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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0567.6-2022

Replacing YY/T 0567.6-2011

**Aseptic processing of health care products - Part 6: Isolator
systems**

医疗保健产品的无菌加工 第6部分：隔离器系统

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules of Standardization Documents" drafted.

This document is part 6 of YY/T 0567 "Aseptic Processing of Healthcare Products". YY/T 0567 has issued the following parts.

- Part 1: General requirements;
- Part 2: Sterile filtration;
- Part 3: Freeze-drying;
- Part 4: In-line cleaning technology;
- Part 5: In-line sterilization;
- Part 6: Isolator systems;
- Part 7: Alternative processing of medical devices and combination products.

This document replaces YY/T 0567.6-2011 "Aseptic processing of healthcare products - Part 6: Isolator systems", and Compared with YY/T 0567.6-2011, in addition to structural adjustment and editorial changes, the main technical changes are as follows.

- Changed the scope of the document (see Chapter 1, Chapter 1 of the 2011 edition);
- Added the terms and definitions of "isolator auxiliary equipment" and "sterile barrier system" (see 3.1 and 3.7);
- Deleted the "design qualification", "leak test", "risk assessment", "isolation device", "surrounding environment", "transfer device" and "worst case condition".

- terms and definitions (see 3.2, 3.5, 3.7, 3.8, 3.9, 3.10 and 3.13 of the 2011 edition);
- Changed the terms and definitions of "Isolator", "Safety Data Sheet" and "Transmission System" (see 3.4, 3.6, 3.9, 2011 edition of 3.3, 3.6, 3.12);
 - Changed the quality system elements of the document (see Chapter 4, Chapter 4 of the 2011 edition);
 - Added "Basic Principles of Isolator System" chapter (see Chapter 5);
 - Added the chapter "Isolator System Specifications" (see Chapter 6);
 - Delete the relevant provisions of "category of isolators" (see 5.2 of the 2011 edition);
 - Changed the relevant provisions of the isolator "structural material" (see 7.2, 5.3 of the 2011 edition);
 - Added the relevant overview of the air handling system (see 7.3.1)
 - Changed the relevant provisions of "ventilation rate" (see 7.3.2, 5.4.1 of the 2011 edition);
 - Changed the relevant provisions of "airflow model" (see 7.3.3, 5.4.2 of the 2011 edition);
 - Changed the relevant provisions of "temperature/humidity" (see 7.3.4, 5.4.3 of the 2011 edition);
 - Changed the relevant provisions of "recirculation of air" (see 7.3.6, 5.4.5 of the 2011 edition);
 - Changed the relevant provisions of the pressure difference between the components of the isolator system and (or) between the components and the external environment (see 7.3.7, 5.4.6 of the 2011 version);
 - Delete the relevant provisions of "filter maintenance" (see 5.4.7 of the 2011 edition);
 - Changed the relevant regulations for the design of isolator gloves and sleeves (see 7.4.1.1, 5.5.1.1 of the 2011 edition);
 - Changed the relevant provisions of the material in and out of the isolator (see 7.4.3, 5.5.3 of the 2011 edition);
 - Changed the relevant provisions of the transfer port (see 7.4.4, 5.6.2 of the 2011 edition);
 - Changed the relevant provisions of waste container design (see 7.5.1.2, 5.6.1.2 of the 2011 edition);
 - Changed the relevant provisions of the background room where the isolator system is installed (see 7.6, 6.1 of the 2011 edition);

- Changed the relevant provisions of public facilities connected to the isolator (see 7.7, 6.2 of the 2011 edition);
- Changed the relevant provisions of the design confirmation of the isolator system (see 8.2.1, 8.2 of the 2011 edition);
- Change the relevant provisions of online cleaning and manual cleaning (see 8.2.4.2, 8.2.4.3, 7.3.2 and 7.3.3 of the 2011 edition);
- Changed the relevant provisions of biological decontamination and selection of biological decontamination agents (see 8.2.5, 8.2.6, 8.2.7, 8.2.8, 8.2.9, 8.2.10, 8.2.11, 8.2.12, 7.4 of the 2011 edition);
- Added relevant provisions for the development and verification of the sterilization process (see 8.2.13);
- Delete the relevant provisions of the power supply when the installation qualification is interrupted [8.3.2n) of the 2011 edition];
- Changed the relevant regulations for the performance confirmation of the isolator system (see 8.5, 8.5 of the 2011 edition);
- Increase the relevant provisions if biological indicators (BI) or chemical indicators (CI) are used in the revalidation process (see 8.7.4);
- Changed the relevant provisions of the isolator system integrity (see 9.2, 9.2 of the 2011 edition);
- Changed the relevant provisions of biological decontamination process monitoring (see 9.3, 9.3 of the 2011 edition);
- Changed the relevant provisions of environmental monitoring (see 9.4, 9.4 of the 2011 edition);
- Changed the relevant provisions of maintenance and calibration (see 9.6, 9.6 of the 2011 edition);
- Changed the relevant provisions of personnel training (see Chapter 10, Chapter 10 of the 2011 edition).

This document is equivalent to ISO 13408-6:2021 "Aseptic processing of healthcare products - Part 6: Isolator systems".

The following minimal editorial changes have been made to this document.

- Added reference to Appendix C in Note 3 of 5.1.