SS ISO 35001:2021+A1:2024

ISO 35001:2019, IDT

(ICS 07.100.01; 03.100.70; 11.100.01)

SINGAPORE STANDARD

Biorisk management for laboratories and other related organisations

Incorporating Amendment No. 1

Singapore Standards Council

SS ISO 35001:2021+A1:2024
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Biorisk management for laboratories and other related organisations

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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 the Biomedical and Health Standards Committee.

This standard is an identical adoption of ISO 35001:2019 “Biorisk management for laboratories and other related organisations” including the amendments to this edition, published by the International Organization for Standardization. The amendment can be found at the back of this standard.

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

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INTERNATIONAL STANDARD

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Biorisk management for laboratories and other related organisations

Système de management des biorisques en laboratoires et autres organismes associés

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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).

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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.

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*.

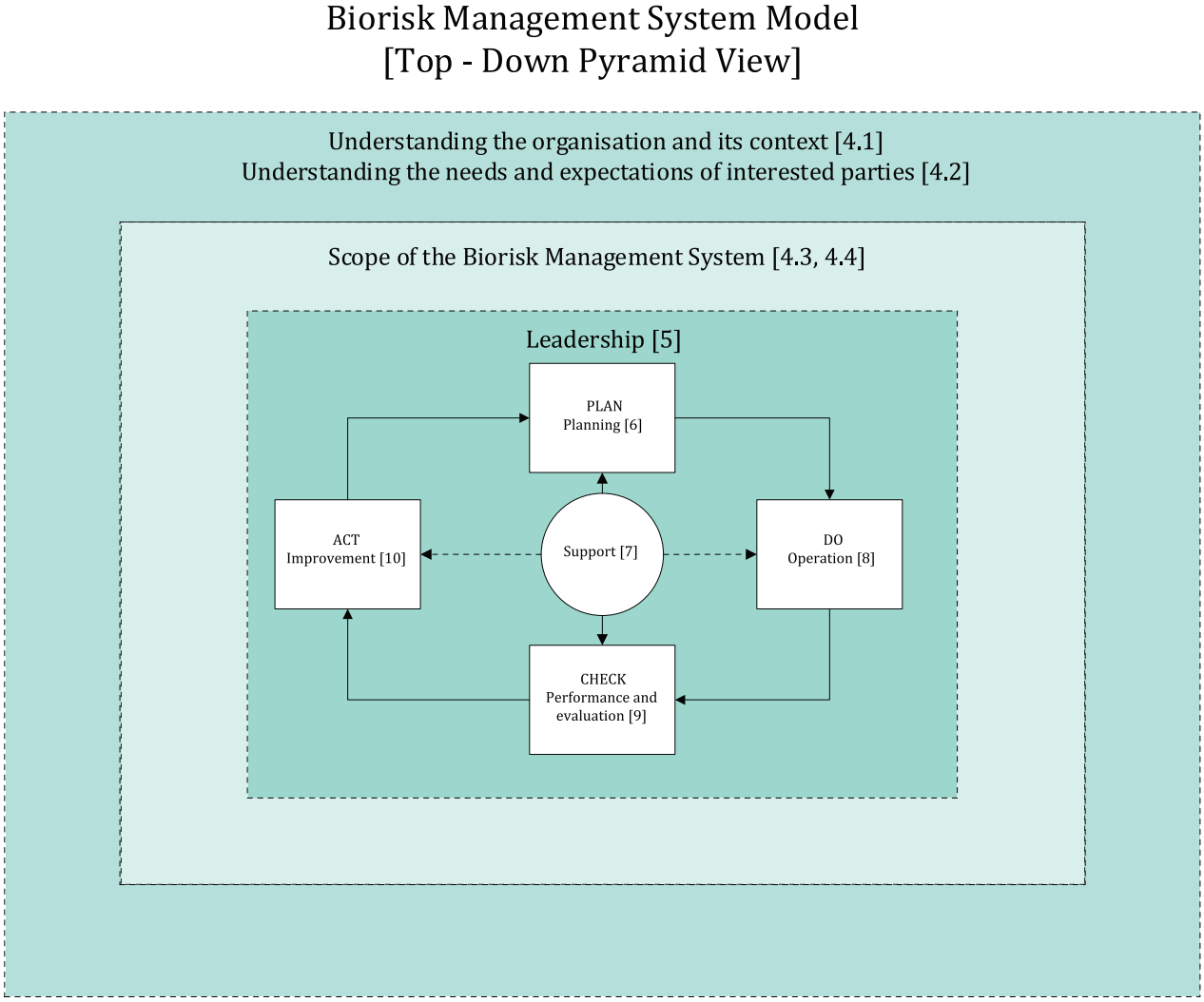

Figure 1 — Top down pyramid view of a biorisk management system model

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.

INTERNATIONAL STANDARD **ISO 35001:2019(E)**

Biorisk management for laboratories and other related organisations

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.