

AS 4273—1999
(Incorporating Amendment No. 1)

AS 4273

Australian Standard™

**Design, installation and use of
pharmaceutical isolators**

This Australian Standard was prepared by Committee ME/60, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 31 December 1998 and published on 5 March 1999.

The following interests are represented on Committee ME/60:

Air-Conditioning & Refrigeration Equipment Manufacturers
Auckland Regional Chamber of Commerce
Australian Chamber of Commerce and Industry
Australian Contamination Control Society
Australian Industry Group
Australian Institute of Refrigeration Air Conditioning and Heating
Australian Pharmaceutical Manufacturers Association
Australian Society for Microbiology
Commonwealth Department of Health and Family Services
CSIRO—Division of Animal Health
Department of Human Services, Vic.
Medical Industry Association of Australia
Ministry of Health, New Zealand
National Association of Testing Authorities Australia
N.S.W. Health Department
Society of Hospital Pharmacists of Australia

Keeping Standards up-to-date

Standards are living documents which reflect progress in science, technology and systems. To maintain 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 Standards may also be withdrawn.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 which may have been published since the Standard was purchased.

Detailed information about Standards can be found by visiting the Standards Australia web site at www.standards.com.au and looking up the relevant Standard in the on-line catalogue.

Alternatively, the printed Catalogue provides information current at 1 January each year, and the monthly magazine, *The Australian Standard*, has a full listing of revisions and amendments published each month.

We also welcome suggestions for the improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.com.au, or write to the Chief Executive, Standards Australia International Ltd, PO Box 1055, Strathfield, NSW 2135.

This Standard was issued in draft form for comment as DR 98018.

AS 4273—1999
(Incorporating Amendment No. 1)

Australian Standard™

**Design, installation and use of
pharmaceutical isolators**

Originated as AS/NZS 4273(Int):1995.
Revised and designated AS 4273—1999.
Reissued incorporating Amendment No. 1 (May 2000).

COPYRIGHT

© Standards Australia International

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.

Published by Standards Australia International Ltd
PO Box 1055, Strathfield, NSW 2135, Australia
ISBN 0 7337 2510 4

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee ME/60, Controlled Environment to supersede AS/NZS 4273(Int):1995, *Guidelines for the design, installation and use of pharmaceutical isolators*. This Standard is the result of a consensus among representatives on the Joint Committee to produce it as an Australian Standard.

This Standard incorporates Amendment No. 1 (May 2000). The changes required by the Amendments are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure, or part thereof affected.

This Standard provides design requirements and guidance for the construction of pharmaceutical isolators, recommendations for the environment in which they are to be used, performance requirements and guidance on their installation and use. Possible uses of isolators include the preparation of products which require a high level of assurance of protection from contamination and the preparation of products which are agents presenting a potential hazard to the operator and the environment.

This document has its origins in one prepared by a working party formed by the Regional Quality Control Pharmacists Subcommittee of the Regional Pharmaceutical Offices (UK). Permission to utilize this document is gratefully acknowledged.

The term 'informative' has been used in this Standard to define the application of the appendix to which it applies. An 'informative' appendix is only for information and guidance.

CONTENTS

	<i>Page</i>
FOREWORD	4
1 SCOPE	5
2 OBJECTIVE	5
3 REFERENCED DOCUMENTS	5
4 DEFINITIONS	6
5 DESIGN PRINCIPLES	7
6 PERFORMANCE	9
7 LABELLING	9
8 SITING OF ISOLATORS	9
9 PHYSICAL, OPERATOR AND ENVIRONMENTAL CONTROL AND MONITORING	10
APPENDICES	
A PURCHASER-SUPPLIER LIAISON	17
B STATUTORY AUTHORITIES FOR RADIATION SAFETY	18
C GUIDELINES FOR OPERATOR TRAINING	20
D GLOVES AND GAUNTLETS	21
E SUMMARY CERTIFICATE OF COMMISSIONING AND ROUTINE RECERTIFICATION TO AS 4273	22

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
 - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-