

Australian Standard[®]

**Laminar flow cytotoxic drug safety
cabinets—Installation and use**

This Australian Standard was prepared by Committee ME/60, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 10 February 1994 and published on 11 April 1994.

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Australian Construction Services (Department of Arts and Administrative Services)
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This Standard was issued in draft form for comment as DR 92162.

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**Laminar flow cytotoxic drug safety
cabinets—Installation and use**

First published as AS 2639—1983.
Second edition 1994.

PUBLISHED BY STANDARDS AUSTRALIA
(STANDARDS ASSOCIATION OF AUSTRALIA)
1 THE CRESCENT, HOMEBUSH, NSW 2140

ISBN 0 7262 8831 4

PREFACE

This Standard was prepared by the Joint Australia/New Zealand Standards Committee on Controlled Environment to supersede AS 2639—1983, *Cytotoxic drug safety cabinets—Installation and use*. It satisfies the need for a guide to the installation and use of the cytotoxic drug safety cabinets specified in AS 2567, *Laminar flow cytotoxic drug safety cabinets*.

The Standard recognises four stages of physical containment provided by the following barriers:

- (a) Primary barriers provide immediate containment at the source. In this Standard, the cytotoxic drug safety cabinet is the primary barrier.
- (b) Secondary barriers provide containment in the event of failure of the primary barrier or a spill outside the primary barrier. An example of a secondary barrier is the room (and its support facilities) within which the primary barrier is located.
- (c) Tertiary barriers are buildings in which the secondary barriers are housed.
- (d) Quaternary barriers are the geographical sites for buildings constituting the tertiary barriers. An example of a quaternary barrier is an island.

Further advice and recommendations about practices relating to laminar flow cytotoxic drug safety cabinets may be found in the Therapeutic Goods Administration's Bulletin No. 3. To obtain copies of this bulletin contact the Therapeutic Goods Administration, PO Box 100, Woden, ACT.

This edition is essentially an update reflecting current technology and policies with editorial amendments to refer to other current Standards and authorities.

The terms 'normative' and 'informative' have been used in this Standard 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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FOREWORD

Compliance with this Standard should achieve the following:

- (a) Protection, by the primary barrier created by the laminar flow cytotoxic drug safety cabinet, of all personnel and the environment from drug aerosols, particles or vapours which may be liberated in the manipulation, preparation and dispensing of cytotoxic drugs.
- (b) Protection of personnel engaged in mechanical maintenance from exposure to the build-up of drug particles which contaminate filters and mechanical components.
- (c) Provision of a secondary barrier in the form of a room set aside exclusively for housing the cabinet.
- (d) Enhancement of asepsis and product containment within the secondary barrier.
- (e) Protection of the surrounding environment and of those personnel not involved in the preparation and use of these drugs.

Cabinet installations, which provide a lesser degree of environmental and containment control than that specified in this document, may not provide an adequate level of protection for personnel and drug products. In particular, the air barrier at the cabinet work opening is vulnerable to disruption by air movements produced by personnel near the cabinet, room ventilation systems, and the opening and closing of doors. Such air movements can cause temporary failure of the cabinet to contain aerosols of drug products. Additionally, operation of the cabinet in a room which does not provide Class 350 air cleanliness may result in premature blockage of the cabinet exhaust filter and a reduced level of personnel and product protection.

The Australian concept of cabinets which operate independently of other air-handling systems is in contrast to that of some other countries, where the cabinet exhaust may be directly connected to a ducted system that discharges to atmosphere. However, direct connection in this way can allow the exhaust system to influence cabinet airflows, with consequent failure of air barrier containment. This Standard specifies a means of entraining cabinet exhaust air into the room exhaust system without a direct connection, thereby minimizing any external influence on cabinet performance.

STANDARDS AUSTRALIA

Australian Standard

Laminar flow cytotoxic drug safety cabinets—Installation and use

1 SCOPE This Standard sets out recommended practices for the installation, operation, maintenance, decontamination and inspection of open-fronted laminar flow cytotoxic drug safety cabinets as specified in AS 2567.

NOTE: Although the cabinets are intended specifically for handling injectable cytotoxic drugs, they may have wider application in the handling of other hazardous drugs and materials. These applications may require additional precautions.

2 REFERENCED DOCUMENTS The following documents are referred to in this Standard:

AS

- 1324 Air filters for use in air conditioning and general ventilation
- 1339 Code of practice for manual handling of materials
- 1386 Cleanrooms and clean workstations
 - 1386.1 Part 1: Principles of clean space control
 - 1386.3 Part 3: Non-laminar flow cleanrooms—Class 350 and cleaner
- 1470 Health and safety at work—Principles and practices
- 1807 Cleanrooms, workstations and safety cabinets—Methods of test
- 1837 Ergonomics in factory and office work
- 2013 Cleanroom garments
 - 2013.1 Part 1: Product requirements
- 2567 Laminar flow cytotoxic drug safety cabinets

3 TERTIARY BARRIER Consideration shall be given to the design or choice of the building, with due regard being given to the requirements of the secondary barrier and the intended processes.

4 SECONDARY BARRIER

4.1 General The secondary barrier shall be a cleanroom set aside exclusively for housing the cytotoxic cabinet.

This room shall be designed to facilitate asepsis in the handling and preparation of cytotoxic drugs. The room shall also be designed to provide containment of cytotoxic drugs particularly in the event of the failure of the cytotoxic drug safety cabinet or a spillage outside the cabinet. A suitable arrangement of the room is shown in Figure 1.

4.2 Asepsis To facilitate asepsis, the room housing the cytotoxic drug safety cabinet shall be a Class 350 cleanroom in accordance with AS 1386.3 as varied by the requirements of this Standard.

Asepsis is facilitated by the following:

- (a) The maintenance of pressure differentials between the room and the anteroom, and the anteroom and the adjacent areas which minimizes the passage of air and hence airborne particulate matter from the adjacent areas into the room.