AS 2567—1982
UDC 615.012:331.82:614.44:542.2

Australian Standard 2567—1982

CYTOTOXIC DRUG SAFETY CABINETS

STANDARDS ASSOCIATION OF AUSTRALIA
Incorporated by Royal Charter

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This Australian standard was prepared by Committee MS/28, Controlled Environment. It was approved on behalf of the Council of the Standards Association of Australia on 13 July 1982 and published on 8 November 1982.

The following interests were represented on the committee responsible for 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 New South Wales

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

This standard was issued in draft form for comment as DR 81241.

AUSTRALIAN STANDARD

CYTOTOXIC DRUG SAFETY CABINETS

AS 2567—1982

First published 1982

PUBLISHED BY THE STANDARDS ASSOCIATION OF AUSTRALIA
STANDARDS HOUSE, 80 ARTHUR ST, NORTH SYDNEY, N.S.W.

ISBN 0 7262 2689 0

PREFACE

This standard was prepared by the Association's Committee on Controlled Environment, to satisfy a need for a standard for a laminar flow safety cabinet for personnel and product protection in the preparation, manipulation and dispensing of cytotoxic drugs, and which would overcome the problems associated with decontamination.

Its preparation was undertaken following representations from the National Biological Standards Laboratory.

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

Appendix B, Procedures for Post-installation Inspection and Testing, is provided as an interim measure pending the issue of AS XXXX.*

*AS XXXX, Cytotoxic Drug Safety Cabinets—Installation and Use (in course of preparation).

CONTENTS

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Australian Standard
for
CYTOTOXIC DRUG SAFETY CABINETS

FOREWORD

The influx of new cytotoxic drugs has introduced special problems in their preparation, manipulation and dispensing.

Many of these drugs are known to be mutagens and are suspected of being carcinogens and teratogens. The effects are insidious as they may not manifest themselves for some years.

The requirements are threefold, viz—

(a) protection of all personnel and the environment from any aerosol, particles or vapours which may be liberated in the preparation, manipulation, and dispensing of cytotoxic drugs;

(b) protection of drug products so that they may be prepared or dispensed in an environment essentially free from particulate (including biological) matter;

(c) protection of maintenance personnel engaged in routine testing, component replacement and/or repair from the build-up of drug particles which contaminate filters and mechanical components.

It has been the practice in hospital pharmacies to dispense cytotoxic drugs in clean work-stations complying with AS 1386. This practice has been identified as being hazardous as aerosols of cytotoxic drugs generated during this procedure are directed towards the operator. The use of laminar flow biological safety cabinets complying with AS 2252, Part 2 provides operator and product protection but transfers the hazard to maintenance personnel.

SPECIFICATION

1 SCOPE. This standard specifies requirements for a laminar flow cytotoxic drug safety cabinet which is intended to provide protection for all personnel against exposure to cytotoxic drugs and for the product and/or experiment against contamination.

NOTE: Although the cabinet is designed specifically for cytotoxic drugs, it may be used for other drugs and chemicals requiring both containment and aseptic manipulation.

Procedures for post-installation inspection and testing are described in Appendix B.

2 REFERENCED DOCUMENTS. The following standards are referred to in this standard:

AS 1217	Methods of Measurement of Airborne Sound Emitted by Machines
AS 1319	Safety Signs for the Occupational Environment
AS 1324	Air Filters for use in Air Conditioning and General Ventilation
AS 1386	Cleanrooms and Work-stations
AS 1449	Wrought Alloy Steels—Stainless and Heat-resisting Steel Plate, Sheet and Strip
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 1939	Classification of Degrees of Protection Provided by Enclosures for Electrical Equipment
AS 2243	Code of Practice for Safety in Laboratories Part 7—Electrical Aspects
AS 2252	Biological Safety Cabinets Part 2—Laminar Flow Biological Safety Cabinets (Class II) for Personnel and Product Protection
AS 3100	Approval and Test Specification for Definitions and General Requirements for Electrical Materials and Equipment
AS XXXX	Cytotoxic Drug Safety Cabinets—Installation and Use*

3 GENERAL REQUIREMENTS. A laminar flow cytotoxic drug safety cabinet shall comply with the following general requirements (see Figs 1 and 2):

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

(b) It shall not be directly connected to any other air-handling system.

(c) The working face of the enclosure shall include a viewing window and a work access opening (see Fig. 1). Air shall pass into 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 activated carbon filter.

The combination of barrier air and laminar flow air shall pass from beneath the work floor through an exhaust HEPA filter to the lower plenum, then to the upper plenum for partial exhausting and partial recirculation.

(d) The exhaust air outlet may face horizontally or vertically as specified by the purchaser (see Appendix A, Paragraph A2.1(b)). However, the installation shall allow for a clearance of not less than 600 mm in the direction of discharge except when the cabinet exhaust discharges towards a room exhaust system. In this case, clearance in the direction of discharge shall be reduced to 200 mm.

An activated carbon filter shall be fitted to the exhaust opening to remove volatile agents.

(e) To reduce potentially hazardous maintenance procedures, motor(s) and blower(s) shall be installed downstream of the exhaust HEPA filter through which the barrier air and laminar flow air is initially passed.

(f) To contain potentially hazardous materials within the cabinet, all potentially contaminated zones shall be under a negative pressure relative to the surrounding room.

All zones under positive pressure shall be surrounded by zones under negative pressure relative to the surrounding room atmosphere.

(g) All filter seals which may come into contact with potentially hazardous materials shall be under negative pressure in respect to non-contaminated zones, so that any air by-passing the seal flows inwards to the contaminated zone.

(h) Where reticulated pipe services are connected to the unit, suitable measures shall be taken to provide biological/chemical isolation.

NOTE: The use of gas is not recommended.

4 CONSTRUCTION REQUIREMENTS (See Fig. 1).

4.1 Outer Shell. The outer shell shall be of metal, impervious to chemical penetration and sufficiently robust to prevent fracture in transport, installation and operation.

*In course of preparation.