

Australian/New Zealand Standard™

Cleanrooms and associated controlled environments

Part 4: Design, construction and start-up

AS/NZS ISO 14644.4:2002

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee ME-060, Controlled Environment. It was approved on behalf of the Council of Standards Australia on 31 May 2002 and on behalf of the Council of Standards New Zealand on 23 May 2002. It was published on 10 July 2002.

The following are represented on Committee ME-060:

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 of Microbiology
CSIRO Australian Animal Health Laboratory
Commonwealth Department of Health and Aged Care
Medical Industry Association of Australia
N.S.W. Health Department
National Association of Testing Authorities
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 Standards may also be withdrawn.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 joint Australian/New Zealand Standards can be found by visiting the Standards Australia web site at www.standards.com.au or Standards New Zealand web site at www.standards.co.nz and looking up the relevant Standard in the on-line catalogue.

Alternatively, both organizations publish an annual printed Catalogue with full details of all current Standards. For more frequent listings or notification of revisions, amendments and withdrawals, Standards Australia and Standards New Zealand offer a number of update options. For information about these services, users should contact their respective national Standards organization.

We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia International or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR 02031.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

RECONFIRMATION

OF

AS/NZS ISO 14644.4:2002

**Cleanrooms and associated controlled environments
Part 4: Design, construction and start-up**

RECONFIRMATION NOTICE

Technical Committee ME-060 has reviewed the content of this publication and in accordance with Standards Australia procedures for reconfirmation, it has been determined that the publication is still valid and does not require change.

Certain documents referenced in the publication may have been amended since the original date of publication. Users are advised to ensure that they are using the latest versions of such documents as appropriate, unless advised otherwise in this Reconfirmation Notice.

Approved for reconfirmation in accordance with Standards Australia procedures for reconfirmation on 23 December 2015.

Approved for reconfirmation in New Zealand on behalf of the Standards Council of New Zealand on 18 May 2016.

The following are represented on Technical Committee ME-060:

Airconditioning & Refrigeration Equipment Manufacturers Association of Australia
Auckland Regional Chamber of Commerce
Australian Chamber of Commerce and Industry
Australian Industry Group
CSIRO
Engineers Australia
Human Factors & Ergonomics Society of Australia
International Society for Pharmaceutical Engineering
Medical Technology Association of Australia
National Association of Testing Authorities Australia
NSW Health
Society of Hospital Pharmacists of Australia
Therapeutic Goods Administration

This is a free 7 page sample. Access the full version online.

NOTES

Australian/New Zealand Standard™

Cleanrooms and associated controlled environments

Part 4: Design, construction and start-up

Originated as part of AS 1386—1976 and AS 1387—1976.
Previous editions AS 1386.1—1989, AS 1386.2—1989,
AS 1386.3—1989 and AS 1386.4—1989.
AS 1386.1—1989, AS 1386.2—1989, AS 1386.3—1989 and
AS 1386.4—1989 jointly revised, amalgamated and
redesignated as AS/NZS ISO 14644.4:2002.

COPYRIGHT

© Standards Australia/Standards New Zealand

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.

Jointly published by Standards Australia International Ltd, GPO Box 5420, Sydney, NSW 2001 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 4611 X

PREFACE

This Standard was prepared by the Joint Australia/New Zealand Committee ME-060, Controlled Environment.

This Standard is identical with and has been reproduced from ISO 14644-4:2001, *Cleanrooms and associated controlled environments, Part 4: Design, construction and start-up*. It is part of a series of Joint Australian/New Zealand Standards that will supersede in part the AS 1386 series titled *Cleanrooms and clean workstations*.

It is expected that a guide will be published to include informative material from the AS 1386 series that is not covered in the adopted ISO series.

The objective of this Standard is to specify the requirements for the design and construction of cleanroom facilities.

As this Standard is reproduced from an International Standard, the following applies:

- (a) Its number appears on the cover and title page while the International Standard number appears only on the cover.
- (b) In the text, 'this part of ISO 14644' should be read 'this Australian/New Zealand Standard'.
- (c) A full point substitutes for a comma when referring to a decimal marker.

References to international Standards should be replaced by references to the following Australian/New Zealand Standards.*

<i>Reference to International Standards</i>		<i>Australian/New Zealand Standard</i>	
ISO		AS/NZS ISO	
14644	Cleanrooms and associated controlled environments	14644	Cleanrooms and associated controlled environments
14644-1	Part 1: Classification of air cleanliness	14644.1	Part 1: Classification of air cleanliness

* Any international Standards not listed do not have an equivalent Australian/New Zealand Standard.

CONTENTS

1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Requirements	3
5	Planning and design	4
5.1	Planning procedure	4
5.2	Design	5
6	Construction and start-up	5
7	Testing and approval	6
7.1	General	6
7.2	Construction approval	6
7.3	Functional approval	6
7.4	Operational approval	6
8	Documentation	6
8.1	General	6
8.2	Record of an installation	6
8.3	Operational instructions	6
8.4	Instructions for performance monitoring	7
8.5	Maintenance instructions	7
8.6	Maintenance record	7
8.7	Record of operation and maintenance training	8
	Annex A (informative) Control and segregation concepts	9
	Annex B (informative) Classification examples	16
	Annex C (informative) Approval of an installation	19
	Annex D (informative) Layout of an installation	23
	Annex E (informative) Construction and materials	27
	Annex F (informative) Environmental control of cleanrooms	32
	Annex G (informative) Control of air cleanliness	35
	Annex H (informative) Additional specification of requirements to be agreed upon between purchaser/user and designer/supplier	37
	Bibliography	50

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

AS/NZS ISO 14644.4 : 2002 : EN : COMBINED PDF

- ⊙ Looking for additional Standards? Visit SAI Global Infostore
- ⊙ Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation

Need to speak with a Customer Service Representative - Contact Us