Australian Standard™

Biological safety cabinets

Part 1: Biological safety cabinets (Class I) for personnel and environment 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 16 September 2002 and published on 13 November 2002.

The following are represented on Committee ME-060:

Air-Conditioning and Refrigeration Equipment Manufacturers Association of Australia

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—Livestock Industries

Department of Human Services, Vic.

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Part 1: Biological safety cabinets (Class I) for personnel and environment protection

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PREFACE

This Standard was prepared by the Joint Australia/New Zealand Standards Committee ME-060, Controlled Environment to supersede AS 2252.1—1994, *Biological safety cabinets*, Part 1: *Biological safety cabinets (Class I) for personnel and environment protection.* After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

This Standard is one of a two-part series which addresses 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 (this Standard)
2252.2	Part 2:	Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection

The separate parts of this Standard specify cabinets which provide protection from hazardous biological materials, in the broadest sense. 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 requirements and recommended practices for most aspects of the use of these cabinets. Reference should be made to that 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). At the date of publication, there is no Australian, New Zealand or Australian/New Zealand Standard for Class III cabinets. Self-contained devices for the aseptic transfer of pharmaceutical products are addressed in AS 4273, *Design, installation and use of pharmaceutical isolators.*

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

This edition is essentially an update, reflecting current technology and policies, with editorial amendments to refer to other current Standards and authorities. An appendix has been added to provide guidance on ergonomic considerations. It should be noted that Committee ME-060 is likely to make adjustable cabinet height a mandatory requirement in the next edition of this Standard.

During the preparation of this edition, consideration was given to using performance requirements, rather than design or construction requirements, in order to encourage innovation in product design and development. However, while a specification based only on performance would, in principle, be preferable, Committee ME-060 lacked evidence that stable, consistent and safe operation of a Class I biological safety cabinet could be assured on this basis. Therefore, the simplest available specifications to achieve the desired criteria have been chosen.

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

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.

The Committee is considering the adoption of EN 12469, *Biotechnology—Performance criteria for microbiology safety cabinets* together with BS 5726, *Microbiological safety cabinets,* Part 2: *Recommendations for information to be exchanged between purchaser, vendor and installer and recommendations for installation* and Part 4: *Recommendations for selection, use and maintenance,* as future revisions of this Standard, AS 2252.2 and AS 2647. Note that EN 12469 includes Class III cabinets. EN 12469 contains two alternative barrier containment test methods to the DOP method of AS 1807.22. The Potassium-Iodide Particle Method of EN 12469 is in preparation for publication as an Australian/New Zealand Standard by Committee ME-060. If the Potassium-Iodide particle method is published, the Committee proposes to withdraw AS 1807.22 in due course.

Note also that EN 12469 excludes a containment test for Class I cabinets.

CONTENTS

FOREWORD

Surveys conducted in the 1970s on 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 laboratory infections resulted from exposure to aerosols that were 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 or the environment, but there are usually effective preventive measures or treatments 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 high 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 Gene Technology Regulator in Australia and the Environmental Risk Management Authority in New Zealand have published guidelines for working with genetically manipulated material. Three levels of containment are described for small-scale laboratory work and two levels of containment are described for large-scale work. Biological safety cabinets are required where work produces significant quantities of aerosols.

In Australia the user is referred to the Office of the Gene Technology Regulator, 2001 Guidelines—*Handbook on the Regulation of Gene Technology* in Australia, Canberra.

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

In New Zealand, the user is referred to the Hazardous substances and New Organisms (Low-risk Genetic Modifications) Regulations and the New Zealand Code of Practice for small-scale genetic manipulation research.

STANDARDS AUSTRALIA

Australian Standard
Biological safety cabinets

Part 1: Biological safety cabinets (Class I) for personnel and environment protection

1 SCOPE

This Standard specifies requirements for Class I biological safety cabinets which are intended to provide protection from hazardous biological agents for personnel and the environment. The cabinets are exhaust-ventilated and provide protection by means of an inward flow of air away from the operator and by high efficiency particulate air (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 use 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	
1324	Air filters for use in general ventilation and airconditioning	
1324.2	Part 2:	Methods of test
1807	Cleanrooms, workstations, safety cabinets and pharmaceutical isolations—Methods of test	
1807.2	Method 2:	Determination of performance of clean workstations, laminar flow safety cabinets and pharmaceutical isolators under loaded filter conditions
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
1807.21	Method 21:	Determination of inward air velocity of Class I biological safety cabinets
1807.22	Method 22:	Determination of air barrier containment of laminar flow safety cabinets
1807.23	Method 23:	Determination of intensity of radiation from germicidal ultraviolet lamps