March 2002*). The changes required by the Amendment are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.*

The AS 1807 series of Standards provides methods for the testing of cleanrooms, workstations, safety cabinets and pharmaceutical isolators and lists the apparatus required to perform these tests. This Standard specifies requirements for all testing apparatus used in the test methods in the AS 1807 series.

The objectives of the revision of the AS 1807 series of Standards are to replace construction requirements with performance requirements where practicable, allow the use of alternative test aerosols to cold DOP (cold di-octyl phthalate) and insert precautions regarding the use of cold DOP or its alternatives.

Methods 9, 19 and 25 have been excluded from the current revision of the AS 1807 series pending the establishment of new or modified test methods.

Subsequent revision of Method 9: *Particle counting in cleanrooms by microscopic sizing and counting*, and Method 19: *Sizing and counting of particulate contaminants in and on cleanroom garments*, is likely to take cognizance of updated methods for manual particle counting reflected in Standards currently being developed by ISO Technical Committee 209, Cleanrooms and Associated Controlled Environments, Working Group 5, Cleanroom Operation.

The current edition of Method 25: *Determination of gastightness of outer shell of biological safety cabinets*, requires leak testing with chlorodifluoromethane (Refrigerant 22). Because this substance is an ozone depleter, its use is now severely restricted. A number of organizations worldwide are currently investigating alternative approaches to leak testing of biological safety cabinets. Committee ME/60 recognizes the need to revise AS 1807.25 as a matter of urgency. A revised Standard will be issued as soon as an environmentally friendly, standardized and reproducible test method has been established as a viable alternative to the Refrigerant 22 leak test.

LIST OF METHODS

AS Number	Title
1807.1	Determination of air velocity and uniformity of air velocity in clean workstations, laminar flow safety cabinets and pharmaceutical isolators
1807.2	Determination of performance of clean workstations, laminar flow safety cabinets and pharmaceutical isolators under loaded filter conditions
1807.3	Determination of air velocity and uniformity of air velocity in laminar flow cleanrooms
1807.4	Determination of performance of laminar flow cleanrooms under loaded filter conditions
1807.5	Determination of work zone integrity
1807.6	Determination of integrity of terminally mounted HEPA filter installations
1807.7	Determination of integrity of HEPA filter installations not terminally mounted
1807.8	Particle counting in work zone by automatic particle counter
1807.9	Particle counting in cleanrooms by microscopic sizing and counting
1807.10	Determination of air pressure of cleanrooms and pharmaceutical isolators
1807.11	Determination of airflow parallelism in laminar flow cleanrooms
1807.12	Determination of temperature in work zones
1807.13*	Determination of relative humidity in cleanrooms
1807.15	Determination of illuminance
1807.16	Determination of sound level in cleanrooms
1807.17	Determination of vibration in cleanrooms
1807.18	Determination of vibration in workstations, safety cabinets and pharmaceutical isolators
1807.19	Sizing and counting of particulate contaminants in and on cleanroom garments
1807.20	Determination of sound level at installed workstations, safety cabinets and pharmaceutical isolators
1807.21	Determination of inward air velocity of Class I biological safety cabinets
1807.22	Determination of air barrier containment of laminar flow safety cabinets
1807.23	Determination of intensity of radiation from germicidal ultraviolet lamps
1807.24	Determination of recovery times of cleanrooms
1807.25	Determination of gastightness of outer shell of biological safety cabinets

* AS 1807.14 was incorporated in Method 13 and withdrawn without replacement in 1989. To avoid confusion, the numbers of the individual methods have been left unchanged in later editions of the AS 1807 series of Standards.

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1 SCOPE

This Standard specifies requirements for all testing apparatus used in the testing of cleanrooms, workstations, safety cabinets and pharmaceutical isolators in accordance with the test methods set out in the AS 1807 series of Standards. This Standard also provides definitions used in the specific test methods.

NOTE: If not otherwise specified, calibration, certification and performance specifications for instruments should be determined by the tester, using methods and intervals acceptable to the relevant Authority. Manufacturer's claimed performance data are not considered a suitable alternative.

2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS
1259 Acoustics—Sound level meters
1259.1 Part 1: Non-integrating

1386 Cleanrooms and clean workstations
1386.1 Part 1: Principles of clean space control

AS/NZS
1716 Respiratory protective devices

ISO
4677 Atmospheres for conditioning and testing—Determination of relative humidity
4677-1 Part 1: Aspirated psychrometer method
4677-2 Part 2: Whirling psychrometer method

IEC
60051 Direct acting indicating analogue electrical measuring instruments and their accessories
60051-1 Part 1: Definitions and general requirements common to all parts
60051-2 Part 2: Special requirements for ammeters and voltmeters

3 DEFINITIONS

For the purpose of this Standard the definitions given in AS 1386.1 and those below apply.

3.1 Authority

Body that has legal powers and rights.

3.2 Fibre

A particle larger than 100 μm with a length-to-width ratio exceeding 10:1.