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Biotechnology — Biobanking — Requirements for animal biological material

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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 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).

The tools for collection (e.g. instruments, consumables, PPE) should be prepared and checked prior to collection. Preparing a checklist before collection can help to ensure an uninterrupted and efficient procedure.

Leak-proof cryotubes with secure screw top lids or straws with seals can be used for samples that will be stored in liquid nitrogen or in freezers. Plastic bags should be avoided when storing biological material at temperatures below –20 °C.

Single-use consumables shall not be re-used, whenever possible, and shall be appropriately disposed of. Whenever single-use consumables are re-used this shall be documented.

Documented procedures to clean and, when necessary, disinfect non-disposable instruments used in collection (e.g. skin sampler, ear puncher, scissors, scalpel) and the relevant work area between uses shall be implemented to avoid cross-contamination or infection, or both.

Measures shall be taken to avoid contamination by RNase in the environment, if the analytical objective is RNA extraction or use. The same precaution shall be applied for other analytical objectives.

The biological material shall be appropriately tagged at collection in accordance with ISO 20387:2018, 7.5.1, a).

5.2 Collection

5.2.1 General

Unnecessary destructive or lethal injury to the animal during collection from live animals shall be avoided, where possible. If accidental or unnecessary destructive or lethal injury occurs during collection, it shall be documented.

Where collection is lethal, the biobank shall use a documented procedure that:

a) minimizes fear and distress;

b) achieves rapid unconsciousness or death;

c) is suitable for the age, species and health condition of the donor;

d) is reliable and simple to administer;

e) is safe for biobank personnel.

For road-kill or field-acquired dead donors, the biobank can consider alternative collection techniques including freezing (of the whole donor or a part) for downstream research purposes.

5.2.2 Animal restraint

The biobank shall establish, document and implement an animal restraint procedure to avoid or minimize discomfort, distress and pain to the animal during restraint including the following:

a) The duration of the hold or restraint should be as short as feasible for the collection, in order to minimize donor distress.

b) For each species, a method suitable for pick up, transportation or restraint should be chosen. During restraint, the donor should be held firmly and securely, but not too tightly as to cause discomfort, breathing compromises or bruising.

NOTE 1 Restraint can be physical or achieved by suitable sedation or anaesthesia. See Table B.1 for more information.

c) During handling and restraint, the donor's response should be observed and the restraint should be adjusted, when required, to ensure the donor's wellbeing.

NOTE 2 Donor observation, including post-restraint, can provide insight for improvements on the restraint procedure.

5.2.3 Blood collection

A blood collection method suitable for the donor species shall be used.

The safe blood collection volume shall be evaluated and documented according to:

a) the donor species;

b) the donor's body mass;

c) the donor's individual health status.

For non-lethal collections, a blood draw in a single collection shall be limited to an amount that does not affect the homoeostasis of the donor.

When blood volumes taken in a single collection can affect the homoeostasis of the donor, the biobank shall facilitate appropriate donor recovery intervals (e.g. over weeks or months) prior to any additional collection.

NOTE 1 For a single non-lethal collection of blood exceeding the recommended maximum blood draw volume, isotonic fluid replacement can be used.

Blood biological material should be collected from veins; however, collection from arteries or heart chambers can also be performed for large volumes.

Embryonic blood can be collected for harvesting circulating primordial germ cells.

Catheters can be used to enable long-term collection or repeated collection over a relatively short time period, in order to reduce stress and discomfort, provided that there is close observation of the donor for thrombosis or infection or both.

NOTE 2 The blood collection route can vary depending on the species, see Table B.3 as reference.

For live animals, the skin shall be aseptically prepared prior to blood collection.

NOTE 3 For post-mortem blood collection, aseptic preparation depends on the procedure.

Any requirement for using an anti-clotting agent [e.g. ethylene diamine tetraacetic acid (EDTA), heparin] shall be identified before collection according to the intended use. When using anti-clotting agents, appropriate containers shall be chosen and an appropriate collection method shall be applied, e.g. as described in Annex B.

5.2.4 Solid tissues

A tissue collection method suitable for the donor species shall be used. For examples of methods for collecting solid tissues, see Table B.2.

Collecting tissue from internal organs can require a specific dissection method depending on the donor's anatomy.

5.2.5 Nail and hair

A nail or hair collection method suitable for the donor species shall be used.

Appropriate instruments (e.g. surgical scissors) for nail, claw and hair collection shall be used.

A method for hair collection fit for the intended purpose shall be used (e.g. plucking sufficient hair to allow adequate DNA yield from follicle cells, use of a comb to collect hair from the back, abdomen, neck, and tail for metabolomics).

For the non-invasive collection of hair (e.g. from free and semi-free herds in winter), the hair can be collected directly from the habitat. Such hair should be collected carefully to avoid damaging the bulbs. Cross-contamination from other sources should be prevented.

5.2.6 Faecal biological material

A faecal material collection method suitable for the donor species shall be used.

Faeces can be:

a) used fresh for immediate analysis; or

b) frozen for later use.

A preservation solution can be used, if required, to maintain integrity of the biological material.

The habitat of wild animals can be surveyed in order to find and collect faecal biological material, where required.

When a pure sample of faecal biological material (i.e. containing no urine) is needed from an avian species donor, it shall be collected from the lower digestive system (e.g. colon) after death.

5.2.7 Urine

A urine collection method suitable for the donor species shall be used.

Minimally invasive collection techniques for the collection of urine shall be used, where possible (e.g. metabolic-cages).

Where minimally invasive collection techniques are not possible, invasive techniques can be used (e.g. catheterization or cystocentesis).

NOTE Table B.4 gives more details on urine collection methods.

5.2.8 Milk

A milk collection method suitable for the donor species shall be used.

Where possible, the following shall be documented for milk collection:

a) litter size;

b) optimum time for milking post-parturition;

c) separation time of the dam from the litter prior to milking;

d) method of stimulating milk production;

e) method of milk collection, and whether an anaesthetic is used;

f) optimal time to return the dam to the litter after milking.

NOTE For an example of the milk collection procedure for ruminants and small mammals, see Table B.5.

Milk can be processed as soon as possible (i.e. within 4 h) after collection or frozen immediately, either pure or with a preservative. The biological material can be held at cool temperatures until initial processing.

5.2.9 Germplasm

A germplasm collection method suitable for the biological material type, species and intended purpose shall be used (e.g. collection methods for livestock as outlined in Clause 8 of "Cryoconservation of animal genetic resources"[22]).

Gonads shall be collected in an appropriate environment (e.g. laboratory biosafety cabinet, isolation area, surgical room).

Semen or oocyte cells shall be collected using a clean technique, or under aseptic conditions. Oocytes can be collected by harvesting from ovaries that have been removed from a donor or by ultrasound-guided aspiration from a living donor. Germ cells can be frozen in sealed ampoules, bottles or straws after collection.

In the case of spermatozoa, volume, motility score and concentration shall be documented, unless the biobank has documented valid reasons for not doing so.

5.2.10 Other biological materials of animal origin

5.2.10.1 A collection method suitable for the biological material and donor species shall be used.

5.2.10.2 Growing feathers shall be collected directly from the donor, if the intended purpose is to extract genetic material from feather pulp. Moulted feathers can be collected, when required. Cross-contamination shall be avoided, where possible.

5.2.10.3 For fin collection, the fish donor shall be anesthetized before fin collection from the distal end of the target fin. The fin (e.g. pelvic, anal or caudal fin) and quantity of fin tissue shall be selected in a way that preserves viability of the donor animal. Fin biological material can be preserved in an appropriate container and with preservative (e.g. 95 % non-denatured ethanol), when required.

5.2.10.4 For live fish scale collection, an appropriate quantity of scales shall be collected (e.g. by scraping) from an area located behind the dorsal fin and just above the lateral line. The scale material can be placed on filter paper in pre-tagged appropriate containers.

5.2.10.5 For reptiles, scutes of the tail or ventral scales can be collected, see Table B.6.

5.2.10.6 Mucosal biological material can be collected from rectal, genital, nasal, oral, conjunctival and other mucosa with clean cytological brushes or swabs. Precautions shall be taken to avoid excessive injury to the donor animal when collecting mucosal biological material.

5.2.10.7 For egg biological material, material such as albumen can be collected using a syringe and can be stored in appropriate containers with dry ice.

5.2.11 Additional information

Additional collection-relevant information and requirements for the biological materials listed in 5.2 can be found in Table D.1. The relevant parts of Annex D shall be applied.

6 Transport of biological material and associated data

Where biological material and associated data are transported, ISO 20387:2018, 7.4, shall be followed.

An appropriate method for shipment shall be selected to maintain biological material integrity.

When shipping cold or frozen biological material, methods to maintain the temperature throughout the transport shall be used, including an allowance for prolonged shipping duration. For transport:

a) at room temperature (15 °C to 25 °C), insulated packaging to reduce the potential of temperature fluctuations and maintain the biological material integrity can be used;

b) at refrigerated temperature (2 °C to 8 °C), refrigerants such as ice bags, gel packs or others can be used;

c) at frozen temperatures (≤ –20 °C), coolants such as gel packs, dry ice pellets, blocks or sheets (e.g. use of dry ice for biological material intended for RNA isolation), or alternative solutions that deliver equivalent temperature protection, can be used;

d) at ultra-low temperatures (≤ –80 °C), appropriate technical solutions (e.g. cooling boxes) can be used, taking into account the requirement for physical freezers during stop-overs in shipment;

e) at cryogenic temperatures (≤ –140 °C), liquid nitrogen (with adequate ventilation), or alternative solutions that deliver equivalent temperature protection, can be used.

Prior to the transport of rare biological material, the biobank should perform a risk assessment. For example, the biobank can simulate the conditions of transport prior to biological material transport to identify potential risks. Any resulting solution shall appropriately mitigate damage to the biological material and shall be used as deemed necessary.

The temperature of the biological material should be monitored throughout transport, where necessary and possible.

7 Reception

For reception of biological material and associated data, ISO 20387:2018, 7.3.2, shall be followed.

Transport information (e.g. transport batch number, specifications, relevant dates and responsible transport personnel) should be documented.

The biobank should communicate effectively with the provider or shipper for details of the shipment, including the anticipated arrival date and time and any preparation required for the biological material reception.

The transport status shall be tracked, where possible. The biobank shall address nonconformities that impact the fitness for the intended purpose of the biological material.

When receiving a shipment, the biobank shall follow the established procedures for reception, including documenting the shipment arrival date and time, and determining the condition of the biological material, at least by verifying:

a) package integrity;

b) the temperature of the biological material;

c) the refrigerant condition;

d) the integrity of the biological material container(s) (e.g. tube, cryovial, sealed bag).

The recipient should verify that requested information related to the biological material is provided, including the appropriate permits and MTA.

8 Preparation and preservation of biological material

8.1 To ensure fitness for the intended purpose, collected biological material shall be prepared or preserved in a timely manner.

8.2 Subdividing biological material (e.g. aliquoting) shall be performed, if appropriate, to avoid repetitive thawing and freezing, and to preserve the quality of the biological material. The biobank shall establish, implement and document processing and preservation procedures to include, as necessary:

a) the optimal processing temperature;

b) critical timing(s) (e.g. pre-centrifugation delay, time delay between steps such as centrifugation and freezing, duration of fixation);

c) the selection of the preservatives and additives, and preservation methods (including equipment);

d) the criteria for subdividing biological material (e.g. representativeness, number of aliquots or volume).

NOTE Heterogeneity can result from subdivision of biological material (e.g. solid tissue).

8.3 During processing, measures to protect biological material from unintended changes in composition shall be implemented (e.g. use of multiple aliquots to avoid refreezing after thawing).

8.4 Nonconformities during processing and preservation shall be identified and documented in accordance with ISO 20387:2018, 7.11 and 8.7.

8.5 Quality control (QC) procedures shall be performed, whenever appropriate, to verify the critical characteristics of the biological material relating to fitness for the intended purpose, for example:

a) histological examination to verify tissue morphology and tissue integrity or validate a given pathological finding, or both;

b) determination of the integrity of targeted molecules (e.g. DNA, RNA, proteins and other small molecules);

c) physiological assays (e.g. hormonal levels and antibody titres).

8.6 In accordance with ISO 20387:2018, 7.9, the preparation and preservation methods for critical activities shall be validated or verified, or both, where possible, to ensure that the methods are reproducible and robust. For preparation and preservation recommendations and requirements of specific biological materials, see and apply Table D.1, where relevant.

9 Storage of biological material

Storage requirements in accordance with ISO 20387:2018, 7.7, shall be followed.

Critical environmental conditions necessary for safe biological material storage (e.g. adequate ventilation, use of oxygen sensors, pressure-relief devices for cryogenic vessels) should be identified, documented, monitored, recorded and controlled.

10 Distribution, disposal and destruction of biological material

10.1 Distribution

The biobank shall work in accordance with the requirements for distribution included in ISO 20387:2018, 7.3.3.

The biobank shall develop and implement written policies and procedures governing the access, sharing and distribution of biological material and associated data, including:

a) principles governing access to the biological material and associated data in accordance with ISO 20387:2018, 7.3.1.1;

NOTE 1 Limitations on use can be included in an MTA or equivalent documents (see Annex C).

b) procedure for submitting requests;

c) authorization process and responsible personnel for reviewing requests;

d) criteria for determining whether a request can be fulfilled;

e) designated governance;

f) process for appeal of rejected requests;

g) acknowledgement of biobanks in publications and report requirements.

NOTE 2 For report requirements concerning the distributed biological material or associated data, or both, see ISO 20387:2018, 7.12.

10.2 Destruction and disposal

The biobank shall establish criteria for continued retention or destruction. Reasons for destruction and disposal can include:

a) the original purpose of the collection has been achieved;

b) decline in interest for use of the biological material;

c) biological material or associated data has been lost or is not available;

d) biological material or samples are no longer fit for the intended purposes;

e) when required by consent, study design or other;

f) nonconformity with the approved protocol.

All sample destruction shall be reviewed and documented.

11 Information collection

The biobank should use relevant standards and ontologies, e.g. Darwin Core for taxonomy and UBERON or BRaunschweig ENzyme DAtabase (BRENDA) for describing the anatomical source of a biological material. For mutations associated with abnormal phenotypes, the appropriate international nomenclature should be used (e.g. see ISO/TR 3985).

The donor species for each biological material shall be documented using recognized national or international identification methods, where available.

Annex A
(informative)

Exemplary data collection table for animal biological material

Table A.1 gives an example of a data collection sheet, which is defined by each biobank and describes the relevant requirements and recommendations for each individual biological material type. Such requirements and recommendations can be derived from this document or ISO 20387 or any other relevant documents.

Table A.1 — Example for a data collection sheet for animal biological material

Data	Example(s)	Comments	Requirement or recommendation
Sample ID	RL0600	One unique identifier or code for each individual sample. For samples within population collections, a unique identifier of the locality associated with the taxon is given.	Requirement
Sample type	Blood, tissue cell, urine, hair, faeces	Sample type and additional relevant information, for example: — multiple tissue types collected; — contamination or symbiosis or infection detected; — post-collection treatment performed.	Requirement
Anatomical site	Skin, heart, muscle	Anatomical site can be annotated using ontologies (e.g. UBERON).	Requirement
Permits		Permits for collection, transport, export and import.	Requirement
Genus	*Ovis*	The full scientific name of the genus in which the taxon is classified.	Requirement
Species	*Ovis ammon*	The full scientific name of the species in which the taxon is classified.	Requirement
Subspecies	*Ovis ammon jubata*	The full scientific name of the subspecies in which the taxon is classified.	Requirement
Date of collection	YYYY-MM-DD	In accordance with ISO 8601-1.	Requirement
Breed	Southdown	The breed name.	Requirement
Sex	Female, male, hermaphrodite	The sex of the donor, where available.	Requirement
Methods	Snap freezing	Collection, preparation and preservation or fixation(s) methods.	Requirement
Chemicals	Propofol, heparin	Chemicals such as anaesthetics, fixatives and blood tube additives.	Requirement
Phylum	*Chordata*	The full scientific name of the phylum or division in which the taxon is classified.	Recommendation
Class	*Mammalia*	The full scientific name of the class in which the taxon is classified.	Recommendation
Order	*Artiodactyla*	The full scientific name of the order in which the taxon is classified.	Recommendation

Table A.1 *(continued)*

Data	Example(s)	Comments	Requirement or recommendation
Family	*Bovidae*	The full scientific name of the family in which the taxon is classified.	Recommendation
Subfamily	*Caprinae*	The full scientific name of the subfamily in which the taxon is classified.	Recommendation
Donor photograph(s)	Full body, collection site	Any donor photographs deemed necessary.	Recommendation
Cohort characteristics	Native, introduced, naturalized, invasive, managed, domestic	Additional information about the donor cohort	Recommendation
Reproductive state	Non-reproductive, pregnant, lactation	The reproductive condition of the donor(s).	Recommendation
Disease status	Amphistomiasis, calf diphtheria, white nose syndrome	Diagnosis, where possible.	Recommendation
Mutation	Missense, frameshift, aneuploidy	Mutation, where identified.	Recommendation
Life stage	Egg, eft, juvenile, adult	The age class or life stage of the donor(s).	Recommendation
Date of birth or death or both	YYYY-MM-DD	If the date of birth or death or both is(are) available, it(they) should be registered in accordance with ISO 8601-1.	Recommendation
Latitude	−41,0983423	As precise as is required for intended purpose.	Recommendation
Longitude	−121,1761111	As precise as is required for intended purpose.	Recommendation
Altitude	2 154 9 meters	As precise as is required for intended purpose.	Recommendation
Habitat	Savanna, steppe, riverbank, forest, lake	The ecosystem in which the donor naturally occurred or established.	Recommendation
Location photograph and information	Country, state, department or province, and locality	Geographic location and photograph, where possible.	Recommendation

Annex B
(informative)

Collection methods for animals of different natures and sizes

Table B.1 — Restraint methods for different animals

Animal	Examples	Restraint
Small animals	Mice	Manual or appropriate restraining devices (e.g. handling tunnels)
Medium or large domestic animals	Farm animals, dogs, cats, poultry, fish	Physical (e.g. hold to secure position and keep donor immobile)
Wild animals	Tiger, hippopotamus, moose, wild boar, python, trout	Physical or chemical (e.g. anaesthetic), as required

Table B.2 — Examples of solid tissue collection

Animal type	Collection method
Invertebrates	The collection methods differ according to taxon and life stage. A microscope is required for collection from microscopic sized invertebrates. When applicable, parasite(s) should be isolated from the host before collection. Microscopic or clonal invertebrates should be collected in a single container, and treated as a single sample, to ensure sufficient quantity. Collection of biological material from invertebrates can require the use of analgesics and anaesthetics.
Small vertebrates	Appropriate tools (e.g. sharp scissors or scalpel blades) can be used. Analgesics or anaesthetics, or both, can be used for collection of biological material from small vertebrates (e.g. ear punch).
Medium to large-sized vertebrates	When collecting skin biopsies, remove hair (e.g. shaving) or feathers (e.g. plucking) at the anatomical site of collection. The collection area should be washed with sterile saline, disinfected (e.g. using 70 % alcohol) and washed again with sterile saline. A suitable skin biopsy punch tool should be selected according to the donor species. A punch biopsy of 3 mm to 5 mm in depth can be taken. The sampled area should be appropriately sutured or bandaged. Collection of biological material from medium- to large-sized vertebrates can require the use of analgesics and anaesthetics.

Table B.3 — Examples of selected blood collection methods

Blood collection site	Blood collection method		Donor types
	Donor specifics and preparation	Method	
Ear	Recommended collection method for some terrestrial mammals, e.g. see Reference [20].	A sterile needle, with a diameter chosen according to the vein to be punctured, should be used to ensure rapid blood withdrawal without collapsing the vein and creating haematoma. Needles should always be single use to avoid contamination. Depending on the species and the expected blood flow rate, it can be necessary to first rinse the syringe with a sterile solution of an anti-clotting agent to avoid initiation of clotting. Blood should be withdrawn slowly to prevent shock, vein collapse or destruction of blood cells. Pressure should be applied for about 30 s after removing the needle in order to avoid haematoma and further pain for the animal. The absence of external or subcutaneous bleeding should be checked.	Rabbit, swine
Tail	Stand behind the donor and keep the tail in a vertical line with the body, and collect blood from the vein located ventral to tail vertebra. Care should be taken to prevent tail loss in species that are capable of tail autotomy.		Reptiles, amphibians, fish, marine mammals, small rodents, cattle
Jugular	Restrain the donor's head. Disinfect the collection site. Press the jugular sulcus for vasodilatation.		Sheep, cattle, small mammals, horse, birds
Cephalic or saphenous vein	The cephalic, lateral or medial saphenous veins can be used for blood collection. Anaesthesia or sedation can be used for this blood collection method.		Primates, dogs, cats and small rodents
Wing vein or leg vein	The small subcutaneous vein at the level of the humerus or medial metatarsal vein can be chosen.		All birds
Sublingual vein	Suitable for the removal of large volumes of rodent blood (e.g. 0,2 ml to 1 ml) at frequent intervals.		Rodents
Nail	Nail clipping can be used for collection of small blood volumes and involves reaching the germinal vascular portion of the nail.		Vertebrates

Table B.4 — Examples of urine collection methods

Urine collection method	Detailed information
Cystocentesis	The donor can be anesthetized and restrained. After sterile preparation of the puncture site, stabilize the bladder, carefully insert the needle and aspirate urine.
Catheterization	The donor can be anesthetized and restrained. After sterile preparation of the catheterization site, insert the catheter and drain urine.
Manual expression	This method is suitable for some donor species (e.g. dogs, cats, rabbits). Exert sufficient pressure to relax the bladder sphincter to allow the release of urine.

Table B.5 — Examples of milk collection methods for ruminants and small mammals

Animal type	Milk collection method
Ruminants	The collection area should be cleaned. For species not routinely milked, the young should be encouraged to latch on and feed for a few minutes in order to stimulate milk let-down and facilitate subsequent milk collection. Midstream milk should be collected by suction and placed in sterile, air-tight containers.
Small mammals	Consider litter size when choosing donor, to ensure sufficient milk quantity for the young (e.g. litter size fewer than six, if possible). Optimal time for collection is 8 days to 12 days post parturition. Allow sufficient milk to accumulate by separating the dam from the litter prior to milking, if required. Determine the optimal dose of exogenous oxytocin, when used to improve milk yield. Donors such as mice should be anaesthetized before milking. As oxytocin begins to take effect, milk can be expressed manually using the thumb and forefinger to massage and squeeze the mammary tissue until a visible bead of milk begins to form at the base of the teat. Milk can be collected or aspirated using a vacuum device (e.g. rubber suction bulb connected with a pipette).

Table B.6 — Examples of collection methods for other samples

Biological material type	Collection method
Feathers	Determine the collection area, use clean tweezers to clamp the feather shaft close to the skin and pull in one direction, consistent with the growth direction. Feathers can also be collected by dissection, for dermal papilla inclusion, under anaesthesia or after death, when necessary.
Scales	Minimize handling time, to ensure donor wellbeing. Scale collection from reptiles can be a surgical procedure, done under general anaesthesia. Pre-tagged coin envelopes and filter paper can be used to store or transport the scales in to keep them from coiling.

Annex C
(informative)

Information in a material transfer agreement or equivalent document

An MTA[23] or equivalent document can incorporate the following:

a) legal entities involved in the agreement;

b) definition of terms such as biological material(s) or associated data, or both, and derivatives;

c) intended purpose and limitations on the use of the material(s), including third-party permissions;

d) specific provisions to protect confidential information;

e) specific existing or future intellectual property rights;

f) declaration that the material is not under warranty;

g) liability or indemnification, or both;

h) specific governing laws by origin or destination location(s);

i) termination conditions;

j) expiration date for the agreement;

k) authorizing signatures of the legal entities involved;

l) detailed description of the research, protocol or list of materials.

Annex D
(normative)

Collection, preparation and preservation methods

Table D.1 — Recommendations, requirements and information for the collection, preparation or preservation, or multiple of them, for selected biological material

Biological material type		Method	Recommendations and requirements
Solid tissue		Liquid nitrogen freezing	Complex organs can require dissection prior to liquid nitrogen freezing. The biological material can be: — subdivided as samples; — embedded for further isolation of cell types by laser microdissection. To preserve target analytes for downstream analysis, the biological material can be frozen in liquid nitrogen.
		Preservation in protective solution	Preservation media [e.g. ethanol, dimethylsulphoxide (DMSO), saline solution, commercial fluids] can be used to maintain the stability of biological material. The selection of preservation media should be appropriate, and should not adversely affect the fitness for the intended purpose. When freezing tissue in liquids, the biobank should restrict the volume of protective solution to compensate for volume expansion. The biobank should minimize tissue size or thickness (e.g. less than 5 mm), or both, for complete penetration by protective solution.
		Cell isolation	Tissue should be dissociated for cell isolation mechanically or enzymatically, or with both methods, before being used (e.g. for flow cytometry, single-cell analysis). The isolated cells can be cryopreserved for future use with protective solution suitable for the tissue type(s), where appropriate. For requirements and practices on cell isolation and culture, see ISO 21709.
		Nucleic acid and protein extraction	For pre-analytic information for DNA or RNA or protein isolation from formalin-fixed paraffin-embedded (FFPE) tissue and frozen tissue, see ISO 20166-1, ISO 20166-2 and ISO 20166-3, ISO 20184-1, ISO 20184-2 and ISO 20184-3.
Germplasm	Embryos		Embryos (including pre-implantation embryos) shall be preserved, stored and revitalized according to documented protocols. The methods should be appropriate for the biological material type, species and intended purpose. The biobank shall document genetic origin, stage, preservation and revitalization protocols and the number of embryos.
	Oocyte, sperm		Oocyte or sperm shall be preserved, stored and revitalized according to documented protocols. The methods should be appropriate for the biological material type, species and intended purpose.

Table D.1 *(continued)*

Biological material type		Method	Recommendations and requirements
Faecal material	DNA	DNA extraction	For faecal material collected at different time points and destined for DNA extraction, it is recommended to consider immediate partial processing (e.g. freezing after cell lysis) to allow temporary preservation to extract DNA in batches at a later time point. Fresh faeces should be collected in sterile cryotubes with screw top lids and immediately frozen, if 5.2.6 b) applies. If a preservation solution is used, it should be removed by centrifugation before final storage for DNA extraction. Further processing will be facilitated if the samples are calibrated to a given weight just before freezing begins. For small-size faeces, the entire faecal material should be collected.
Urine and milk		Separation, preservation	Urine should be preserved or processed at temperatures between 2 °C to 8 °C within 24 h of collection, to maintain integrity. Milk should be preserved or processed at temperatures between 2 °C to 8 °C within 4 hours of collection, to maintain integrity. Urine and milk can contain cellular and other components that should be removed prior to aliquoting and storage. Centrifugation can be used to separate the cells and any debris. Preservatives (e.g. EDTA, sodium metabisulfite) can be used for urine. The choice for preservation (e.g. acidification) can be influenced by planned analysis, transport duration and conditions (e.g. environmental, storage), depending on the intended purpose.