



BSI Standards Publication

Biotechnology — Biobanking — Requirements for animal biological material

National foreword

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matériel biologique animal*



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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	4
4.1 General	4
4.2 Ethical requirements	4
4.3 Health and safety	4
4.3.1 General principles	4
4.3.2 Chemical safety	5
4.3.3 Biosafety	5
5 Biological material collection	5
5.1 Prior to collection	5
5.1.1 Pre-acquisition information	5
5.1.2 Collection plan	5
5.1.3 Preparation of collection containers, tools, supplies, reagents and consumables	6
5.2 Collection	7
5.2.1 General	7
5.2.2 Animal restraint	7
5.2.3 Blood collection	8
5.2.4 Solid tissues	8
5.2.5 Nail and hair	8
5.2.6 Faecal biological material	9
5.2.7 Urine	9
5.2.8 Milk	9
5.2.9 Germplasm	10
5.2.10 Other biological materials of animal origin	10
5.2.11 Additional information	10
6 Transport of biological material and associated data	10
7 Reception	11
8 Preparation and preservation of biological material	11
9 Storage of biological material	12
10 Distribution, disposal and destruction of biological material	12
10.1 Distribution	12
10.2 Destruction and disposal	13
11 Information collection	13
Annex A (informative) Exemplary data collection table for animal biological material	14
Annex B (informative) Collection methods for animals of different natures and sizes	16
Annex C (informative) Information in a material transfer agreement or equivalent document	19
Annex D (normative) Collection, preparation and preservation methods	20
Bibliography	23

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).

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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.

Introduction

This document contains requirements and recommendations to enable biobanks handling animal material to demonstrate competent biobank operation and the ability to provide animal biological material and associated data of appropriate quality for research and development.

This document supports processes that maintain animal welfare, as it is anchored in the principle of the three Rs: to “Replace, Reduce and Refine the use of animals”^[18].

The use of this document helps to ensure the quality of animal biological material and the reliability of research results under the application of [ISO 20387](#).

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.

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Biotechnology — Biobanking — Requirements for animal biological material

1 Scope

This document specifies requirements for the collection, reception, preparation, preservation, transport, storage, distribution, destruction and disposal of biological materials obtained from animals, excluding humans. Such resources include solid tissues, fluid samples and associated cells, excretory products and associated data.

This document is applicable to biological material or associated data, or both, that can be used for research and development and to biomolecules derived from the biological material, e.g. nucleic acids, proteins and metabolites.

This document is applicable to all organizations performing biobanking for research and development.

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

This document does not apply to the establishment of cell lines derived from animal biological material.

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

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 20387:2018](#), *Biotechnology — Biobanking — General requirements for biobanking*

WHO. *Laboratory biosafety manual*. World Health Organization, 4th edition, 2020

3 Terms and definitions

For the purposes of this document, the terms and definitions given in [ISO 20387:2018](#) 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

animal

multicellular, heterotrophic organism, that has sensation and the power of voluntary movement, and whose cells differ from those of most plants by the absence of cell walls

3.2

associated data

any information affiliated with *biological material* (3.5) including but not limited to research, phenotypic, clinical, epidemiologic, genetic, taxonomic, systematic and procedural data

Note 1 to entry: Associated data can include metadata.

[SOURCE: ISO 20387:2018, 3.3, modified — “genetic, taxonomic, systematic” and Note 1 to entry have been added.]

3.3

biobank

legal entity or part of a legal entity that performs *biobanking* (3.4)

[SOURCE: ISO 20387:2018, 3.5]

3.4

biobanking

process of acquisition and storing, together with some or all of the activities related to collection, preparation, *preservation* (3.15), testing, analysing and distributing defined *biological material* (3.5) as well as related information and data

[SOURCE: ISO 20387:2018, 3.6]

3.5

biological material

any substance derived or part obtained from an organic entity such as a human, *animal* (3.1), plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g. brown seaweed, fungi)

Note 1 to entry: For this document, biological material applies only to animals and derivatives thereof.

Note 2 to entry: For this document, biological material can refer to the whole animal.

[SOURCE: ISO 20387:2018, 3.7, modified — Notes 1 and 2 to entry have been added.]

3.7

biosafety

practices and controls that reduce the risk of unintentional exposure or release of *biological materials* (3.5)

Note 1 to entry: The release of biological material can refer to live *animals* (3.1).

Note 2 to entry: This definition includes unintentional exposure, for example, to pathogens and toxins, or their accidental release as a biosafety risk.

[SOURCE: ISO 35001:2019, 3.22, modified — Notes 1 and 2 to entry have been added.]

3.8

clean technique

non-sterile practice involving strategies used to reduce the overall contamination or to prevent or reduce the risk of transmission of contaminants

Note 1 to entry: A clean technique can involve meticulous handwashing, preparing and maintaining an uncontaminated environment by using uncontaminated consumables and sterile instruments, and preventing direct contamination of materials and supplies.

3.9

destruction

process of eliminating *biological material* (3.5) and/or deleting *associated data* (3.2), beyond any possible reconstruction

[SOURCE: ISO 20387:2018, 3.18]

3.10

germplasm

biological material (3.5) derived from germ cells, somatic cells or stem cells used in sexual reproduction or assisted reproductive technologies

3.11

invasive collection

any collection procedure that requires the *animal* (3.1) to be handled

Note 1 to entry: Most clinically acceptable *sample* (3.17) collection procedures are minimally invasive (e.g. buccal swab).

3.12

life cycle

consecutive and interlinked processes applied to *biological material* (3.5) and *associated data* (3.2) from collection, if applicable, acquisition or reception to distribution, disposal or *destruction* (3.9)

Note 1 to entry: This term refers to the *biobanking* (3.4) life cycle only.

[SOURCE: ISO 20387:2018, 3.29]

3.13

material transfer agreement

MTA

documented agreement governing the transfer of *biological material* (3.5) and *associated data* (3.2) between a *biobank* (3.3) and a recipient

Note 1 to entry: An MTA document contains information about the *in situ* origin or the source of the biological material and associated data, information about the provider and recipient, and information that defines the limits of the use of the biological material and associated data.

Note 2 to entry: An MTA can also be associated with a biological material being deposited to meet the need of its depositor country/country of origin, particularly those that are the parties of the Convention of Biological Diversity (CBD) and Nagoya Protocol (NP).

3.14

non-invasive collection

collection procedure performed without handling the *animal* (3.1)

3.15

preservation

act to prevent or retard biological or physical deterioration of *biological material* (3.5)

[SOURCE: ISO 20387:2018, 3.34]

3.16

processing

performing any activity on *biological material* (3.5) and *associated data* (3.2) during all stages of the *life cycle* (3.12)

[SOURCE: ISO 20387:2018, 3.36]

3.17

sample

portion of or the entire whole

[SOURCE: ISO 20387:2018, 3.45, modified — “or the entire” has replaced “a”.]

3.18

storage

maintenance of *biological material* (3.5) under specified conditions for future use

[SOURCE: ISO 20387:2018, 3.47]