AS 2252.2:2025

Australian STANDARD®

STANDARDS Australia

Controlled environments

Part 2: Biological safety cabinets Class II — Design



AS 2252.2:2025

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The following are represented on Committee ME-060:

Advanced Pharmacy Australia
Airconditioning & Refrigeration Equipment Manufacturers Association of Australia
Association of Biosafety for Australia and New Zealand
Australian Chamber of Commerce and Industry
Australian Institute of Refrigeration Air Conditioning and Heating
CSIRO
Human Factors and Ergonomics Society of Australia
Institute of Healthcare Engineering Australia
International Society for Pharmaceutical Engineering
Medical Technology Association of Australia
National Association of Testing Authorities Australia
NSW Health
Therapeutic Goods Administration (TGA)

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Part 2: Biological safety cabinets Class II — Design

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How to read this Standard

This page explains the meaning of the language and structure of this Standard.

Refer to Standards Australia's Standardisation Guide 006 for more details about drafting rules.

Australian and Australian/New Zealand Standards are voluntary unless they are referenced in legislation or called up in contracts.

Requirements

To conform to a Standard, all requirements in the Standard need to be met.

A requirement is any statement in the Standard which uses the word "shall".

Recommendations, permissions and possibilities

The following words are commonly used in Standards, but statements using them do not have to be followed to conform to the Standard:

(a) "should" means that something is recommended.

(b) "may" means that something is permitted.

(c) "can" means that something is possible.

Structure of Standards

A Standard always has the following parts:

(i) The Preface states who developed the Standard, what the Standard is aiming to do, and how it relates to other documents.

(ii) The Scope states what the Standard is about, what it covers and what it does not cover.

(iii) The Normative references clause lists other documents that are referenced in the Standard as part of requirements.

(iv) The Terms and definitions clause defines important terms to help with understanding the Standard.

A Standard may also include other parts, such as the following:

(1) A normative appendix sets additional requirements that need to be conformed to.

(2) An informative appendix provides additional information or guidance. An informative appendix provides additional information or guidance. They usually do not contain requirements. If an informative appendix does contain requirements, the Standard will explain when those requirements apply.

(3) A Bibliography lists documents referenced in the Standard but not as part of requirements.

Many Standards include notes. Notes provide recommendations and/or guidance only. They never contain requirements.

Preface

This Standard was prepared by the Australian members of the Joint Australia/New Zealand Standards Committee ME-060, Controlled Environment, to supersede AS 2252.2:2009.

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 document is one of a series which addresses biological safety cabinets, and other separative devices.

A list of all parts in the AS 2252 series can be found in the Standards Australia online catalogue.

The separate parts of this document 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, II or III) or may need to be handled in controlled unidirectional air flow clean space for the protection of the product as well as for the safety of the operator (Class II or III).

NOTE In this document, the term “unidirectional air flow” is applied to the controlled air within the Class II or III cabinet work zone as the air is not “laminar” when defined on the Reynolds scale.

Separative devices covered under the AS 2252 series of Standards rely upon the AS 1807 methods of test to determine the required operating performance.

Class I and Class II biological safety cabinets are unsuitable for handling cytotoxic drugs, because many have been demonstrated to be mutagens and some to be carcinogens in cell DNA and chromosomal studies, animal models and from experience with treated patients. While effects of exposure to these compounds may not manifest themselves for many years and aerosol exposure to the cabinet fans and internal plenums can expose service personnel to contaminated surfaces. Users of cytotoxic drugs are referred to AS 2252.5.

This edition is an update reflecting current technology and policies with editorial amendments to refer to other current Standards and authorities. An appendix has been included on ergonomics to provide specific guidance on safety cabinets and isolators and these can be considered in consideration with HB 59-2016.

During the preparation of this edition, consideration was given to performance design and construction requirements.

Conformance to an Australian Standard does not in itself confer immunity from legal obligations. Reference to or the application of an Australian Standard does not diminish the user’s obligation or risk under WHS regulations when selecting, purchasing and maintaining safety cabinets.

The terms “normative” and “informative” are used in Standards to define the application of the appendix to which they apply. A “normative” appendix is an integral part of a Standard, whereas an “informative” appendix is only for information and guidance.

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Introduction

The largest published Laboratory Acquired Infection "LAI" survey was conducted by Pike in 1976. From the reported incidents it showed only about 20 % of the cases were spills from infectious material or from a needle-stick injury. The remaining 80 % 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 μm. 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.

AS/NZS 2243.3 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 treatments 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 Class II biological safety cabinet, the principal device for containment of aerosols produced in microbiological procedures. 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 gloves fitted to the cabinet front. 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.

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Clean workstations only provide product protection and must not be used when handling hazardous biological materials, due to any aerosol produced from the work zone will be discharged towards the operator and into the environment. They are only suitable for aseptic processing of benign products.

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.

The methods of test provide a baseline for safe cabinet performance at the users place of work. Applying a practical approach, independent of any manufacturers recommendation allows for uniformity in any BSC. It enables regular six month or annual cabinet adjustment to a set of defined operational values that ensures safety and conformance. These tests can be conducted on any device manufactured in accordance with these, and comparable standards, in any location in the world and provides the user with a pass or fail conformance certificate immediately following completion of the tests.

In comparison standards such as NSF and EN depend heavily upon manufacturers data and a type test completed on the product design. NSF will list manufacturers data for compliant models for on-site testing and calibration purposes. If the model isn't listed, then the model may not conform and no default measurement exists to validate the equipment effectively in the user's working environment. EN applies the same methodology with reliance on manufacturers data although EN only administers product conformance within the EU. The EU takes no responsibility for products manufactured outside the EU which are labelled or sold to an EN standard, whereby applying the Australian Standard will eliminate uncertainty.

Annual conformance product certification to AS 1807 assists in the reduction in cross contamination and improves workplace safety for users and maintenance personnel. This test can be conducted on any manufacturers BSC and in any location in the world. Completion of the test will provide users with a pass/fail conformance certificate using the same set of defined operational criteria. Suitably trained accredited service agents can be engaged for competency in carrying out the various BSC test methods.

Products exhibiting conformance to this document should be factory tested prior to sale to the market, and capable of adjustment and regular annual service accreditation to AS 1807. A manufacturer is a person or business that makes or assembles products, or has their name on the product. For the purposes of this document, the importer (seller) is referred to as the manufacturer and conducts factory testing in accordance with these Standards if the overseas manufacturer of the product does not have an office in Australia.

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