

Australian/New Zealand Standard™

Cleanrooms and associated controlled environments

Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000, MOD)

AS/NZS 14644.2:2002

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 16 August 2002 and on behalf of the Council of Standards New Zealand on 20 August 2002. It was published on 25 September 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 Society of Microbiology
CSIRO Livestock Industries
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 Standards may also be withdrawn.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.

Australian/New Zealand Standard™

Cleanrooms and associated controlled environments

Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000, MOD)

First published as AS/NZS 14644.2:2002.

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 4786 8

PREFACE

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

This Standard has been reproduced from ISO 14644-2:2000, *Cleanrooms and associated controlled environments, Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1* with national modifications.

Additional requirements, including a more stringent minimum time frame for pharmaceutical applications within Australia and New Zealand, are given in Appendix ZZ. Margin bars indicate changes to the ISO text.

This Standard is the second in a series of Joint Australian/New Zealand Standards that will supersede, in part, the AS 1386 series titled *Cleanrooms and clean workstations*. The first part, AS/NZS ISO 14644-1, adopted the ISO classification and numbering system for levels of cleanliness, together with its methods for determining the classification.

The optional pharmaceutical tests in Annex A were made mandatory to maximize safety for Australian and New Zealand conditions.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the annex and/or Appendix to which they apply. A ‘normative’ annex and/or Appendix is an integral part of a Standard, whereas an ‘informative’ annex and/or Appendix is only for information and guidance.

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 source text, ‘this ISO Standard’ should read ‘this Australian Standard’.
- (c) A full point substitutes for a comma when referring to a decimal marker.

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

<i>Reference to International Standard</i>		<i>Australian or 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
14644-3	Part 3: Metrology and test method	—	

CONTENTS

Introduction	iv
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 General terms	1
3.2 Terms concerning frequency intervals	2
4 Demonstration of continued compliance	2
4.1 Principle	2
4.2 Testing for continued compliance	2
4.3 Monitoring	4
4.4 Documentation	4
4.5 Records	5
Annex A (informative) Optional tests	6
Annex B (informative) Guidance on the influence of risk assessment on cleanroom or clean zone tests and monitoring	7

INTRODUCTION

This part of ISO 14644 provides a process to prove continued compliance with ISO 14644-1 and specifies minimum requirements for testing and monitoring. In any testing plan, consideration should also be given to the particular operational requirements, risk assessment of the installation, and its use.

Cleanrooms and associated controlled environments provide for the control of airborne particulate contamination to levels appropriate for accomplishing contamination-sensitive activities. Products and processes that benefit from the control of airborne contamination include aerospace, microelectronics, pharmaceuticals, medical devices, healthcare, food and others. Many factors besides airborne particulate cleanliness should be considered in the design, specification, operation and control of cleanrooms and other controlled environments.

In some circumstances, relevant regulatory agencies may impose supplementary policies or restrictions. In such situations, appropriate adaptations of the standard testing procedures may be required.

AUSTRALIAN/NEW ZEALAND STANDARD

Cleanrooms and associated controlled environment

Part 2:

Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000, MOD)

1 Scope

This part of ISO 14644 specifies requirements for periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

These requirements invoke the test described in ISO 14644-1 for classification of a cleanroom or clean zone. Additional tests are also specified, to be carried out in accordance with the requirements of this part of ISO 14644. Optional tests, to be applied at the user's discretion, are also identified.

This part of ISO 14644 also specifies requirements for monitoring of a cleanroom or clean zone (hereafter referred to as an installation) to provide evidence of its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

2 Normative references

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 14644. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14644 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*.

ISO 14644-3:—¹⁾, *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods*.

3 Terms and definitions

For the purposes of this part of ISO 14644, the terms and definitions given in ISO 14644-1 and the following apply.

3.1 General terms

3.1.1

requalification

execution of the test sequence specified for the installation to demonstrate compliance with ISO 14644-1 according to the classification of the installation, including the verification of the selected pre-test conditions

1) To be published.