Australian Standard®

Controlled environments

Part 2: Biological safety cabinets Class II—Design

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- Airconditioning & Refrigeration Equipment Manufacturers Association of Australia
- Association of Accredited Certification Bodies
- Auckland Regional Chambers of Commerce
- Australian Chamber of Commerce and Industry
- Australian Industry Group
- Australian Institute of Refrigeration Air Conditioning and Heating
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- Commonwealth Department of Health and Ageing
- Engineers Australia
- Human Factors and Ergonomics Society of Australia
- International Society for Pharmaceutical Engineering
- NSW Health Department
- National Association of Testing Authorities Australia
- Office of the Gene Technology Regulator

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Part 2: Biological safety cabinets Class II—Design

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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—2004, *Biological safety cabinets*, Part 2: *Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection*.

This Standard incorporates Amendment No. 1 (June 2010). 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.

It is recommended that a risk assessment be undertaken to assess the suitability of a particular class of cabinet for its application and intended location.

This revision of the Standard incorporates significant changes and should be read in its entirety. In particular the following changes were made:

(a) EN 12469 or NSF/ANSI 49 or equivalent Standards are acceptable alternatives to AS 2252.2 for the manufacture and certification of negative pressure plenum cabinets.

Where these cabinets are selected, certification for on-site commissioning and periodic test requirements are to be performed to comply with the requirements of the relevant Standard of manufacture or AS 2252.2.

(b) Factory test requirements have been introduced in addition to the existing test requirements.

(c) Field test requirements have been amended.

(d) Previous prescriptive requirements have been amended in favour of performance based requirements.

This Standard is Part 2 of a series on biological safety cabinets. When complete, the series will comprise the following:

AS
2252.1 Controlled environments—Part 1: Biological safety cabinets Class I—Design
2252.2 Controlled environments—Part 2: Biological safety cabinets Class II—Design
2252.3 Controlled environments—Part 3: Biological safety cabinets Class III—Design
2252.4 Controlled environments—Part 4: Biological safety cabinets Class I, II and III—Installation and use
2252.5 Controlled environments—Part 5: Cytotoxic cabinets—Design, installation and use
2252.6 Controlled environments—Part 6: Clean workstations—Design, installation and use
2252.7 Controlled environments—Part 7: Pharmaceutical isolators—Design, installation and use

The separate parts of this series specify cabinets that provide protection from hazardous biological materials. These materials may need to be handled in contained spaces for the safety of the operator (Classes I, II and III) or if product protection only is required this can be handled in laminar flow* clean space.

AS 2252.4, 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.

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

AS/NZS 2647:2000 will be withdrawn on publication of AS 2252.4.

Total containment devices (commonly known as Class III cabinets) should be used when handling agents of Risk Group 4 (see Foreword).

Class I and Class II biological safety cabinets are unsuitable for handling cytotoxic drugs. Users are referred to AS 2252.5.

Self-contained devices for the aseptic preparation of pharmaceutical products are addressed in AS 2252.7.

There are two methods of containment test, AS 1807.22 Polydisperse di-octyl phthalate (Cold DOP) and Potassium iodide (KI Discus). As there is ongoing research in this area it is recommended that users consult the available literature on the above two containment tests and base their decision on an appropriate risk assessment.

An interim standard AS 2252.3, Controlled environment—Part 3: Biological safety cabinets Class III—Design is available.

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 Australian/New Zealand Standard does not in itself confer immunity from legal obligations.

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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 or animal disease.

(b) *Risk Group 2 (moderate individual risk, limited community risk)*—a microorganism that is unlikely to be a significant risk 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 to moderate community risk)*—a microorganism that usually causes serious human or animal disease and may present a significant risk to laboratory workers. It could present a limited to moderate risk if spread in the community or the environment, but there are usually effective preventive measures or treatment available.

(d) *Risk Group 4 (high individual and community risk)*—a microorganism that usually produces life-threatening human or animal disease, represents a significant risk to laboratory workers and may be 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 Gene 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.ogtr.gov.au/

[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 practice for small-scale genetic manipulation research.* Wellington: The Committee, 1994.

STANDARDS AUSTRALIA

Australian Standard

Controlled environments

Part 2: Biological safety cabinets Class II—Design

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 intended that this Standard be read in conjunction with AS 2252.4 which describes recommended practices for installation and use of these cabinets.

NOTES:

1 These cabinets are intended only for handling materials that can be inactivated or rendered safe by an effective decontamination procedure such as that described in AS 2252.4 .

2 Additional design requirements may apply to cabinets that 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 2252.5.

4 Consideration of ergonomics 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 Clean rooms, 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

1807.5 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

1807.20 Method 20: Determination of sound level at installed workstations, safety cabinets and pharmaceutical isolators

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