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

Singapore Standards Council

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Published by Enterprise Singapore

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

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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

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).

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).

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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.

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.

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.

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*.

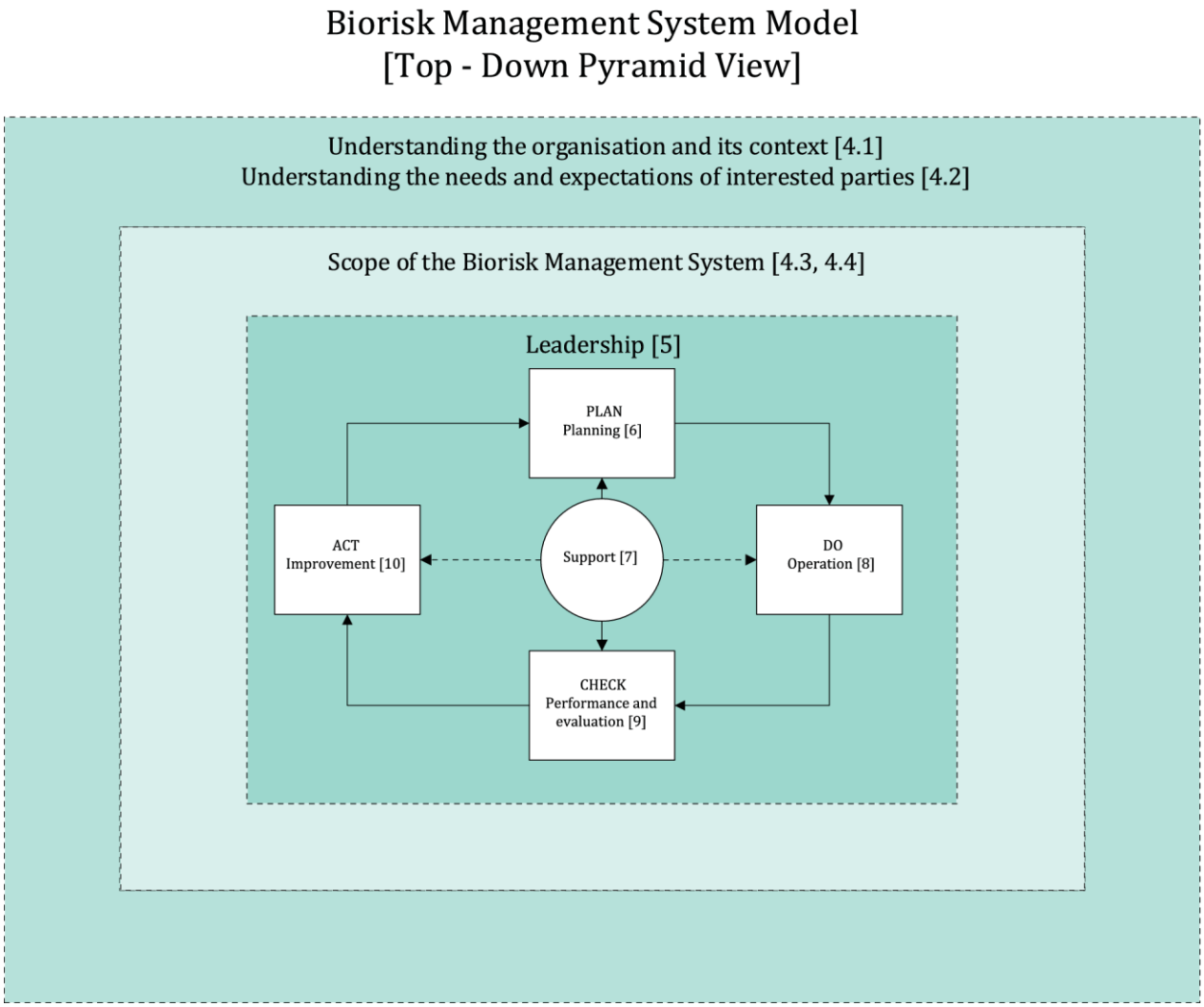

Figure 1 — Top down pyramid view of a biorisk management system model

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)