

Australian Standard[®]

Controlled environments

**Part 3: Biological safety cabinets
Class III—Design**

STANDARDS
Australia



This Australian Standard® was prepared by Committee ME-060, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 15 June 2011. This Standard was published on 29 June 2011.

The following are represented on Committee ME-060:

- Airconditioning & Refrigeration Equipment Manufacturers Association of Australia
 - Auckland Regional Chambers of Commerce
 - Australian Chamber of Commerce and Industry
 - Australian Institute of Refrigeration Air Conditioning and Heating
 - Australian Society for Microbiology
 - CSIRO Australian Animal Health Laboratory
 - Commonwealth Department of Health and Ageing
 - Engineers Australia
 - Human Factors and Ergonomics Society of Australia
 - International Society for Pharmaceutical Engineering
 - Ministry of Agriculture and Forestry New Zealand
 - NSW Health Department
 - National Association of Testing Authorities Australia
 - Office of the Gene Technology Regulator
 - Therapeutic Goods Administration
-

This Standard was issued in draft form for comment as DR AS 2252.3.

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.

Keeping Standards up-to-date

Australian Standards® are living documents that reflect progress in science, technology and systems. To remain in their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued.

Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments that may have been published since the Standard was published.

Detailed information about Australian Standards, drafts, amendments and new projects can be found by visiting www.standards.org.au

Standards Australia welcomes suggestions for improvements, and encourages readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.org.au, or write to Standards Australia, GPO Box 476, Sydney, NSW 2001.

Australian Standard[®]

Controlled environments

**Part 3: Biological safety cabinets
Class III—Design**

First published as AS 2252.3—2011.

COPYRIGHT

© Standards Australia Limited

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of the publisher, unless otherwise permitted under the Copyright Act 1968.

Published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 0 7337 9880 1

PREFACE

This Standard was prepared by the Standards Australia Committee ME-060, Controlled Environment.

The objective of this Standard is to set the minimum performance criteria for safety cabinets for work with micro-organisms and specifies test procedures for microbiological safety cabinets with respect to protection of the worker and the environment, product prevention and cross contamination.

This Standard is identical with, and has been reproduced from EN 12469:2000, *Biotechnology—Performance criteria for microbiological safety cabinets*, while giving due regard to local differences in mechanical and electrical regulations and related standards.

This Standard should be considered only for Class III biological safety cabinets, as this one. It is the intention of the Committee to obtain feedback for consideration and adoption of EN 12469:2000 in its entirety.

As this Standard is reproduced from a European Standard, the following applies:

- (a) Its number appears on the cover and title page while the European Standard number appears only on the cover.
- (b) In the source text ‘this European Standard’ should read ‘this Interim Australian Standard’.
- (c) A full point substitutes for a comma when referring to a decimal marker.

References to European Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard</i>		<i>Australian Standard</i>	
EN		AS	
1822	High efficiency air filters (HEPA and ULPA)	4260	High efficiency particulate air (HEPA) filters—Classification, construction and performance
1822-1	Part 1: Classification, performance testing, marking		
12296	Biotechnology—Equipment—Guidance on testing procedures for cleanability	—	
12297	Biotechnology—Equipment—Guidance on testing procedures for sterilizability	—	
12298	Biotechnology—Equipment—Guidance on testing procedures for leaktightness	—	
15821	Biotechnology—Performance criteria for filter elements and filtration assemblies	4260	High efficiency particulate air (HEPA) filters—Classification, construction and performance

The terms ‘normative’ and ‘informative’ are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

CONTENTS

	<i>Page</i>
Introduction	4
1 Scope	4
2 Normative references	4
3 Definitions	5
4 Hazards	6
5 Performance classes	6
7 Safety requirements	12
8 Marking and packaging	13
9 Documentation	14
Annex A (informative) Guidance on materials, design and manufacture	15
Annex B (normative) Test method for leakage of containers for class I and II MSCs	18
Annex C (normative) Test methods for the retention efficiency at the front aperture	19
Annex D (informative) Aerosol challenge test method for installed HEPA filter system leakage detection	30
Annex E (normative) Test method for product protection for class II MSCs	32
Annex F (normative) Test method for cross contamination protection for class II MSCs	34
Annex G (informative) Method of measurement of volumetric airflow rate	36
Annex H (informative) Design of MSCs and airflow velocities in MSCs	38
Annex J (informative) Recommendations for decontamination, cleaning and fumigation of MSCs and filters	40
Annex K (informative) Recommendations for routine maintenance of MSCs	42
Bibliography	44

AUSTRALIAN STANDARD

Controlled environments

Part 3:

Biological safety cabinets Class III—Design

Introduction

Microbiological safety cabinets are intended to reduce the risk to the operator when handling hazardous or potentially hazardous micro-organisms. They do not necessarily protect the operator from all hazards involved. Some types of safety cabinet can also protect the materials being handled in them from environmental contamination.

1 Scope

This European Standard specifies basic requirements for microbiological safety cabinets (MSCs) with respect to safety and hygiene.

This European Standard sets the minimum performance criteria for safety cabinets for work with micro-organisms and specifies test procedures for microbiological safety cabinets with respect to protection of the worker and the environment, product protection and cross contamination. Mechanical, electrical, chemical or radioactive safety precautions are not covered in the standard but are covered in EN 61010-1, EN 292-1 and EN 292-2 (see Bibliography [1], [2] and [3]).

This European Standard does not cover safety precautions for aspects not associated with the use of micro-organisms such as those covering mechanical and electrical hazards, which are covered in EN 61010-1 (see Bibliography [1]), nor does it cover safety requirements regarding flammable gas and inert gases.

NOTE Some features of MSCs in addition to those for performance and safety are given for guidance in this European Standard and in EN 12741 (see Bibliography [4]).

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of the cited publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 182-1	High efficiency air filters (HEPA and ULPA) - Part 1: Classification, performance testing, marking
EN 12296	Biotechnology - Equipment - Guidance on testing procedures for cleanability
EN 12297	Biotechnology - Equipment - Guidance on testing procedures for sterilizability
EN 12298	Biotechnology - Equipment - Guidance on testing procedures for leaktightness
EN 13091:1999	Biotechnology - Performance criteria for filter elements and filtration assemblies