



Technical Specification

ISO/TS 7446

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*

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Foreword

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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].

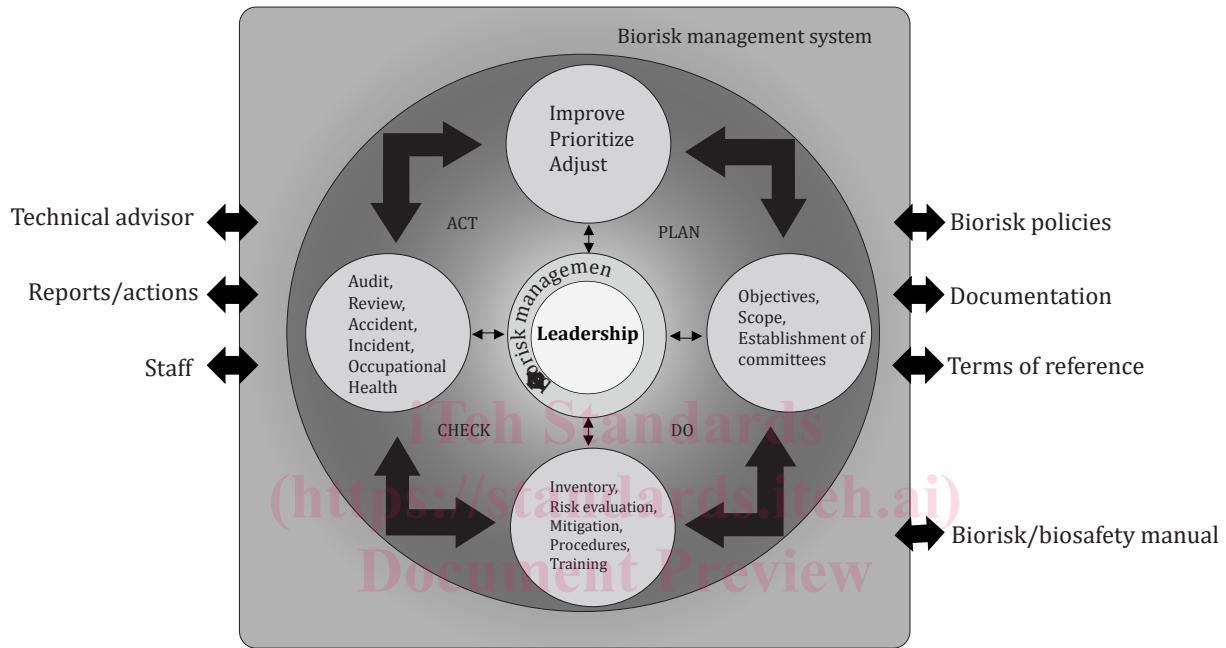


Figure 1 — PDCA framework and its relationship to the requirements of ISO 35001

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.