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Biotechnology — Biobanking — Requirements for primary containers for storing biological materials in biobanks

Biotechnologie — Biobanking — Exigences relatives aux contenants primaires pour le stockage des matériaux biologiques dans les biobanques

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Foreword

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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).

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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.

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.

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Introduction

Biobanks represent a central element of biological research and development. By providing biological materials and their associated data of defined quality, they enable meaningful and reproducible research results. Prerequisites for this are not only validated methods and qualified equipment, but also consumables that ensure a defined quality of the biological material. Most of the consumables used come into contact with the biological material only temporarily and can therefore influence the quality of the biological material only to a limited extent. However, primary containers for storage, particularly when storage is over a period of several years, can influence the properties of the biological material. This can occur, for example, through adsorption or absorption of components of the biological material on the surface of the container, contamination of the biological material through released contents of the container material, penetration of foreign substances, or loss of components of the biological material through leaks in the primary container. Furthermore, the material properties of the primary container can change during longer storage periods (ageing). The properties of these primary containers can have a crucial effect on the quality of the biological material.

This document specifies minimum requirements for primary containers that serve the purpose of storing biological materials in biobanks. The requirements described in this document form the basis for verification of the usability of primary containers for the storage of biological materials to ensure that there are no adverse effects on the intrinsic quality of the biological material. In addition, test criteria and test methods are specified to enable proof of conformity with the minimum requirements.

The requirements included are intended to enable biobanks to provide biological materials of suitable quality for research and development. The specification of requirements for primary containers and methods for verifying conformity with these requirements enables manufacturers of primary containers to demonstrate the suitability of their products for their intended purpose. The standardization of primary containers facilitates the exchange and gathering of biological materials from different biobanks for large-scale research projects and use in automated processes.

This document supports biobanks in achieving defined quality targets, collaborating with researchers, and in harmonizing the quality of biological materials for the benefit of research and development. This document is primarily aimed at manufacturers that produce primary containers for the storage of biological materials. Biobanks, submitters and users of biological material, and organizations that monitor or control the work of biobanks can also use this document.

The following verbal forms are used in this document:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or a capability.

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Biotechnology — Biobanking — Requirements for primary containers for storing biological materials in biobanks

1 Scope

This document specifies requirements for primary containers intended for the storage of biological materials in biobanks. In addition to general requirements, this document also specifies special requirements depending on the storage conditions, the biological material and the intended use, as well as requirements for documentation and quality control. These requirements establish the framework for ensuring that primary containers meet the necessary quality criteria.

This document specifies test criteria and test methods that enable proof of conformity with the requirements.

This document is primarily aimed at manufacturers that produce primary containers for the storage of biological materials. Biobanks, submitters and users of biological material, and organizations that monitor or control the work of biobanks can also use this document.

NOTE For primary containers intended for biological material for therapeutic use, other requirements can apply.

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/IEC 15416, *Information technology — Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols*

ISO 20387, *Biotechnology — Biobanking — General requirements for biobanking*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 2859-2, *Sampling procedures for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387 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/

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3.1
extractable
substance that is released from a *primary container* (3.6) or material of construction when the primary container or material is extracted using laboratory extraction conditions and vehicles

[SOURCE: ISO 10993-18:2020, 3.16, modified — Note 1 to entry has been removed, “medical device” has been replaced by “primary container”.]

3.2
leachable
substance that is released from a *primary container* (3.6) or material during its use

[SOURCE: ISO 10993-18:2020, 3.22, modified — Note 1 to entry has been removed, “medical device” has been replaced by “primary container”, and “clinical use” has been replaced by “use”.]

3.3
microplate
flat plate with an array of wells

Note 1 to entry: Some dimensions of microplates are defined in ANSI/SLAS standards[13-17].

[SOURCE: ISO 23783-1:2022, 3.29]

3.4
minimum durability date
validated minimum time interval during which a *primary container* (3.6) can be used under recommended conditions while retaining appropriate quality

3.5
nominal volume
actual volume of the *primary container* (3.6) in closed condition

Note 1 to entry: Particularly in the case of primary containers with internal threads, the closure of the primary container can significantly reduce the volume.

[SOURCE: DIN 13279:2022, 3.10]

3.6
primary container
receptacle that is in direct contact with the biological material for storage and/or transportation of a biological material, and adapted to the type of biological material and to the kind of subsequent examination or analysis

Note 1 to entry: Adapted from ISO 11609:2017, 3.4 and ISO 11074:2025, 4.4.19.

3.7
risk analysis
systematic use of available information to identify hazards and to estimate the risk

[SOURCE: ISO/IEC Guide 51:2014, 3.10]

3.8
risk assessment
overall process comprising a *risk analysis* (3.7) and a *risk evaluation* (3.9)

[SOURCE: ISO/IEC Guide 51:2014, 3.11]

3.9
risk evaluation
procedure based on the *risk analysis* (3.7) to determine whether tolerable risk has been exceeded

[SOURCE: ISO/IEC Guide 51:2014, 3.12]

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3.10
sample
representative unit taken from a lot

3.11
sample size
number of items in the *sample* (3.10)

[SOURCE: ISO 2859-1:1999, 3.1.16]

3.12
stability
ability of a biological material, when stored under specified conditions, to maintain a specified property value within specified limits for a specified period of time

[SOURCE: ISO Guide 30:2015, 2.1.15, modified — "characteristic of a reference material" has been replaced by "ability of a biological material"; Note 1 to entry has been deleted.]

3.13
measurement uncertainty
uncertainty (of measurement)
parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

Note 1 to entry: The parameter can be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

Note 2 to entry: Uncertainty of measurement comprises, in general, many components. Some of these components can be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which also can be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

[SOURCE: ISO/IEC Guide 98-3:2008, 2.2.3, modified — Note 3 to entry has been removed; "may" has been replaced by "can".]

3.14
working volume
actual usable proportion of the *nominal volume* (3.5) of the *primary container* (3.6)

[SOURCE: DIN 13279:2022, 3.1]

4 Requirements

4.1 Requirements for the manufacturer

4.1.1 General

The product design shall be validated according to the following:

a) leak-resistance;

b) extractables;

c) leachables;

d) dimensional stability with regard to temperature and pressure.

The production process of the material shall be validated.

Revalidation of the production process or the product design on the basis of the product properties shall be carried out, if the manufacturing process, the conditions of manufacturing or the tools used have been

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