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ISO 35001:2019Biorisk management for laboratories and other related organisations

What is ISO 35001:2019 Biorisk management for laboratories and other related organistion?

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.

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.

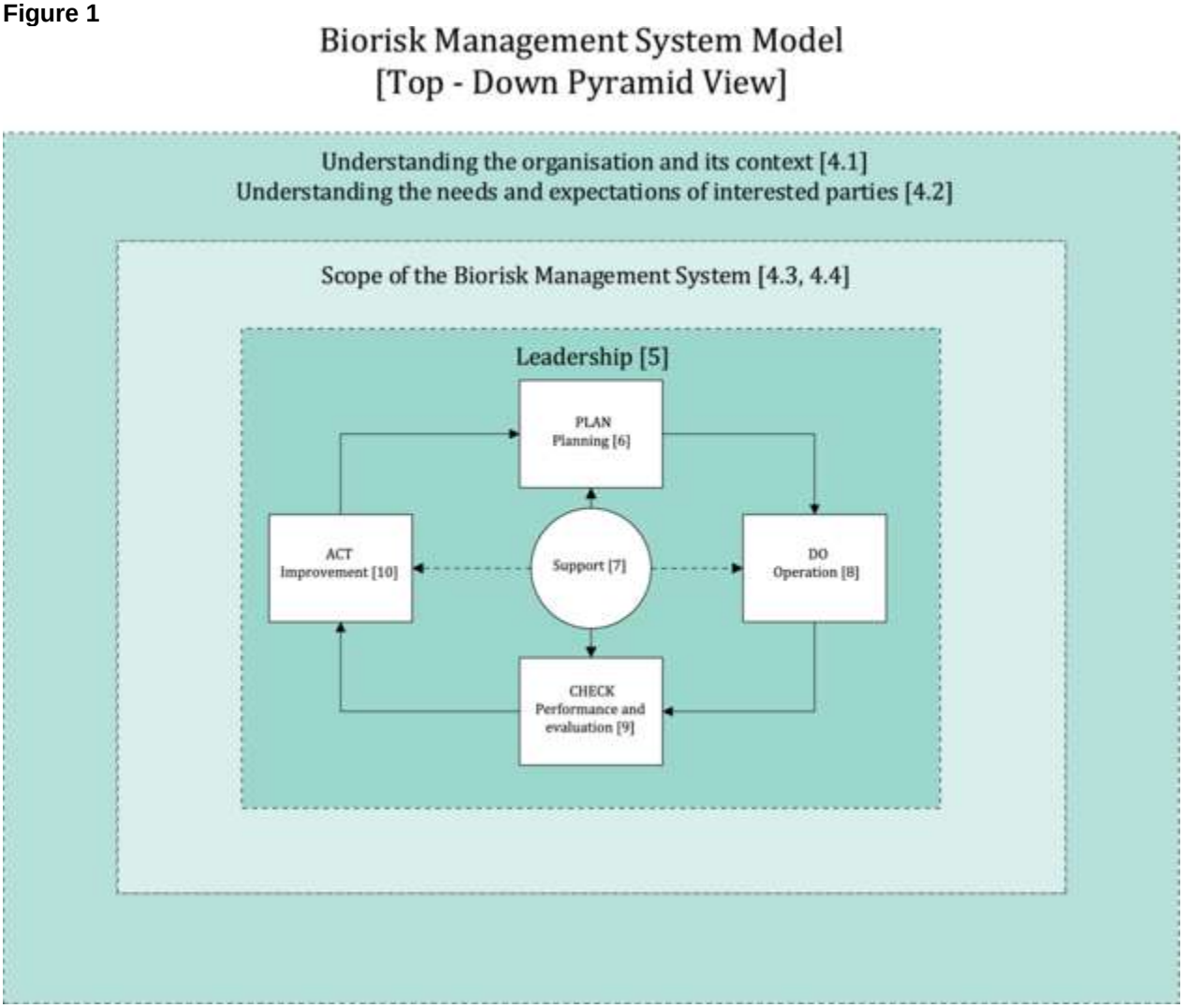
The biorisk management system is based on a management system approach, which enables an organization to effectively identify, assess, control, and evaluate the biosafety and biosecurity risks inherent in its activities. As such, this document is intended to define requirements for a biorisk management 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:

Scope

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 outcome

Figure 1



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Normative references

There are no normative references in this document.

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
- — IEC Electropedia: available

List of International Organization for Standardization standards

This is a list of publishedInternational Organization for Standardization (ISO) standards and other deliverables. For a complete and up-to-date list of all the ISO standards, see the ISO catalogue.

The standards are protected by copyright and most of them must be purchased. However, about 300 of the standards produced by ISO and IEC's Joint Technical Committee 1 (JTC 1) have been made freely and publicly available.

ISO Brand

This is a dynamic list and may never be able to satisfy particular standards for completeness. You can help by adding missing items with reliable sources.

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Conformance testing

(Redirected from Conformity assessment)
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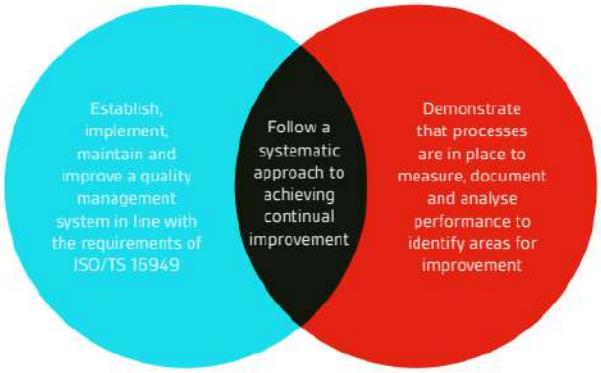
Conformance testing — an element of conformity assessment, and also known as compliance testing, or type testing — is testing or other activities that determine whether a process, product, or service complies with the requirements of a specification, technical standard, contract, or regulation. Testing is often either logical testing or physical testing. The test procedures may involve other criteria from mathematical testing or chemical testing. Beyond simple conformance, other requirements for efficiency, interoperability or compliance may apply. Conformance testing may be undertaken by the producer of the product or service being assessed, by a user, or by an accredited independent organization, which can sometimes be the author of the standard being used. When testing is accompanied by certification

The principal requirements of the standard are illustrated below:

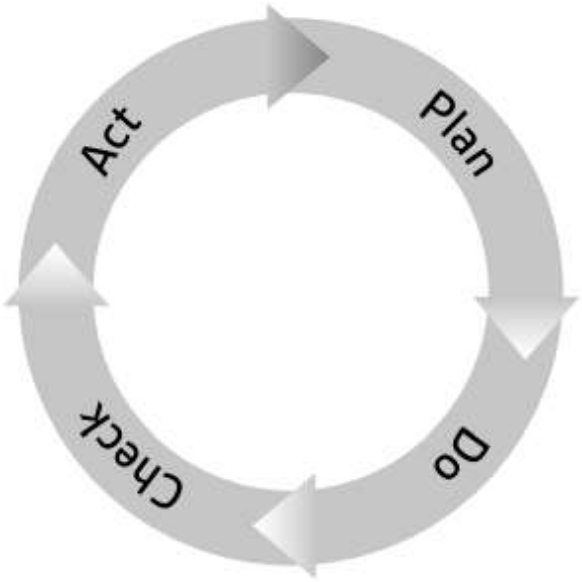


The next few pages of the guide takes you through the Plan-Do-Check-Act (PDCA) methodology, common in all ISO management systems and how DCS can help and support you on your ISO/TS 16949 journey.

Understanding the principles of continual improvement

Act

Correct and improve your plans to meet and exceed your planned results



Plan

Establish objectives and draft your plans (analyse your organization's current systems, establish overall objectives, set interim targets for review and develop plans to achieve them)

Check

Measure and monitor your actual results against your planned objectives

Do

Implement your plans within a structured management framework