SS 696:2023
(ICS 11.020.01; 13.100)

SINGAPORE STANDARD

Specification for high containment (biosafety level 3) facility

Singapore Standards Council

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Foreword

This Singapore Standard was prepared by the Working Group on Biosafety Level 3 Facilities set up by the Technical Committee on Biotechnology and Laboratory Testing under the purview of the Biomedical Standards Committee.

It is presupposed that in the course of their work, users will comply with all relevant regulatory and statutory requirements. Some examples of relevant regulations and acts are listed in the Bibliography. The Singapore Standards Council and Enterprise Singapore shall not be responsible for identifying all of such legal obligations.

In preparing this standard, reference was made to the following publications:

1. CEN Workshop Agreement, CWA 16393 (2012)

2. Code of Practice for Risk Management, Third Revision, 2021, published by the Workplace Safety and Health Council.

Permission has also been sought from the following organisations for the reproduction of materials from their publications into this standard:

1. European Committee for Standardization, CEN Workshop Agreement, CWA 16393 (2012)

2. Ministry of Health, National Biosafety Standards for Maximum Containment Facilities

3. PUB, Singapore's National Water Agency, Requirements for BSL/ABSL-3 and above Facilities

4. Workplace Safety and Health Council, Code of Practice on Workplace Safety and Health (WSH) Risk Management

Acknowledgement is made for the use of information from the above publications.

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all such patent rights.

NOTE

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions. Where SSs are deemed to be stable, i.e. no foreseeable changes in them, they will be classified as "mature standards". Mature standards will not be subject to further review unless there are requests to review such standards.*

2. *An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore and the Singapore Standards Council shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR. Although care has been taken to draft this standard, users are also advised to ensure that they apply the information after due diligence.*

3. *Compliance with a SS or TR does not exempt users from any legal obligations.*

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0 Introduction

The purpose of this standard is to assist persons, organisations and industries involved in the possession, handling and/or working with dangerous hazardous biological agents (i.e. risk group 3 agents) through the systematic planning, designing and implementing appropriate and sound biosafety and biosecurity strategies, procedures and measures so that work can be carried out safely and securely, in a sustainable manner.

NOTE – More information related to high containment facilities can be found in the Ministry of Health's website (www.moh.gov.sg/biosafety).

1 Scope

This standard covers the physical containment requirements and recommendations, administrative control and operating practices, performance verification for high containment facilities (also termed as Biosafety Level 3 or BSL-3 facilities), which are handling hazardous biological agents. The scope of this standard includes the use of animals that can be handled within primary containment isolators/cages, whereby a room is the secondary containment, the use of loose pen animals, whereby the room is the primary containment, and the use of arthropods.

Requirements involving the handling of agricultural animals, animals infected with high consequence or otherwise regulated livestock pathogens, plants, autopsy, vaccine or large-scale production (in aggregate 10 or more litres at any one time) activities are not detailed in this standard. Users are advised to seek guidance from the relevant authorities and/or the corresponding standards (or requirements) for such work and any other works which are not covered in this standard.

2 Normative references

The following referenced documents are indispensable for the application of this standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

AS 1807	Separative devices – Biological and cytotoxic drug safety cabinets, clean workstations and pharmaceutical isolators – Methods of test
ASME AG-1	Code on nuclear air and gas treatment
ASME N511	In-service testing of nuclear air-treatment, heating, ventilating and air-conditioning systems
EN 12469	Biotechnology. Performance criteria for microbiological safety cabinets
IEST-RP-CC034	HEPA and ULPA filter leak tests
ISO 11138-1	Sterilization of health care products – Biological indicators – Part 1: General requirements
ISO 11138-3	Sterilization of health care products – Biological indicators – Part 3: Biological indicators for moist heat sterilization processes

NSF/ANSI 49	Biosafety cabinetry: Design, construction, performance, and field certification
SMACNA 016	HVAC air duct leakage test manual