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Australian Standard 2252, Part 2—1980

BIOLOGICAL SAFETY CABINETS

Part 2—LAMINAR FLOW BIOLOGICAL SAFETY CABINETS (CLASS II) FOR PERSONNEL AND PRODUCT PROTECTION

STANDARDS ASSOCIATION OF AUSTRALIA
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THE FOLLOWING SCIENTIFIC, INDUSTRIAL AND GOVERNMENTAL ORGANIZATIONS and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Institute of Refrigeration, Air Conditioning and Heating

Australian Medical Association

Commonwealth Serum Laboratories

Confederation of Australian Industry

CSIRO, Division of Animal Health

Department of Housing and Construction

Department of Defence

Department of Public Works, N.S.W.

Firms and consultants specializing in equipment and design for controlled environments

Health Commission of N.S.W.

Health Commission of Victoria

National Association of Testing Authorities, Australia

National Biological Standards Laboratory

National Council of Chemical and Pharmaceutical Industries

Royal Australian Institute of Architects

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AUSTRALIAN STANDARD

BIOLOGICAL SAFETY CABINETS

Part 2
LAMINAR FLOW BIOLOGICAL SAFETY CABINETS (CLASS II) FOR PERSONNEL AND PRODUCT PROTECTION

AS 2252, Part 2—1980

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PREFACE

This standard was prepared by the Association's Committee on Controlled Environment. It is Part 2 of a three-part standard for biological safety cabinets.

The other parts of the standard are—

Part 1 Biological Safety Cabinets (Class I) for Personnel Protection

Part 3 Gas-tight Biological Safety Cabinets (Class III), for Personnel Protection against Agents for Extreme Hazard*

The issue in 1972 of a draft standard for public review for cleanrooms and work-stations drew a comment from the Commonwealth Serum Laboratories that certain biological work needed to be done under aseptic conditions, and also that potentially dangerous materials had to be contained; the fact was that the proposed standards† did not adequately cater for these situations. A need was also established for standards applying to cabinets designed to minimize the inherent risks to personnel working with hazardous biological agents.

The CSL submission led to the decision to prepare AS 2252, Biological Safety Cabinets in three parts.

In the preparation of this standard, reference was made to the booklet published by the Public Health Service of the United States Department of Health, Education and Welfare, entitled 'Classification of Etiological Agents on the Basis of Hazard'. Although written for American conditions, this booklet describes the basis for the classification of such hazardous agents, and lists bacterial, fungal, parasitic, viral, rickettsial and chlamydial agents in five classes. The least hazardous agents are in Class 1 and those requiring the greatest restrictions are in Class 4. Class 5 contains agents which are specifically excluded from the U.S. by law. The list of organisms prohibited in Australia differs somewhat from the American list. Details can be obtained from the Quarantine Division of the Department of Health, Canberra.

Laminar flow biological safety cabinets (Class II) are not to be confused with laminar flow work-stations described in AS 1386 which do not provide protection for personnel.

Appendix A, Purchasing Guidelines, provides a basis for contractual matters.

This standard may require reference to the following standards:

AS 1217	Methods of Measurement of Airborne Sound Emitted by Machines
AS 1324	Air Filters for use in Air Conditioning and General Ventilation
AS 1449	Wrought Alloy Steels—Stainless and Heat-resisting Steel Plate, Sheet and Strip
AS 1677	SAA Refrigeration Code
AS 1680	Code of Practice for Interior Lighting and the Visual Environment
AS 1807	Methods of Test for Cleanrooms, Work-stations and Their Accessories 1807.1—Air Velocity and Uniformity of Clean Work-stations 1807.2—Air Velocity Under Loaded Filter Conditions of Clean Work-stations 1807.5—Induced Air Leakage 1807.6—Final Filter Installation Integrity 1807.15—Light Intensity 1807.18—Vibration in Work-stations
AS 2243	Code of Practice for Safety in Laboratories Part 3—Microbiology
AS C100	Approval and Test Specification for Definitions and General Requirements for Electrical Materials and Equipment
AS	Guide for Installation and Use of Biological Safety Cabinets*
BS 5726	Specification for Microbiological Safety Cabinets

*In course of preparation.
†Since published as AS 1386, Cleanrooms and Work-stations and AS 1387, Code of Practice for Cleanrooms and Work-stations.

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PART 2—LAMINAR FLOW BIOLOGICAL SAFETY CABINETS (CLASS II) FOR PERSONNEL AND PRODUCT PROTECTION

FOREWORD

In order to adequately guard against inherent risks to personnel, products and experiments associated with hazardous biological agents, consideration is necessary in respect of the type of cabinet containment required and of the competence of operators. This, in turn, calls for definition of the degree of hazard, and the following terms, which relate directly to those used by the United States Public Health Service (PHS), have been adopted:

- *No or minimal hazard*—the risk level of agents and/or operations of no or minimal danger to personnel, animals, or plants under ordinary conditions of handling (PHS Class 1).
- *Ordinary or potential hazard*—the risk level associated with agents which produce disease in man, animals, or plants and which can be contained by normal microbiological techniques. The level of competence for personnel should be that expected of staff in a hospital diagnostic microbiological laboratory (PHS Class 2).
- *Special hazard*—the risk level associated with agents which are highly infectious or toxic for man, animals, or plants with the production of dangerous disease. Also included are agents with genetic alterations and those which may have a synergistic effect with other materials. Appropriate containment measures are required. The level of competence for personnel should be at least that expected in staff of a hospital diagnostic microbiological laboratory. In addition personnel must have had proper training in the handling of dangerous agents (PHS Class 3).
- *Extreme hazard*—the risk level associated with agents which are extremely dangerous for man, animals, or plants, or cause serious epidemic disease. They may have various dangerous combinations of the following characteristics:
  - (a) Low infective doses.
  - (b) High pathogenicity.
  - (c) Potential for spread outside the laboratory.
  - (d) Concentration.
  - (e) Genetic alteration or genetic recombination that significantly increases pathogenicity.

Stringent containment measures are required. Personnel must have high level of competence in microbiology and must have had special training in the handling of dangerous agents (PHS Class 4).

To cope with risks posed by hazardous biological agents, it has been necessary to design cabinets which fall into three separate classes. Each class has a specific application according to the hazard and as to whether protection is required for product and experiment in addition to personnel.

The applications relevant to the defined hazards are shown in the following table:

Class of cabinet	Definition of hazard	Application	
		Oncogenic viruses*	Aetiological agents PHS classification†
Class I	Ordinary and special	Low and moderate hazards	2 and 3
Class II	Ordinary and special	Low and moderate hazards	2 and 3
Class III	Extreme	Low, moderate and high hazards	4

*U.S. Department of Health, Education and Welfare, National Cancer Institute, Office of Research Safety. Safety standards for research involving viruses. Bethesda, Md 20014, 1974.
†U.S. Department of Health, Education and Welfare, Public Health Service, Centre for Disease Control. Classification of etiologic agents on the basis of hazard. Atlanta, Ga 30333, 1976.

For recombinant DNA containment, the use of a biological safety cabinet (Class II) is appropriate. The Australian Academy of Science has established a Committee on Recombinant DNA Molecules and application for advice on containment conditions for specific experimental proposals should be submitted to the Executive Secretary, Australian Academy of Science, Canberra.

SPECFICATION

1 SCOPE. This standard specifies requirements for Class II biological safety cabinets which are intended to provide protection both for personnel against ordinary and special biological hazards and for the product and/or experiment against contamination.

Procedures for location, inspection and testing after installation are described in Appendix B.

2 GENERAL REQUIREMENTS. A Class II biological safety cabinet shall comply with the following general requirements:

(a) It shall be self-contained and consist essentially of a work zone, a recirculating blower for laminar airflow, an exhaust blower, and filters as shown in Fig. 1.

(b) It shall be independent of any other air-handling system, and shall be either free-standing or bench-mounted.

(c) The exhaust air outlet may face horizontally (as in Fig. 2) or vertically in any appropriate direction, but the installation shall always allow for a clearance of not less than 600 mm in the direction of discharge.

(d) The working face of the enclosure shall include a viewing window and a work access opening (see Figs 1 and 2). Air shall be recirculated within the work zone through high efficiency particulate air (HEPA) filters in a unidirectional, vertical, downward manner, thus providing contamination-free air for product protection.

An air barrier between the work zone and the room shall be created across the full width of the access opening by the induction of room air downwards into the sump (see Fig. 2). A quantity of air, equal to that of the barrier air, shall be exhausted from the cabinet through the exhaust HEPA filter.

(e) To contain potentially hazardous materials within the cabinet, all zones under positive pressure shall be surrounded by zones under a negative pressure relative to the work room atmosphere.

(f) All controls associated with the cabinet shall be integral parts of the cabinet.

(g) Where reticulated pipe services are connected to the unit, suitable measures shall be taken to provide microbiological isolation.

NOTES:

1. The use of flammable materials of construction is not recommended.
2. Provision for the removal of odour may be made.

(h) If (for some special purposes), there is provision for gas supply to the inside of the cabinet, e.g. for bunsen burner, this gas supply shall be controlled by a second valve that will allow gas to pass only when the fan is switched on and that needs to be manually reset after any interruption of the current. This will reduce the fire and explosion hazard.

NOTES:

1. The use of electrical heaters is preferred and recommended and the use of reticulated gas is prohibited by certain regulatory bodies.
2. Low profile burners with touch control to provide full flame as required produce less disturbances to the air-flow.

3 CONSTRUCTION REQUIREMENTS (see Fig. 1).

3.1 Outer Shell. The outer shell shall be of metal and shall be gastight (see Clause 4.1.1) and, when subjected to the decontamination procedures described in AS . . . .*, all the decontaminants shall be contained within the outer shell.

3.2 Work Zone.

3.2.1 *General.* Except for the viewing window, the work zone, including a sump and the front grille, shall be constructed entirely of series 300 stainless steel with a 2B finish.

NOTE: Series 300 stainless steels are specified in AS 1449. Information on surface finishes is also given.

The area and shape of the work zone shall match that of the effective filter media of the main or laminar flow filter(s) to ensure laminar flow adjacent to the viewing glass.

The lower section of the work zone back panel shall be removable for cleaning and service access to the rear plenum (see Fig. 1).

3.2.2 *Viewing window.* The working face shall consist of a panel of laminated safety glass or equivalent which can be opened to allow access to the work zone. The viewing window shall be vertically aligned with the front boundary of the laminar flow delivery area. No means shall be provided for holding the viewing window in an open position.

3.2.3 *Work access opening.* The work access opening shall be the full width of the working space below the viewing window. The lower edge shall be formed in a manner that avoids turbulence at the entry.

NOTE: A height of not greater than 225 mm is a suitable dimension for the opening.

3.2.4 *Work access opening cover.* A loose cover to fit the work access opening shall be provided to seal the cabinet during decontamination. It shall be capable of being fixed and sealed to provide a gastight seal without damage to the outer shell.

NOTE: The cover may also be used to seal off the cabinet when not in use.

3.2.5 *Work zone illumination.* The work zone shall be illuminated by fluorescent lamps. The fitting, tubes and lamp housing shall be external to the work zone but shall allow light transmission through a glass panel fitted to the housing, or alternatively, through the top portion of the viewing section.

Replacement of the fluorescent tubes shall be from outside the cabinet.

3.2.6 *Work floor.* The work floor shall be firm, not fastened and readily removable. It may be solid or perforated. Where the work floor is solid, it shall have a retaining lip around the perimeter sized to retain liquid to a minimum depth of 25 mm. All corners of the floor shall be radiused to facilitate cleaning and disinfection.

3.3 Sump. The sump (which provides the base of the lower air plenum) shall be watertight and all joints shall be welded, ground flush and dressed. The sump shall be sized to retain fluid to a minimum depth of

*AS . . . ., Guide for Installation and Use of Biological Safety Cabinets (in course of preparation).