Technical Specification

ISO/TS 7446

First edition
2026-01

Implementation guidance for biorisk management for laboratories and other related organizations

Recommandations de mise en œuvre pour le management des biorisques dans les laboratoires et autres organismes associés

Reference number
ISO/TS 7446:2026(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Medical laboratory and in vitro diagnostic 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

ISO 35001 [1] defines a process to identify, assess, control, and monitor the risks associated with hazardous biological material. ISO 35001 [1] is applicable to any laboratory or organization that is involved in any or all the following activities with hazardous biological material: handling, storage, transportation, or disposal. This document is intended to provide practical and easy to understand guidance for laboratories and other organizations to implement ISO 35001 [1]. It aims to support organizations and biorisk management advisors in implementing a practicable and robust biorisk management system. The reader is encouraged to first review ISO 35001 [1] and refer to this document in parallel.

Figure 1 illustrates how documentation fits into the Plan-Do-Check-Act cycle of ISO 35001 [1], although not all listed documentation is a requirement of ISO 35001 [1].

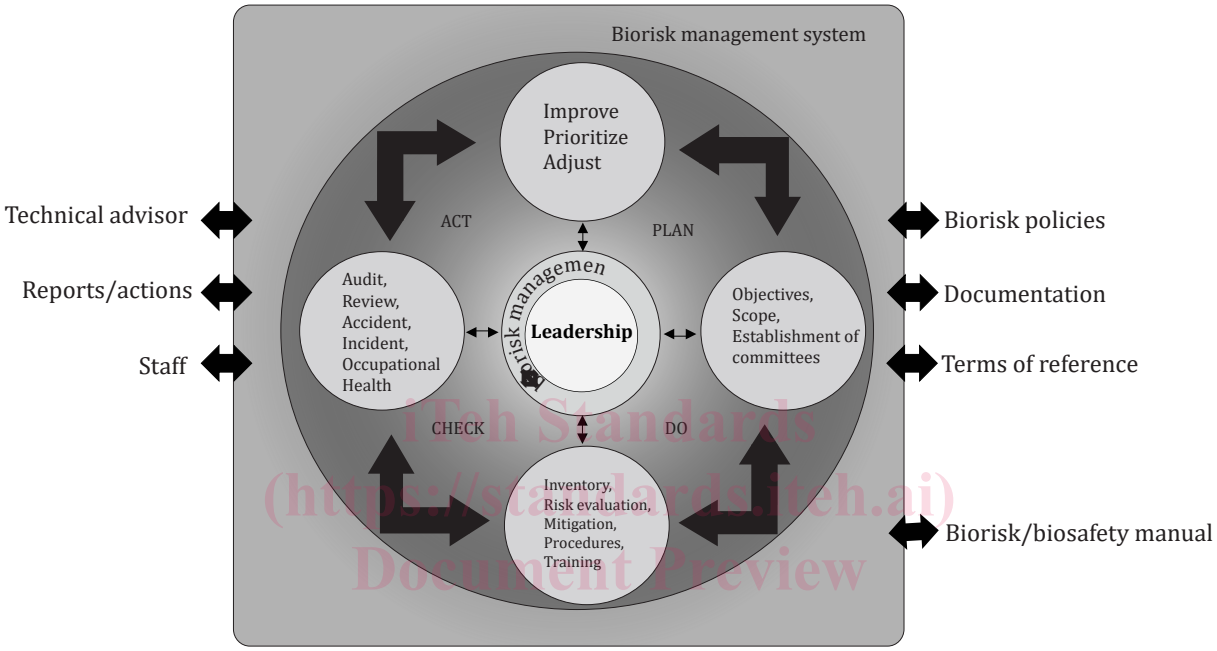

Figure 1 — PDCA framework and its relationship to the requirements of ISO 35001

An effective management system approach should be 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 goals. This is known as the PDCA (Plan-Do-Check-Act) principle:

— Plan: Planning, including identification of hazard and risk and establishing goals;

— Do: Implementing, including training and operational issues;

— Check: Checking, including monitoring and corrective action;

— Act: Reviewing, including process innovation, and acting to make needed changes to the management system.