AS 4273—1999
(Incorporating Amendment No. 1)

Australian Standard™

Design, installation and use of pharmaceutical isolators

Standards Australia

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

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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.

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