

ISO 13408-6:2021 (E)

Aseptic processing of health care products — Part 6: Isolator systems

Contents

| | |
|-------|---|
| | Foreword |
| | Introduction |
| 1 | Scope |
| 2 | Normative references |
| 3 | Terms and definitions |
| 4 | Quality system elements |
| 5 | Basic principle of isolator systems |
| 5.1 | General |
| 5.2 | Negative pressure isolators |
| 6 | Isolator system specification |
| 6.1 | General |
| 6.2 | Risk management |
| 6.2.1 | General |
| 6.2.2 | Negative pressure isolator systems |
| 6.3 | User requirement specification |
| 7 | Design of isolator systems |
| 7.1 | General |
| 7.2 | Materials of construction |
| 7.3 | Air-handling system |
| 7.3.1 | General |
| 7.3.2 | Air change rate |
| 7.3.3 | Airflow pattern |
| 7.3.4 | Temperature/humidity |
| 7.3.5 | Particulate air specifications |
| 7.3.6 | Recirculation of air |
| 7.3.7 | Pressure differentials |
| 7.4 | Operator interface |
| 7.4.1 | Isolator gloves/sleeves |
| 7.4.2 | Suits/half-suits |
| 7.4.3 | Access to the isolator/transfer systems |
| 7.4.4 | Devices acting as transfer ports |
| 7.5 | Ancillary isolator equipment |
| 7.5.1 | Portable and mobile equipment |
| 7.6 | Surrounding room classification |
| 7.7 | Process utilities |
| 8 | Validation |
| 8.1 | General |
| 8.2 | Design qualification |
| 8.2.1 | General |
| 8.2.2 | Product/process application |
| 8.2.3 | Ergonomics |
| 8.2.4 | Cleaning |
| 8.2.5 | Bio-decontamination |
| 8.2.6 | Selection of bio-decontamination agent |
| 8.2.7 | Development and validation of bio-decontamination processes |

- 8.2.8 Bio-decontamination agent generation and testing
- 8.2.9 Bio-decontamination parameters
- 8.2.10 Aeration and residue limits
- 8.2.11 Log reduction
- 8.2.12 Surface bio-decontamination of items
- 8.2.13 Development and validation of sterilization processes
- 8.3 Installation qualification
 - 8.3.1 General
 - 8.3.2 Installation
- 8.4 Operational qualification
- 8.5 Performance qualification
 - 8.5.1 General
 - 8.5.2 Cleaning
 - 8.5.3 Bio-decontamination
 - 8.5.4 Process simulation tests
- 8.6 Review and approval of validation
- 8.7 Requalification
- 9 Routine monitoring and control
 - 9.1 Procedures
 - 9.2 System integrity
 - 9.3 Bio-decontamination process monitoring
 - 9.4 Environmental monitoring
 - 9.5 Change control
 - 9.6 Maintenance and calibration
- 10 Personnel training
- Annex A (informative) Devices acting as transfer ports for portable and mobile equipment
 - A.1 General
 - A.1.1 Ports that include bio-decontamination/sterilization
 - A.1.2 Ports that exclude bio-decontamination/sterilization
- Annex B (informative) Isolator system — Explanation of terms used and flow of air and material
- Annex C (informative) Isolator system — Direct/indirect product contact surfaces

Page count: 25