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Biotechnology — Biobanking — Requirements for animal biological material

Biotechnologie — Banques biologiques — Exigences relatives au matériel biologique animal

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Contents

Page

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.

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.

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 acquisitioning 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]

3.19
zoonosis
disease or infection that is naturally transmissible from vertebrate *animals* (3.1) to humans

[SOURCE: Reference [19]]

4 General requirements

4.1 General

The biobank shall follow ISO 20387.

NOTE 1 Information for the implementation of ISO 20387 is provided in ISO/TR 22758.

The biobank shall ensure the legitimate acquisition of biological material and its associated data and retention of any relevant documentation.

NOTE 2 Legitimate acquisition can refer to purchases, regulations, permits or authorizations.

NOTE 3 Relevant documentation can include sales receipts, import/export certificates, international treaties and agreements, and animal health certificates or passports.

If legitimate acquisition cannot be demonstrated, the biological material and associated data shall be disposed of according to documented procedures, and this shall be documented.

4.2 Ethical requirements

The collection of biological material from live animals shall comply with recognized animal welfare practice. The biobank shall be aware of and able to demonstrate compliance with applicable animal welfare requirements.

NOTE Additional guidance can be found in References [20] and [21].

The biobank shall identify and document the situations where approval by an ethics committee is needed. ISO 20387:2018, 4.1.6, shall be followed. The biobank shall retain appropriate documents as evidence of the approval.

The biological material or associated data, or both, should not be either accepted or distributed, or both, if any of these is found to be non-compliant with applicable regulations.

4.3 Health and safety

4.3.1 General principles

The biobank or the legal entity of which it is a part shall ensure that health and safety requirements conform to ISO 20387:2018, 6.2.1.5, 6.3.4 and 6.3.5.

The bio-risk management of the biobank shall be in accordance with the WHO's *Laboratory Biosafety Manual* or equivalent (e.g. ISO 35001). The biobank facility should be designed in accordance with the WHO's *Laboratory Biosafety Manual* or equivalent.

Health and safety policies shall be established, implemented, documented and reviewed with the appropriate health and safety advisory group and fully outlined in the standard operating procedures (SOPs) of the related processes. All factors that can have an influence on health and safety (e.g. facilities, potential pathogens, chemicals, sharps, liquid nitrogen, dry ice, explosives, fire hazards) should be taken into account.

Appropriate personal protective equipment (PPE) shall be used when handling biological material of animal origin to prevent injury or infection, or both.

NOTE Zoonosis can occur through any route such as via the respiratory passage (e.g. SARS, bird flu) or by direct contact (e.g. rabies, yellow fever, tick borne encephalitis, West Nile virus infection).

Biobank personnel shall be under medical surveillance according to exposure and risk, as required.

All biobanking procedures in accordance with ISO 20387:2018, 4.1.1, that are used shall include measures for prevention of unintended release of materials that are potentially harmful to human and animal health or the environment, or both.

4.3.2 Chemical safety

The biobank shall maintain documentation of all hazardous substances used (e.g. for sample fixation or preservation), together with the corresponding safety data sheets (SDSs) providing information on potential hazards.

The biobank shall ensure that all handling of chemicals is undertaken in such a way as to safeguard human health and the environment. This includes all chemicals, natural and manufactured, and the full range of exposure situations.

4.3.3 Biosafety

The biobank should adhere to the WHO's *Laboratory Biosafety Manual* or equivalent when handling biological material contaminated with pathogens.

Personnel at risk of exposure to vaccine-preventable infectious diseases shall have appropriate immunizations made available to them, when possible.

5 Biological material collection

5.1 Prior to collection

5.1.1 Pre-acquisition information

For pre-acquisition information, ISO 20387:2018, 7.2.2, shall be followed.

NOTE The data to be acquired depend on the different types of animal sources (e.g. livestock, laboratory, domestic or wild animals), shown in Annex A, and the intended use, which can be described in the relevant MTA (see Annex C).

See Clause 11 for more information, recommendations and requirements.

5.1.2 Collection plan

The biobank shall adhere to ISO 20387:2018, 7.2.3, for collection procedures and ISO 20387:2018, 7.3.2.5, for documentation.

The biobank or the recipient/user, or both, shall develop, implement and document collection procedures for each type of biological material or associated data, or both, to maintain the quality of the biological material(s) and to meet the fitness for the intended purpose. These procedures shall address at least the following factors:

a) intended purpose, where known, including the criteria needed in order to meet the potential analytical objective(s) (e.g. required viability, integrity and functionality of the animal biological material);

b) processing method;

c) preservation method;

d) donor identity (e.g. taxonomic level of the donor);

e) geographical or physical location, or both, of the source (e.g. donor animal, body part, excreted material) for collection of biological material;

f) biological material or sample type and associated data;

g) body part and accessibility for collection;

h) biological material quantity or size or both (e.g. blood, urine, tissue);

i) container and suitability for storage;

j) collection tools, consumables, and equipment;

k) the date and time of collection (in a standard format, preferably in accordance with ISO 8601-1);

l) duration of collection procedure for each individual donor, if relevant;

m) collection frequency for a given donor (in cases of multiple collections);

n) sequential order of collection (e.g. if multiple organs are collected);

o) quality criteria (e.g. macroscopic aspect, colour, texture) and pre-analytical workflows in accordance with ISO 20387:2018, 7.2.3.2;

p) competence required to undertake the procedure.

The collection procedure(s) should minimize adverse effects for the donor animal.

The targeted biological material can be obtained from a large variety of tissues (e.g. skin, nail, hair or feather follicles, fins, scales, foot pads, fat deposits, muscle, brain, heart, lung, liver, kidney, gonads, glands, bone, shell, placenta), biological fluids (e.g. blood, urine, milk, egg albumen, semen, cerebrospinal fluid) or other biological materials (e.g. buccal swabs, embryos, faeces).

The biological material shall be of sufficient yield, purity, integrity and viability in order to ensure fitness for the intended purpose.

5.1.3 Preparation of collection containers, tools, supplies, reagents and consumables

The collection procedure shall include the preparation of collection containers, tools and other supplies required for each biological material collection. When practicable, this shall include but not be limited to the following:

a) collection container(s) and seal(s);

b) contamination prevention through appropriate care, cleaning or sterilization, or both, of collection tools such as cutting devices, instruments, containers and reagents;

NOTE When needed, containers, instruments and consumables can be sterilized prior to collection.

c) ink, labels or tags, when not integral to the container(s);

d) collection instruments;

e) collection consumables;

f) PPE;

g) information recording tools;

h) reminder systems (e.g. checklists).