Australian Standard™

Biological safety cabinets

Part 2: Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection

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 14 January 2004 and published on 28 April 2004.

The following are represented on Committee ME-060:

Airconditioning & Refrigeration Equipment Manufacturers Association of Australia

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 (Inc.)

Australian Pharmaceutical Manufacturers Association

Australian Society for Microbiology Incorporated

Commonwealth Department of Health and Ageing

CSIRO Australian Animal Health Laboratory

Ergonomics Facility of Australia

National Association of Testing Authorities Australia

NSW Health Department

Society of Hospital Pharmacists of Australia

This Standard was issued in draft form for comment as DR 02050.

Australian Standard™

Biological safety cabinets

Part 2: Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection

Originated as AS 2252.2—1980.
Previous edition 1994.
Fourth edition 2004.

Published by Standards Australia International Ltd
GPO Box 5420, Sydney, NSW 2001, Australia

ISBN 0 7337 5874 6

PREFACE

This Standard was prepared by the Australian members of the Joint Australia/New Zealand Standards Committee ME-060, Controlled Environment to supersede AS 2252.2—1994, *Biological safety cabinets*, Part 2: *Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection*.

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

This Standard is one of a series which deals with biological safety cabinets, the series being arranged as follows:

AS
2252 Biological safety cabinets
2252.1 Part 1: Biological safety cabinets (Class I) for personnel and environment protection
2252.2 Part 2: Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection (this Standard)

The separate parts of this Standard specify cabinets which provide protection from hazardous biological materials. These materials may need to be handled in contained spaces for the safety of the operator (Classes I and II) or may need to be handled in laminar flow* clean space for the protection of the product as well as for the safety of the operator (Class II).

A separate Standard, AS/NZS 2647, *Biological safety cabinets—Installation and use*, provides recommended practices for most aspects of the use of these cabinets. Reference should be made to this Standard so that the effectiveness of cabinets is not compromised by unsuitable installation. In particular, air turbulence from various sources may adversely affect the air barrier containment.

Total containment devices (commonly known as Class III cabinets) should be used when handling agents of Risk Group 4 (see Foreword). Committee ME-060 may consider, at a future date, the development of an Australian or Australian/New Zealand Standard for Class III cabinets.

Class I and Class II biological safety cabinets are unsuitable for handling cytotoxic drugs. Users are referred to AS 2567, *Laminar flow cytotoxic drug safety cabinets* and AS 2639, *Laminar flow cytotoxic drug safety cabinets—Installation and use* for information on handling cytotoxic drugs.

Self-contained devices for the aseptic preparation of pharmaceutical products are addressed in AS 4273, *Design, installation and use of pharmaceutical isolators*.

This edition has been prepared using, as far as presently possible, performance requirements rather than design or construction requirements, in order to encourage innovation in product design and development. The performance requirements reflect current technology and policies, and offer considerable latitude for ergonomic improvement. However, the Committee sees the principle of independent laminar and barrier airflow adjustment as an essential specification that facilitates cabinet reliability over its operational life.

---

* In this Standard, the term ‘laminar flow’ has the same meaning as the term ‘unidirectional flow’.

Changes introduced by this revision include the updating of referenced documents and editorial changes to bring the Standard into line with the current publishing style. Appendices have been added to provide guidance on ergonomic considerations.

Two methods of barrier test, AS 1807.22 and AS 1807.26—Polydisperse di-octyl phthalate (Cold DOP) and Potassium iodide (KI Discus) respectively—are valid for the duration of this Standard (three years from date of publication). During this time an independent analysis of both test methods will be evaluated to establish whether both methods will be retained.

The term ‘informative’ has been used in this Standard to define the application of the appendix to which it applies. An ‘informative’ appendix is only for information and guidance.

Compliance with an Australian or Australia/New Zealand Standard does not in itself confer immunity from legal obligations.

CONTENTS

Page

FOREWORD 5
1 SCOPE 7
2 REFERENCED DOCUMENTS 7
3 GENERAL REQUIREMENTS 8
4 CONSTRUCTION REQUIREMENTS 12
5 PERFORMANCE REQUIREMENTS 16
6 MARKING 18

APPENDIX A ERGONOMICS 19

FOREWORD

Surveys conducted in the 1970s of the causes of infections acquired in microbiological laboratories showed that only about 20% of the cases investigated followed known accidents, for example from a spill of infectious material or from a needle-stick injury. Many of the remaining 80% of these infections result from exposure to aerosols that are produced from common laboratory procedures, such as pipetting, blending and homogenizing.

An aerosol is a suspension of finely dispersed liquid or solid particles in air, of sizes varying from 0.01 to 100 micrometres. In unsaturated air, water evaporates from droplets, leaving nuclei or residues smaller in size. Aerosols are formed whenever the surface film of a liquid is broken. Greater energy input into aerosol formation produces smaller particles. Aerosol formation may be continuous, as from an operating homogenizer, or discontinuous, as from a dropped container of culture or the spray from a punctured septum. Aerosols containing microorganisms are of concern because they are invisible, they can spread throughout a laboratory and can affect many people.

Specialized containment equipment has been produced to protect laboratory workers where there is risk of exposure to such aerosols. The objectives in the control of microbiological hazards and contamination are to minimize the exposure of laboratory and support staff and to prevent the liberation of microorganisms and other biologically hazardous material from the laboratory into the environment.

The term ‘containment’ is used in describing the control of such hazards, meaning that they are kept within specified limits. *Primary containment* is provided by the use of good microbiological technique and by the use of appropriate safety equipment such as a biological safety cabinet. Such equipment provides the *primary barrier*. *Secondary containment* is provided by the laboratory containing primary containment equipment. It forms the *secondary barrier*.

Following guidelines produced by the World Health Organization, AS/NZS 2243.3, *Safety in laboratories*, Part 3: *Microbiological aspects and containment facilities*, classifies microorganisms according to the degree of risk, based on their pathogenicity, their mode of transmission and host range, the availability of effective preventive measures against infection and availability of effective treatment. There are similar classifications in other countries, for example the United Kingdom.

The risk groups are as follows:

(a) *Risk Group 1 (low individual and community risk)*

A microorganism that is unlikely to cause human, plant or animal disease.

(b) *Risk Group 2 (moderate individual risk, limited community risk)*

A pathogen that can cause human, plant or animal disease, but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause infection, but effective treatment and preventive measures are available, and the risk of spread is limited.

(c) *Risk Group 3 (high individual risk, limited community risk*

A pathogen that usually causes serious human or animal disease and may present a serious hazard to laboratory workers. It could present a risk if spread in the community, but there are usually effective preventive measures or treatment available.

(d) *Risk Group 4 (high individual and community risk)*

A pathogen that usually produces life-threatening human or animal disease, represents a serious hazard to laboratory workers and is readily transmissible from one individual to another. Effective treatment and preventive measures are not usually available.

One of the most widely used pieces of equipment for primary containment is the biological safety cabinet, the principal device for containment of aerosols produced in microbiological procedures. Biological safety cabinets are divided into three classes, relating to the method of construction providing the containment. Class I and Class II biological safety cabinets are partially open-fronted and provide a degree of protection when working with microorganisms of Risk Groups 2 and 3 and where the work produces a significant quantity of aerosol. Biological safety cabinets are only needed for work with microorganisms of Risk Group 1 if large amounts of aerosol are produced. Class III biological safety cabinets are totally enclosed devices where the user works through built-in gloves. This class of cabinet provides the highest degree of protection against aerosols produced when working with microorganisms of Risk Group 4, i.e. those most dangerous to laboratory workers.

Laminar flow clean workstations must be distinguished from biological safety cabinets, as any aerosol produced from work is discharged towards the operator and into the environment. They must not be used when handling hazardous biological materials.

The Office of the Genetic Technology Regulators has published guidelines (see [1] below) for working with genetically manipulated material. Three levels of containment are described for both small-scale and large-scale work. Biological safety cabinets are required where work produces significant quantities of aerosols.

The user is referred to the following publications:

[1] The Office of the Gene Technology Regulator Handbook on the Regulation of Gene Technology in Australia, Canberra: Office of the Gene Technology Regulator, 2001

http://www.health.gov.au/hfs/ogtr/publications/handbook.htm

[2] Hazardous Substances and New Organisms (Low-risk genetic modifications) Regulations 1998. Wellington, New Zealand

[3] ADVISORY COMMITTEE ON NOVEL GENETIC TECHNIQUES. *New Zealand code of practise for small-scale genetic manipulation research.* Wellington: The Committee, 1994.

STANDARDS AUSTRALIA

Australian Standard
Biological safety cabinets

Part 2: Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection

1 SCOPE

This Standard specifies basic requirements for Class II laminar flow biological safety cabinets that are intended to provide protection from hazardous biological agents for personnel and the environment and also to protect material used in the cabinet from exogenous contamination. The cabinets provide protection by inducing an inflow of room air through the work access opening, by delivering recirculated, high efficiency particulate air (HEPA) filtered, laminar flow air downwards through the work zone and by HEPA filtration of exhaust air.

It is essential that this Standard be read in conjunction with AS/NZS 2647 which describes recommended practices for installation and use of these cabinets.

NOTES:

1 These cabinets are intended only for handling materials which can be inactivated or rendered safe by an effective decontamination procedure such as that described in AS/NZS 2647.

2 Additional design requirements may apply to cabinets which are required to afford protection against other hazards such as toxic materials not of biological origin or against radiation.

3 For work with cytotoxic drugs the user is referred to AS 2567.

4 Ergonomic considerations for the design and selection of biological safety cabinets are addressed in Appendix A.

2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS	
1319	Safety signs for the occupational environment
1807	Cleanrooms, workstations, safety cabinets and pharmaceutical isolators—Methods of test
1807.1	Method 1: Determination of air velocity and uniformity of air velocity in clean workstations, laminar flow safety cabinets and pharmaceutical isolators
1807.2	Method 2: Determination of performance of clean workstations, laminar flow safety cabinets and pharmaceutical isolators under loaded filter conditions
1807.5	Method 5: Determination of work zone integrity
1807.6	Method 6: Determination of integrity of terminally-mounted HEPA filter installations
1807.15	Method 15: Determination of illuminance
1807.18	Method 18: Determination of vibration in workstations, safety cabinets and pharmaceutical isolators
1807.22	Method 22: Determination of air barrier containment of laminar flow safety cabinets