Australian/New Zealand Standard™

Biological safety cabinets—Installation and use

Standards Australia

STANDARDS NEW ZEALAND

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee ME/60, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 29 February 2000 and on behalf of the Council of Standards New Zealand on 25 February 2000. It was published on 15 March 2000.

The following interests are represented on Committee ME/60:

Air-Conditioning & Refrigeration Equipment Manufacturers
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—Division of Animal Health
Department of Human Services, Vic.
Medical Industry Association of Australia
Ministry of Health, New Zealand
National Association of Testing Authorities, Australia
N.S.W. Health Department
Society of Hospital Pharmacists of Australia

Additional interests participating in the preparation of this Standard:

Ministry of Agriculture and Forestry, New Zealand

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PREFACE

This Standard was prepared by the Joint Australia/New Zealand Standards Committee ME/60, Controlled Environment to supersede AS 2647—1994, *Biological safety cabinets—Installation and use*.

This Standard provides requirements and recommended practices for the correct installation and use of Classes I and II biological safety cabinets as specified in AS 2252.1, *Biological safety cabinets*, Part 1: *Biological safety cabinets (Class I) for personnel and environment protection* and AS 2252.2, *Biological safety cabinets*, Part 2: *Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection.* Class I and II cabinets provide equal protection for personnel against agents of ordinary, potential or special hazard. Class III cabinets provide protection to personnel against agents of Risk Groups 3 and 4 (see Foreword) or a high level of assurance of product protection and present a special case not presently covered by an Australian or Australian/New Zealand Standard.

The objective of the revision is to update and improve guidance given in regard to procedures used for decontamination of biological safety cabinets and to reflect current technology and policies in the selection and use of cabinets, with editorial amendments to refer to other current Standards and authorities.

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.

CONTENTS

FOREWORD

Surveys of the causes of laboratory-acquired infections have shown that only about 20% of cases followed known accidents with infectious material; for example, from a spillage or from a needle-stick injury. Many of the remaining 80% of these infections were believed to be due to exposure to aerosols of the kind that may be produced from common laboratory operations. Special containment equipment has been designed to protect laboratory workers where there is a risk from exposure to these aerosols.

The objectives in control of biological hazards and contamination are to minimize the potential for exposure of laboratory and support staff to these hazards and to prevent the liberation of micro-organisms or bio-hazardous material from the laboratory into the environment. The term '*containment*' is used in describing the control of such hazards and means that the hazards are to be kept within specified limits.

Primary containment is provided by the use of good microbiological techniques and by the use of appropriate safety equipment. One of the most widely used pieces of such equipment is the biological safety cabinet, the principal device for the containment of aerosols generated in microbiological procedures. Laminar flow clean-air benches are not containment devices and should not be used for work with hazardous biological materials. Biological safety cabinets form the *primary barrier*.

Other barriers are:

(a) *Secondary barriers*

Secondary barriers provide containment in the event of failure of the primary barrier. An example of a secondary barrier is the room (and its support facilities) within which the primary barrier is located.

(b) *Tertiary barriers*

Tertiary barriers are buildings in which the secondary barriers are housed.

(c) *Quaternary barriers*

Quaternary barriers are the geographical sites of buildings constituting the tertiary barriers. An example of a quaternary barrier is an island.

AS/NZS 2243.3, *Safety in laboratories*, Part 3: *Microbiology*, classifies micro-organisms according to the degree of risk, based on their pathogenicity, mode of transmission and host range, the availability of effective preventive measures against infection and the availability of effective treatment. There are similar classifications in Canada and the United Kingdom.

The risk groups are as follows:

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

A micro-organism that is unlikely to cause human, plant or animal disease.

(ii) *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.

(iii) *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.

(iv) *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.

Types of laboratories are also classified in AS/NZS 2243.3, with four containment levels corresponding to the risk groups of micro-organisms.

Biological safety cabinets are divided into three classes. Class I and Class II biological safety cabinets provide a degree of protection against micro-organisms of Risk Groups 2 and 3 where the work may produce significant quantities of aerosols. Class II cabinets also provide a degree of product protection. Class III cabinets are totally enclosed devices to provide a high degree of containment for personnel and environment against the high-risk micro-organisms of Risk Groups 3 and 4. They also provide a high degree of product protection. A Class III cabinet is a closed front, self-contained ventilated cabinet that is operated at negative pressure in relation to the surrounding environment and that provides a higher level of containment for infectious materials. Air enters the cabinet through HEPA filters and is exhausted through two HEPA filters in series to the atmosphere.

The Genetic Manipulation Advisory Committee has published guidelines for working with genetically-manipulated material. Various levels of containment are described for both small-scale and large-scale work. Class I or Class II biological safety cabinets are required where the work produces significant quantities of aerosols.

The user is referred to the following publications:

(A) GENETIC MANIPULATION ADVISORY COMMITTEE. *Guidelines for small scale genetic manipulation work*, Canberra: GMAC, 1998.

(B) GENETIC MANIPULATION ADVISORY COMMITTEE. *Guidelines for large scale genetic manipulation work*, Canberra: GMAC, 1994.

Compliance with this Standard is important in achieving—

(1) protection by the primary barrier of personnel directly engaged in handling infectious materials;

(2) protection of support staff, animals and facilities in the adjacent work environment;

(3) additionally, for Class II cabinets, protection of the product.

Cabinets described in this Standard are self-contained units. If the cabinet exhaust air is connected directly into ventilating, airconditioning or exhaust systems which discharge to the outside atmosphere, the possibility of uncontrollable variations in cabinet airflow, velocity and pressure is introduced.

NOTE: Exhaust arrangements are discussed in Appendix A.

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1 SCOPE

This Standard sets out requirements and recommended practices for the installation, operation, decontamination, maintenance and inspection of the classes of cabinets specified in AS 2252.1 and AS 2252.2. These cabinets form the primary barrier. Safety within secondary and tertiary barriers is the subject of AS/NZS 2243.3 which should be read in conjunction with this document.

NOTE: For work with cytotoxic drugs the user is referred to AS 2567 and AS 4273.

2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard.

AS
1170 Minimum design loads on structures (known as the SAA Loading Code)
1170.2 Part 2: Wind loads

1470 Health and safety at work—Principles and practices

1807 Cleanrooms, workstations, safety cabinets and pharmaceutical isolators—Methods of test (series)

2013 Cleanroom garments
2013.1 Part 1: Product requirements
2013.2 Part 2: Processing and use

2243 Safety in laboratories
2243.4 Part 4: Ionizing radiations
2243.8 Part 8: Fume cupboards

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

2567 Laminar flow cytotoxic drug safety cabinets

4273 Design, installation and use of pharmaceutical isolators

AS/NZS
1715 Selection, use and maintenance of respiratory protective devices

2243 Safety in laboratories
2243.3 Part 3: Microbiology

Exposure standards for atmospheric contaminants in the occupational environment. WorkSafe Australia, [NOHSC:1003(1995)]. Canberra: Australian Government Publishing Service, 1995.

Standards for the uniform scheduling of drugs and poisons No.12. Australian Health Ministers' Advisory Council. Canberra: Australian Government Publishing Service, 1997.