AS 4273—1999
(Incorporating Amendment No. 1)

Australian Standard™

Design, installation and use of pharmaceutical isolators

Standards Australia

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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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FOREWORD

Pharmaceutical isolators are designed to allow individual aseptic transfers to be conducted in a Class 3.5 environment without direct access by the operator and without contact with their external environment. Pharmaceutical isolators potentially provide the equivalent of a laminar flow cabinet operating within a controlled secondary environment. Thus they remove the need for operators to wear sterile cleanroom garments and introduce the possibility of a lower standard of environment in the room in which the device is sited.

Type 1 Pharmaceutical isolators are designed primarily for protection of the product, for example sterile infusions. Type 2 Pharmaceutical isolators are designed for protection of the product, such as cytotoxic drug injections, but are also intended to provide protection—

(a) to the operator;

(b) to the environment; and

(c) to isolator service personnel to an extent equivalent to that provided by devices complying with AS 2567, *Laminar flow cytotoxic drug safety cabinets*.

The type of isolator, the class of transfer device and the intended application will influence the degree of cleanness of the background environment in which the isolator should be located. This Standard addresses this issue. In addition, when selecting or designing, locating, installing and using an isolator, consideration should be given to safety aspects of the handling of starting materials and components, surface disinfection of components and disposal of waste generated during use. The vendor should classify the isolator according to type and the purchaser should locate it according to end use.

The major advantage of isolators is that they constitute a self-contained working environment with annexed transfer facilities. Another advantage is that they can be custom-built for a defined purpose or service. Customization can include variations in size, configuration, materials of construction, inbuilt devices, air flows and pressure differentials. For this reason a highly detailed specification for their construction is impractical and would be restrictive. The present Standard therefore avoids this detail.