SLOVENSKI STANDARD
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Biotechnology - Biobanking - General requirements for biobanking (ISO 20387:2018)

Biotechnologie - «Biobanking» - Exigences générales relatives au «biobanking» (ISO 20387:2018)

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Biotechnologie — «Biobanking» — Exigences générales relatives au «biobanking»

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 276, *Biotechnology*.

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

This document has been developed with the objective of promoting confidence in biobanking. It contains requirements to enable biobanks to demonstrate competent biobank operation and the ability to provide biological material and associated data of appropriate quality for research and development.

This is intended to be achieved by the planning and implementation of policies, processes and procedures covering the life cycle of biological materials and their associated data. The use of this document facilitates cooperation, fosters exchange, and assists in the harmonization of practices among biobanks, researchers and other parties.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Further details can be found in the ISO/IEC Directives, Part 2.

Biotechnology — Biobanking — General requirements for biobanking

1 Scope

This document specifies general requirements for the competence, impartiality and consistent operation of biobanks including quality control requirements to ensure biological material and data collections of appropriate quality.

This document is applicable to all organizations performing biobanking, including biobanking of biological material from multicellular organisms (e.g. human, animal, fungus and plant) and microorganisms for research and development.

Biobank users, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others can also use this document in confirming or recognizing the competence of biobanks.

This document does not apply to biological material intended for food/feed production, laboratories undertaking analysis for food/feed production, and/or therapeutic use.

NOTE 1 International, national or regional regulations or requirements can also apply to specific topics covered in this document.

NOTE 2 For entities handling human materials procured and used for diagnostic and treatment purposes ISO 15189 and other clinical standards are intended to apply first and foremost.

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 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 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 at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
accessioning
logging
documenting the addition of a new biological material and/or associated data to a biobank

3.2
acquisition
act of obtaining possession and/or custody of biological material and/or associated data

3.3
associated data
any information affiliated with biological material including but not limited to research, phenotypic, clinical, epidemiologic, and procedural data

3.4
authentication
process by which biological material is characterized to a defined level of specification using appropriate technology/documentation to establish a conclusive basis for accepting the material as genuine

3.5
biobank
legal entity or part of a legal entity that performs *biobanking* (3.6)

3.6
biobanking
process of *acquisitioning* (3.2) and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data

3.7
biological material
any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g. brown seaweed, fungi)

3.8
biosafety
containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release

[SOURCE: Laboratory Biosafety Manual, third edition, WHO, 2004]

3.9
biosecurity
institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional/unintentional release of pathogens, genetically modified organisms, toxin-producing organisms, or parts thereof, as well as such toxins that are held, transferred and/or supplied by the biobank

3.10
catalogue
systematically arranged list or record often including descriptive information

3.11
cataloguing
act of creating and maintaining a systematically arranged list or record often including descriptive information

3.12
chain of custody
responsibility for or control of materials and associated data as they move through each step of a process

3.13
competence
ability to apply knowledge, experience, and skills to achieve intended results

[SOURCE: ISO 17100:2015, 2.4.9]

3.14
complaint
expression of dissatisfaction other than appeal by any person or organization to a *biobank* (3.5), relating to the activities, products or results of that biobank where a response is expected

Note 1 to entry: The wording "activities, products or results" includes biological material and/or associated data.

Note 2 to entry: "Appeal" is defined in ISO/IEC 17000:2004, 6.4.

[SOURCE: ISO/IEC 17000:2004, 6.5 modified — "conformity assessment body or accreditation body" has been replaced by "biobank", the words "products or results" have been added, Note 1 to entry and Note 2 to entry have been added]

3.15
conformity
fulfillment of a requirement

Note 1 to entry: In English the word "conformance" is synonymous but deprecated. In French the word "compliance" is synonymous but deprecated.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

[SOURCE: ISO 9000:2015, 3.6.11]

3.16
critical
having a potential impact on the fitness for the intended purpose of biological material and/or associated data

3.17
dedicated area
space containing the biological material kept by the *biobank* (3.5) or where the biobank activities take place

3.18
destruction
process of eliminating biological material and/or deleting associated data, beyond any possible reconstruction

3.19
disposal
act of removing a biological material and/or associated data usually for scrapping, destruction or returning to provider/donor

3.20
distribution
process of providing selected biological material and/or associated data to recipient(s)/user(s)

3.21
documented information
information required to be controlled and maintained by an organization and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

— the management system, including related processes;

— information created in order for the organization to operate (documentation);

— evidence of results achieved.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

[SOURCE: ISO 9000:2015, 3.8.6]

3.22
donor
organic entity such as a human, animal, plant etc. from which the biological material and/or associated data is collected for *biobanking* (3.6)

Note 1 to entry: A human donor can also be a *provider* (3.41).

3.23
examination
set of operations having the objective of determining the value or characteristics of a property

[SOURCE: ISO 15189:2012, 3.7, modified — Notes to entry have been deleted]

3.24
fit for purpose
fitness for the intended purpose
in line with prearranged requirements for an intended use

Note 1 to entry: The definition of such requirements can take place within the biobank itself and/or in collaboration with users and should consider analytical and other relevant criteria.

3.25
governance
leadership that sets policy and management of operations and can advise/decide on scientific, administrative, technical, financial and other issues

3.26
impartiality
presence of objectivity

Note 1 to entry: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the biobank.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflicts of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO/IEC 17021-1:2015, 3.2, modified — In Note 1 to entry “certification body” has been replaced by “biobank”]

3.27
interlaboratory comparison
organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO/IEC 17043:2010, 3.4]

3.28
interoperability
capability to communicate, execute programs, or transfer data among various functional units in a manner that requires the user to have little or no knowledge of the unique characteristics of those units

[SOURCE: ISO/IEC 20944-1:2013, 3.6.1.24]

