



**Technical  
Specification**

**ISO/TS 5441**

**Competence requirements for  
biorisk management advisors**

*Exigences de compétences pour les conseillers en management  
des biorisques*

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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 document 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](http://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](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 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](http://www.iso.org/members.html).

## Introduction

Principal factors in managing biorisks include, but are not limited to:

- establishing and maintaining comprehensive biorisk management;
- ensuring that there is qualified and competent advice and support for biorisk management.

Biorisk management advisors are competent individuals who provide advice, guidance, and assurance to the senior management of an organization on issues related to biorisk management.

Examples of biorisk management advisors can include biosafety professionals, biological safety officers, biosafety practitioners, biosafety coordinators, biosafety responsible officials, biosafety advisors, biosecurity officers, policy makers, employers (managers), contractors, consultants, trainers who provide a basis for curricular and learning objectives, recruitment requirements and assurance, and other individuals involved in biorisk management. Competence in biorisk management, within regular biosafety and biosecurity programmes, consisting of respective knowledge, skills and experience, is needed for an advisor to identify, assess, control, and monitor the risks associated with biological materials. Biorisk management competency is specified in this document, relating but not limited to ISO 35001.

This document is applicable to any laboratory or other related organization that handles, stores, transports, and disposes of hazardous biological materials, regardless of the type or size of the facility and biological materials used, where management has identified either the need for biorisk management advice or support or both. It also provides a framework for biorisk management advisors to demonstrate competence in biosafety and biosecurity and to identify areas for biorisk management competence development.



# Competence requirements for biorisk management advisors

## 1 Scope

This document defines the requirements for competence of individuals who provide advice, guidance, and assurance on processes to identify, assess, control, and monitor the risks associated with hazardous biological materials in a laboratory or other related organization that handles, stores, transports, or disposes of biological materials that can be potentially hazardous for people, animals, plants and the environment.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 35001 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>.
- IEC Electropedia: available at <https://www.electropedia.org/>.

### 3.1 attribute

inherent characteristic of a person

### 3.2 biorisk culture

set of values, beliefs and patterns of behaviour instilled and facilitated in an open and trusting environment by individuals throughout the organization who work together to support or enhance best practice for laboratory biosafety and biosecurity

Note 1 to entry: This culture is crucial for the success of biorisk management and is built from mutual trust and the active engagement of all personnel across the organization, with a clear commitment from the organization's management.

### 3.3 biorisk management advisor

competent individual(s) providing unbiased advice, guidance, and assurance on biorisk management issues, reporting directly to the responsible senior management

### 3.4 competence

ability to apply knowledge, skills, and attributes to achieve intended results

Note 1 to entry: Competence is a specific combination of knowledge, skill, attributes and experience.

Note 2 to entry: The necessary knowledge and skills can vary from organization to organization and over time.

Note 3 to entry: An effective combination of competencies comprises overall competence.