



Controlled environments

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



This Australian Standard® was prepared by Committee ME-060, Controlled Environments. It was approved on behalf of the Council of Standards Australia on 12 July 2017. This Standard was published on 27 July 2017.

The following are represented on Committee ME-060:

- 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
 - Engineers Australia
 - Human Factors and Ergonomics Society of Australia
 - 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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This Standard was issued in draft form for comment as DR2 AS 2252.5:2015.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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AS 2252.5:2017

Australian Standard®

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

Originated as AS 2567—2002 and AS 2639—1994.
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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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