

**SS ISO 35001:2021**  
**ISO 35001:2019, IDT**  
(ICS 03.100.70; 07.100.01; 11.100.01)

**SINGAPORE STANDARD**

# **Biorisk management for laboratories and other related organisations**



**SS ISO 35001:2021**

ISO 35001:2019, IDT

(ICS 03.100.70; 07.100.01; 11.100.01)

---

SINGAPORE STANDARD

**Biorisk management for laboratories and other  
related organisations**

---

Published by Enterprise Singapore

All rights reserved. Unless otherwise specified, no part of this Singapore Standard may be reproduced or utilised in any form or by any means, electronic or mechanical, including photocopying and microfilming, without permission in writing from Enterprise Singapore. Request for permission can be sent to: [standards@enterprisesg.gov.sg](mailto:standards@enterprisesg.gov.sg).

© ISO 2019

© Enterprise Singapore 2021

ISBN 978-981-5021-14-2



The content of this Singapore Standard was approved on 16 July 2021 by the Biomedical and Health Standards Committee (BHSC) under the purview of the Singapore Standards Council.

First published, 2021

BHSC consists of the following members:

	<b>Name</b>	<b>Representation</b>
<b>Chairman</b>	: Dr Yong Chern Chet	<i>Individual Capacity</i>
<b>Deputy Chairmen</b>	: Mr Vincent Cheung	<i>Individual Capacity</i>
	: Adj Asst Prof Selina Seah	<i>Changi General Hospital</i>
	: Ms Wong Woei Jiuang	<i>Health Sciences Authority</i>
<b>Advisor</b>	: Ms Jacqueline Monteiro	<i>Individual Capacity</i>
<b>Secretary</b>	: Mr Kevin Tan	<i>Singapore Manufacturing Federation – Standards Development Organisation</i>
<b>Members</b>	: Assoc Prof Abel Ang	<i>Advanced MedTech Holdings</i>
	Mr Terri Chin	<i>Singapore Manufacturing Federation (Testing, Inspection and Certification Interest Group)</i>
	Mr Alec Chow Boon Kuan	<i>Medtronic International Ltd</i>
	Assoc Prof Raymond Chua	<i>Ministry of Health</i>
	Ms Heidi Goh	<i>Singapore Manufacturing Federation (Medical Technology Industry Group)</i>
	Prof James Goh	<i>Biomedical Engineering Society (Singapore)</i>
	Dr Koh Shuwen	<i>National University of Singapore (Industry Liaison Office)</i>
	Dr Joel Lee	<i>Nanyang Polytechnic</i>
	Mr Lee Suen Ming	<i>Parkway East Hospital</i>
	Dr Daniel Li	<i>Integrated Health Information Systems Pte Ltd</i>
	Ms Audrey Lok	<i>Enterprise Singapore</i>
	Dr Margam Chandrasekaran	<i>Individual Capacity</i>
	Dr Ong Siew Hwa	<i>Acumen Research Laboratories Pte Ltd</i>
	Dr Jipson Quah	<i>Singapore Medical Association</i>
	Dr Sidney Yee	<i>Diagnostics Development Hub – Accelerate Technologies Pte Ltd</i>
	Dr Adrian Yeo	<i>Association of Biomedical Laboratory Professionals (Singapore)</i>

BHSC set up the Technical Committee on Laboratory Testing to oversee the preparation of this standard. The Technical Committee consists of the following members:

	<b>Name</b>	<b>Representation</b>
<b>Chairman</b>	: Dr Jipson Quah	<i>Individual Capacity</i>
<b>Secretary</b>	: Mr Kevin Tan	<i>Singapore Manufacturing Federation – Standards Development Organisation</i>
<b>Members</b>	: Dr Amaladoss Anburaj	<i>Temasek Polytechnic</i>
	Dr Eddie Ang Han San	<i>Singapore Association for Medical Laboratory Sciences</i>
	Dr Emily Cheah	<i>Charles River Laboratories Singapore</i>
	Assoc Prof Ge Ruowen	<i>National University of Singapore</i>
	Dr Lai Kin Wai	<i>Singapore Polytechnic</i>
	Dr Lin Jianhua	<i>TÜV SÜD PSB Pte Ltd</i>
	Dr Edmund Lui	<i>Singapore Polytechnic</i>
	Ms Ngog Li Ee	<i>Home Team Science &amp; Technology Agency (HTX)</i>
	Dr Oh Hue Kian	<i>Home Team Science &amp; Technology Agency (HTX)</i>
	Ms Panneer Selvi	<i>Diagnostics Development Hub – Accelerate Technologies Pte Ltd</i>
	Dr Sun Cuilian	<i>Health Sciences Authority</i>
	Ms Jessie Tong Yoke Ling	<i>Singapore Polytechnic</i>

The Technical Committee set up the Working Group on Biosafety Level 3 Facility to prepare this standard. The Working Group consists of the following experts who contribute in their *individual capacity*:

	<b>Name</b>
<b>Convenors</b>	: Dr Se Thoe Su Yun
	: Dr Adrian Yeo
<b>Secretary</b>	: Mr She Long Huai
<b>Members</b>	: MAJ Keith Chua
	Mr George Goh
	Dr Goh Chin Foo
	Ms Relus Kek
	Mr David Lam
	Dr Lim Cheh Peng
	Dr Edmund Lui
	Ms Shirley Phua
	Dr Sabai Phyu
	Mr Siew Chern Chiang

Dr Amit Singhal  
Dr Nancy Tee  
Dr Sarah Teng  
Ms Tracy Toh  
Ms Wong Wai Kwan  
Mr Dan Yoong  
Dr Lois Zitzow

**Resource Member** : Assoc Prof Raymond Lin

The organisations in which the experts of the Working Group are involved are:

*Agency for Science, Technology and Research*  
*Health Sciences Authority*  
*Laboratory Biorisk Consultancy & Training*  
*Ministry of Health*  
*Ministry of Manpower*  
*Nanyang Technological University*  
*National Parks Board*  
*National University Hospital*  
*National University of Singapore*  
*PUB, Singapore's National Water Agency*  
*Singapore Accreditation Council*  
*Singapore Civil Defence Force*  
*Singapore General Hospital*  
*Singapore Polytechnic*  
*World BioHazTec*

## Contents

Foreword .....	7
National Foreword .....	8
Introduction .....	9
Figure 1 — Top down pyramid view of a biorisk management system model .....	10
1 Scope .....	12
2 Normative references .....	12
3 Terms and definitions .....	12
4 Context of the organization .....	20
4.1 Understanding the organization and its context .....	20
4.2 Understanding the needs and expectations of interested parties .....	20
4.3 Determining the scope of the biorisk management system .....	20
4.4 Biorisk management system .....	20
5 Leadership .....	21
5.1 Leadership and commitment .....	21
5.2 Policy .....	21
5.3 Roles, responsibilities, and authorities .....	22
6 Planning .....	25
6.1 Actions to address risks and opportunities .....	25
6.2 Biorisk management objectives and planning to achieve them .....	27
7 Support .....	28
7.1 Resources .....	28
7.2 Competence .....	28
7.3 Awareness .....	29
7.4 Communication .....	30
7.5 Documented information .....	31
7.6 Non-employees .....	32
7.7 Personal security .....	32
7.8 Control of suppliers .....	33
8 Operation .....	33
8.1 Operational planning and control .....	33
8.2 Commissioning and decommissioning .....	34
8.3 Maintenance, control, calibration, certification, and validation .....	34
8.4 Physical security .....	34
8.5 Biological materials inventory .....	34
8.6 Good microbiological technique .....	34
8.7 Clothing and personal protective equipment (PPE) .....	35
8.8 Decontamination and waste management .....	35
8.9 Emergency response and contingency planning .....	35
8.10 Transport of biological materials .....	36
9 Performance evaluation .....	36
9.1 Monitoring, measurement, analysis, and evaluation .....	36
9.2 Internal audit .....	37

<b>9.3</b>	<b>Management review .....</b>	<b>37</b>
<b>10</b>	<b>Improvement .....</b>	<b>38</b>
<b>10.1</b>	<b>General .....</b>	<b>38</b>
<b>10.2</b>	<b>Incident, nonconformity, and corrective action .....</b>	<b>38</b>
<b>10.3</b>	<b>Continual improvement.....</b>	<b>39</b>
	<b>Bibliography .....</b>	<b>40</b>

## **Foreword**

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

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](http://www.iso.org/members.html).

## National Foreword

This Singapore Standard was prepared by the Working Group on Biosafety Level 3 Facility set up by the Technical Committee on Laboratory Testing under the purview of BHSC.

This standard is an identical adoption of ISO 35001:2019, “Biorisk management for laboratories and other related organisations”, published by the International Organization for Standardization.

NOTE – Reference to International/Overseas Standards are replaced by applicable Singapore Standards or Technical References.

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 of 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.*

## **Introduction**

The biorisk management system:

- establishes the biorisk management principles that enable laboratories and related facilities to achieve their biosafety and biosecurity objectives;
- defines the essential components of a biorisk management system framework to be integrated into a laboratory or other related organization's overall governance, strategy and planning, management, reporting processes, policies, values, and culture;
- describes a comprehensive biorisk management process that mitigates biorisks (biosafety and biosecurity risks); and
- provides guidance on the implementation and use of the standard, where appropriate.

The biorisk management system is based on a management system approach, which enables an organization to effectively identify, assess, control, and evaluate the biosafety and biosecurity risks inherent in its activities. As such, this document is intended to define requirements for a biorisk management system that is appropriate to the nature and scale of any organization. The biorisk management system is built on the concept of continual improvement through a cycle of planning, implementing, reviewing, and improving the processes and actions that an organization undertakes to meet its goals. This is known as the Plan-Do-Check-Act (PDCA) principle:

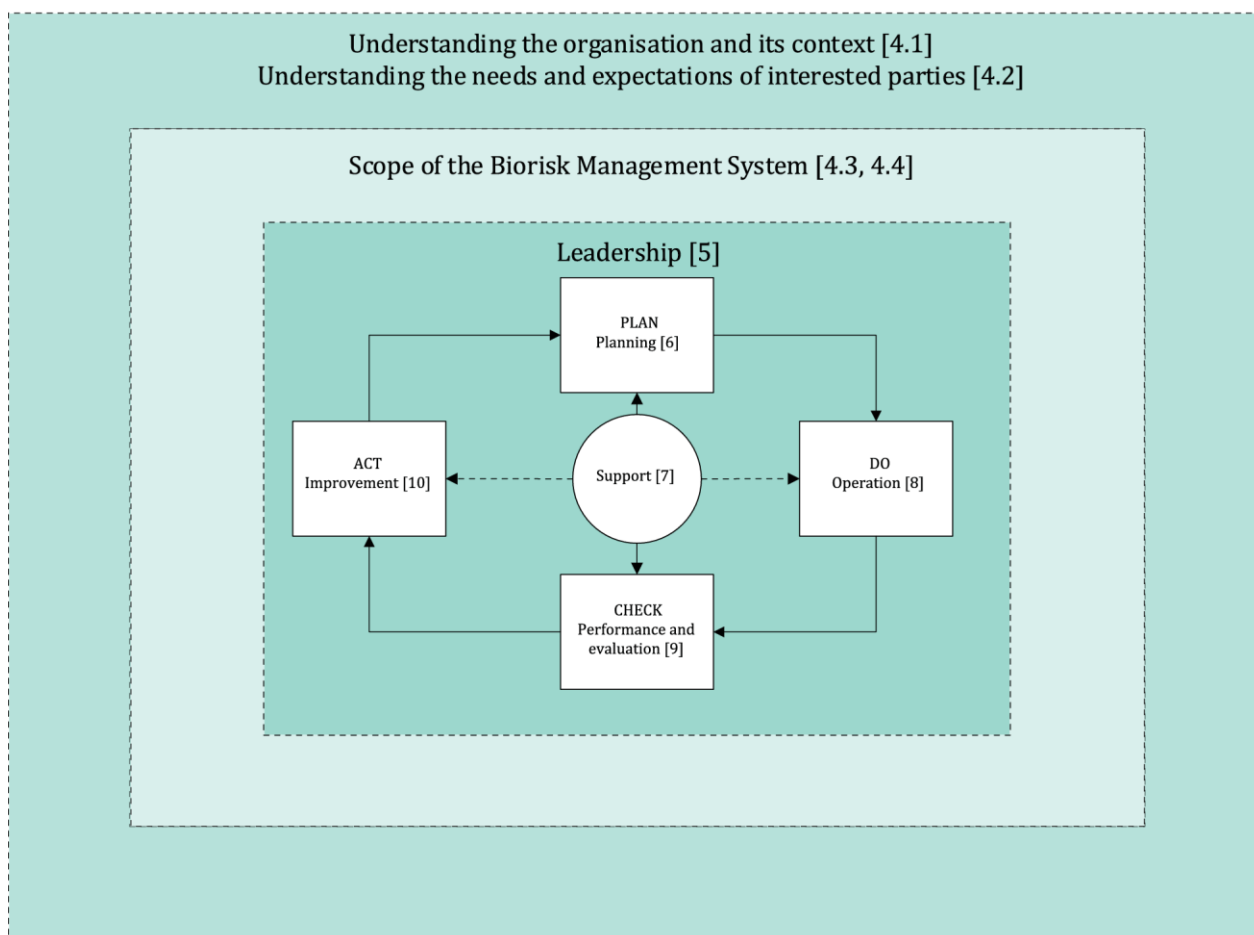
The PDCA model is an iterative process used by organizations to achieve continual improvement of processes and products. It can be applied to a biorisk management system, and to each of its individual elements, as follows:

- Plan: establish objectives, programmes, and processes necessary to deliver results in accordance with the organization's biorisk management policy;
- Do: implement the processes as planned;
- Check: monitor and measure activities and processes with regard to the biorisk management policy and objectives, and report the results;
- Act: take actions to continually improve the biorisk management performance to achieve the intended outcomes.

Figure 1 illustrates the PDCA framework and how it relates to other requirements of this document.

NOTE Figure 1 is adapted from ISO 45001 *Occupational health and safety management system — Requirements with guidance for use*.

## Biorisk Management System Model [Top - Down Pyramid View]



**Figure 1 — Top down pyramid view of a biorisk management system model**

Improving biorisk management requires attention to and understanding of the causes of nonconformities and incidents. Systematic identification and correction of system deficiencies leads to improved performance and control of biorisks.

Key factors in establishing and implementing a biorisk management system include:

- Commitment by top management to:
  - provide adequate resources;
  - prioritize and communicate biosafety and biosecurity policy;
  - establish performance expectations and integrate biorisk management throughout the organization;
  - determine causes of incidents and nonconformities and prevent recurrence; and
  - identify opportunities for improvement and prevention.

- Focus on continual improvement to:
  - make continual improvement a priority for every individual in the organization;
  - use periodic assessment against risk criteria established by the organization to identify areas for potential improvement;
  - continually improve the effectiveness and efficiency of processes;
  - take corrective action for unsafe or unsecure practices, and promote preventive activities;
  - provide workers in the organization with appropriate education and training to support biorisk management, including the methods and tools of continual improvement;
  - establish measures and goals for improvement; and
  - recognize improvement.

A biorisk management program can assist an organization to fulfill its legal requirements and other requirements.

# Biorisk management for laboratories and other related organizations.

## 1 Scope

This document defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. This document is applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials. This document is intended to complement existing International Standards for laboratories.

This document is not intended for laboratories that test for the presence of microorganisms and/or toxins in food or feedstuffs. This document is not intended for the management of risks from the use of genetically modified crops in agriculture.

## 2 Normative references

There are no normative references in this document.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

### 3.1 organization

person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its *objectives* (3.11)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity, or institution, or part or combination thereof, whether incorporated or not, public or private.

### 3.2 interested party stakeholder

person or *organization* (3.1) that can affect, be affected by, or perceive themselves to be affected by a decision or activity

### 3.3 worker

person performing work or work-related activities under the control of the *organization* (3.1)