AS 2252.5:2017

Australian STANDARD

Controlled environments

Part 5: Cytotoxic drug safety cabinets (CDSC)—Design, construction, installation, testing and use

STANDARDS Australia

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- Air Conditioning and Refrigeration Equipment Manufacturers Association of Australia
- Australian Chamber of Commerce and Industry
- Australian Industry Group
- Australian Institute of Refrigeration Air Conditioning and Heating
- CSIRO Australian Animal Health Laboratory
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- International Society for Pharmaceutical Engineering
- Office of the Gene Technology Regulator
- Medical Technology Association of Australia
- National Association of Testing Authorities Australia
- NSW Ministry of Health
- Society of Hospital Pharmacists of Australia
- Therapeutic Goods Administration

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Controlled environments

Part 5: Cytotoxic drug safety cabinets (CDSC)—Design, construction, installation, testing and use

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PREFACE

This Standard was prepared by the Australian members of Joint Australia/New Zealand Standards Committee ME-060, Controlled Environments, to supersede AS 2567—2002, *Laminar flow cytotoxic drug safety cabinets*, and AS 2639—1994, *Laminar flow cytotoxic drug safety cabinets—Installation and use*.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this Standard is to specify the basic requirements for cytotoxic drug safety cabinet (CDSC) design, construction, installation, testing and use.

A cytotoxic drug safety cabinet (CDSC) is designed to provide both an aseptic environment and containment of cytotoxic materials. However, in order to provide these conditions, the unit requires assistance from a network of specially designed cleanrooms. AS 2567 and AS 2639 are therefore being combined.

This Standard is Part 5 of the AS 2252 series on controlled environments. When the revisions of AS 2252.1—2002 and AS 4273—1999 (to be AS 2252.7) are completed, the series will comprise the following:

AS		
2252		Controlled environments
2252.1	Part 1:	Biological safety cabinets Class I—Design
2252.2	Part 2:	Biological safety cabinets Class II—Design
2252.3	Part 3:	Biological safety cabinets Class III—Design
2252.4	Part 4:	Biological safety cabinets Class I and II—Installation and use (BS 5726:2005, MOD)
2252.5	Part 5:	Cytotoxic drug safety cabinets—Design, construction, installation, testing and use (this Standard)
2252.6	Part 6:	Clean workstations—Design, installation and use
2252.7	Part 7:	Pharmaceutical isolators—Design, installation and use

Compliance with an Australian Standard does not of itself confer immunity from legal obligations.

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

The use of cytotoxic drugs creates special problems in their preparation, manipulation and compounding. Many have been demonstrated to be mutagens and some to be carcinogens or teratogens in cell DNA and chromosomal studies, in animal models, and from experience with treated patients.

Some effects of exposure to these compounds may not manifest themselves for many years.

The aim of this Standard is to provide the following:

(a) Protection of personnel and the immediate surrounding environment from aerosols, particles or vapours, which may be liberated in the preparation, manipulation, and compounding of hazardous products.

(b) Protection of products so that they can be manipulated or compounded aseptically in a clean, controlled environment.

(c) Protection of maintenance and testing personnel from exposure to toxic materials that may be found in cabinet filters and internal cabinet surfaces.

This Standard aims to provide mechanisms that form an integral part of an overall risk based approach that will provide a risk level that is as low as is reasonably achievable (ALARA) when cytotoxic materials are exposed within a CDSC.

As defined by AS 2252.1 and AS 2252.2, Class I and Class II biological safety cabinets are unsuitable for handling cytotoxic materials that are not inactivated by routine decontamination. In addition, Connor, T.H., Anderson, R.W., Sessink, P.J., Broadfield, L. and Power, L.A., ‘Surface contamination with antineoplastic agents in six cancer treatment centres in Canada and the United States’, *Am J Health Pharm*, July 1 1999, Vol. 56, No. 14, pp. 1427–1432, demonstrated that when cytotoxic drugs were compounded in Class II biological safety cabinets the exhaust HEPA filters alone did not totally arrest all cytotoxic drug residues released as aerosols within the work zone. Some drugs in regular clinical use, such as Cyclophosphamide, have the potential to sublime into the vapour phase, pass through the sump HEPA filter and potentially condense as solid drug films on surfaces within and surrounding the cabinet.

STANDARDS AUSTRALIA

Australian Standard
Controlled environments

Part 5: Cytotoxic drug safety cabinets (CDSC)—Design, construction, installation, testing and use

1 SCOPE

This Standard specifies the basic requirements for cytotoxic drug safety cabinet (CDSC) design, construction, installation, testing and use. In addition, this Standard provides design requirements for the surrounding environment in which the CDSC is located and its installation.

2 APPLICATION

These are open-fronted safety cabinets which are primarily designed to be used with substances that are incapable of gaseous inactivation. The design of the CDSC provides greater protection to maintenance personnel than is possible with a Class II biological safety cabinet. CDSC design provides protection to the operator via an air barrier provided by an inward flow of air, protection to the product via a top-mounted fan and HEPA filter that provides clean, unidirectional air to the work zone of the cabinet and protection of maintenance personnel by a HEPA filter under the work zone that protects the cabinet internals from contamination.

A CDSC is designed to provide both an aseptic environment and containment of cytotoxic materials. It should be noted however that not all processes that occur within a CDSC are aseptic, such as work with prions (as specified in AS 2243.3) or other non-sterile processes where cytotoxic materials are potentially exposed.

NOTE: Appendix C deals with the use of CDSC with prions in microbiological containment laboratories.

Further to this, some processes will require regulation by local or national health authorities which may require additional testing, monitoring or enhanced design features.

Due to the broad range of processes and rapidly evolving technologies that incorporate a CDSC, this standard does not provide any guidance on any actual activity in a CDSC, with the exception of general housekeeping, cleaning, maintenance and spill management.

The superseded CDSC standards (AS 2567 and AS 2639) have mandated that the exhaust of the CDSC be passed through a carbon filter in order to capture any cytotoxic materials in a gaseous form. There is no doubt that some cytotoxic materials do volatize, however, the level of risk that they can later condense on surfaces outside the cabinet, such as the room or exhaust ducting, cannot be determined. As a result the committee has decided that a carbon filter on the exhaust is still compulsory and is to be used in conjunction with a facility set up where the discharge of the cabinet is exhausted completely and immediately out of the room.

NOTES:

1 While providing protection from aerosols, a CDSC on its own is not capable of providing complete protection against gases and vapours that may be produced during compounding procedures. Gases produced by volatilized substances may be able to migrate through the cabinet HEPA filters and be discharged from the cabinet. Use of a CDSC with a carbon filter on its exhaust, operating in a cleanroom and discharging to a dedicated exhaust extraction system close to the cabinet is the most effective method to counter this problem.