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Aseptic processing of health care products —

Part 6: Isolator systems

Traitement aseptique des produits de santé —

Partie 6: Systèmes isolateurs

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Contents

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 13408-6:2005), which has been technically revised. It also incorporates the Amendment ISO 13408-6:2005/Amd.1:2013. The main changes compared to the previous edition are as follows:

— changes to the Introduction;

— changes to the Scope;

— addition of the new Clause 5 "Basic principle of Isolator system";

— addition of risk management approach in Clause 6 "Isolator system specification";

— addition of new informative Annex A "Devices acting as transfer ports for portable and mobile equipment";

— addition of new informative Annex B "Isolator system – Explanation of terms used and flow of air and material";

— addition of new informative Annex C "Isolator system – Direct/indirect product contact surfaces "

A list of all parts in the ISO 13408 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A health care product that is labelled “sterile” is manufactured using suitably designed, validated and controlled processes. Wherever possible, it is terminally sterilized in its final, sealed container. When this is not possible, the product is aseptically processed.

Aseptic processing is an exacting and demanding discipline designed to maintain sterility through all stages of preparation, manufacturing, filling and sealing in final containers. It relies on a number of independent factors for prevention of recontamination of previously sterilized components during the assembly or filling of product into a final container.

An effective risk management system addressing aseptic processing design (including the use of barrier separation technology), validation and control, and which identifies, assesses, eliminates (where applicable) and controls contamination risks is a prerequisite to provide assurance of sterility for aseptically processed product.

Various separation systems exist to protect the critical processing zone of an aseptic processing area from non-viable particulate and microbiological contamination and to separate process operators from the critical processing zone.

These systems range from controlled airflow devices based on aerodynamic protection through to separation barriers that combine physical and aerodynamic protection to separate the external cleanroom environment from the critical processing zone, minimizing exposure of this zone to process operators and thereby reducing the opportunities for contamination during processing.

Isolator systems provide physical separation whilst facilitating operator intervention into the controlled processing environment under barrier conditions typically via sealed glove-sleeve systems that are physically connected with glove-ports to the isolator barrier screen(s). To establish a controlled environment, reduction of viable and non-viable particulates within isolators is achieved by validated and reproducible cleaning and bio-decontamination processes, principally achieved through the use of automated methods.

In addition to control of bio-contamination and non-viable particulates, isolator systems can include control features, which together with operating practices provide product containment to control cross contamination between process contaminants and product batches, and to manage risk to operators.