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Biotechnology — Biobanking of parasites —

Part 1: Helminths

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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 document 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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This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

A list of all parts in the ISO 18209 series can be found on the ISO website.

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

The biological industry has been using helminths to treat diseases such as Crohn's disease, ulcerative colitis, auto-immune disease like allergic asthma, and even incurable disease like cancer. The industry is also developing anthelmintic drugs and rapid infection diagnosis methods.

A biobank that can fulfil the role as a platform for collecting, storing and distributing parasitic resources is of urgent need.

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"[20].

This document deals with the management and operation of the biobank: Helminth, which can safely manage and supply uncontaminated parasitic resources for the biological industry to develop treatment of autoimmune diseases, parasite infection diagnostic tests, and anthelmintics.

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 of parasites —

Part 1: Helminths

1 Scope

This document provides requirements for the biobanking of helminths as parasitic resources including the collection, safeguarding, classification, proliferation, preservation, storage and distribution of helminths.

This document sets requirements for the quality of helminths and their associated data, the data collection, and safety management when handling the helminths as a source of human disease infection.

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

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 15190:2020, *Medical laboratories — Requirements for safety*

ISO 20387:2018, *Biotechnology — Biobanking — General requirements for biobanking*

ISO 21710:2020, *Biotechnology — Specification on data management and publication in microbial resource centers*

ISO 24088-1, *Biotechnology — Biobanking of microorganisms — Part 1: Bacteria and archaea*

ISO 35001, *Biorisk management for laboratories and other related organisations*

ISO 45001:2018, *Occupational health and safety management systems — Requirements with guidance for use*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387 and ISO 24088-1 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
biobank
parasite resource bank
legal entity or part of a legal entity that performs biobanking of *parasites* (3.8)

[SOURCE: ISO 20387:2018, 3.5, modified — The accepted term "parasite resource bank" was added and the words "of parasites" were added to the definition.]

3.2
cyst
form in which *parasites* (3.8) are surrounded by resistant covers or membranes

3.3
final host
organism that nourishes a *parasite* (3.8), which undergoes a stage of reproduction from the final adult stage

3.4
helminth
relatively large multicellular invertebrate *parasites* (3.8)

Note 1 to entry: Helminth can be found in the gastrointestinal tract and other parts of the stomach as well as in other organs and parts of the body.

Note 2 to entry: Typical helminth include acanthocephalan, nematode and platyhelminth (monogenean, trematode, cestode).

3.5
host
organism that nourishes a *parasite* (3.8) and is either an *intermediate host* (3.6) or a *final host* (3.3)

3.6
intermediate host
organism that nourishes a *parasite* (3.8) during the larva stage

3.7
minimum dataset
MDS
collection of technical and scientific data digitized in specific fields of a database, which is necessary to distinguish unambiguously a particular biological material and provides a minimum amount of information available for each accession in a *biobank* (3.1)

[SOURCE: ISO 21710:2020, 3.15, modified — Note 1 to entry was deleted; in the definition, "microbial material" was replaced by "biological material" and "an MRC" was replaced by "a biobank".]

3.8
parasite
organism that temporarily or permanently resides in the body of another organism and receives the necessary nutrients therefrom

3.9
parasite life cycle
life history stage of the parasite
chain of consecutive life stages, in which the growth of *parasites* (3.8) is divided into eggs, larvae and adults

3.10
recommended data set
RDS
collection of data that includes useful information for an improved description of the functions and properties of a biological material

Note 1 to entry: This includes optional data fields for use by the *biobank* (3.1) in the catalogue, when available.

[SOURCE: ISO 24088-1:2022, 3.17, modified — In the definition, “microbial material” was replaced by “biological material”; in the note, “microbial biobank” was changed to “biobank”.]

3.11
room temperature
temperature in the range of 18 °C to 25 °C

Note 1 to entry: The definition is given for the purposes of this document. Local or national regulations can have different definitions.

[SOURCE: ISO 20186-1:2019, 3.23]

4 General requirements

4.1 General

The biobank shall meet the requirements described in ISO 20387, in addition to those in this document. ISO/TR 22758 can be used as additional reference for the implementation of ISO 20387.

Properly trained personnel shall carry out the sampling and identification of samples.

The biobank for helminths shall prepare, implement and document procedures for the preservation, identification, information provision, distribution, etc. of parasitic resources.

NOTE Annex A includes a visualization of the helminths management process within a biobank.

The biobank shall determine the optimal storage environment for its use, and ensure that sufficient equipment, facilities and funds should be secured to store parasitic samples until they are necessary.

The biobank shall establish an effective utilization plan for parasitic resources by defining the collection, pre-treatment, identification, preservation, storage and distribution of parasite resources and associated data.

The biobank shall define and document the scope of activities in accordance with this document. The biobank should insist on the suitability of this document only to the defined extent of banking activities.

4.2 Legal and ethical requirements

The collection of biological material from live animals shall comply with applicable 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 [2] and [3].

National and international legislation can require the biobank to retain documented information. This can include:

— evidence of compliance with applicable health and safety requirements;

— parasite risk classification;

— quarantine requirements;

— intellectual property rights;

— international treaties;

— access and benefit-sharing including biological material and associated data access, exchange and transfer.

4.3 Health and safety

4.3.1 General

The biobank or the legal entity of which it is a part shall ensure that health and safety procedures are in accordance with ISO 20387:2018, 6.2.1.5. All procedures shall be performed according to the appropriate biosafety classification (see ISO 35001 and WHO 4th guideline[26]).

The helminth egg concentration index of irrigation water is closely related to human health protection, such as the risk of direct contact and the risk related to crop types. Since helminth eggs can adversely affect the human body through crops, irrigation water applied to crops is regulated by many countries. In this regard, sewage and wastewater from the laboratory handling parasites or biological material derived from them shall be treated appropriately for the water quality of irrigation water.

Since helminth eggs are different in shape and size, they can only be identified by properly trained personnel. The personnel shall be familiar with the work of the laboratory handling parasites or biological material derived from them.

Procedures for separating adults and larvae from the host's organs or separating them from the host's feces or sputum shall be established, implemented and documented. These procedures shall take all necessary safety procedures into account (e.g. ISO 15190).

When conducting an experiment to separate adults and larvae from the host's organs or to separate them from the host's feces or sputum, personnel shall wear appropriate personal protective equipment (gloves, gowns, eye protection, etc.) to prevent infection or transmission of infective forms and conduct personal hygiene.

The biobank shall prepare procedures to respond to incidents, exposures and accidents in accordance with the relevant parts of ISO 15190 and ISO 35001.

4.3.2 Chemical safety

The biobank shall be in accordance with ISO 15190 when handling chemicals.

The biobank shall establish, document and implement policies and procedures concerning the storage, handling, use and disposal of chemicals, taking into account the applicable regulations of each country or region in which the biobank operates.

Handling chemicals related to biobank activities can include but is not limited to extraction, synthesis, industrial production, transportation, use and disposal.

The safety data sheet (SDS) for all chemicals used by the biobank shall be prominently displayed or readily available.

The biobank's laboratory, culture room, and sample room dealing with chemicals shall indicate physical and chemical hazards such as explosiveness, flammability, oxidation, etc. and health hazards shall be marked at the entrance.

4.3.3 Biosafety, biosafety levels and biorisk

The biobank should follow ISO 35001 or WHO 4th guideline[26] when handling biological material contaminated with pathogens.

The biobank shall ensure that risks to health are managed effectively, including consideration for preventive and protective measures. Personnel shall be medically examined periodically according to exposure and risk.

The requirements of the personnel health programme, including requirements for record management and confidentiality, shall be determined by a biosafety risk assessment.

The biobank shall:

a) establish and implement a vaccination policy as part of the personnel health surveillance;

b) ensure that the required and/or recommended vaccines and their information are made available to the personnel. In the cases where no vaccines are available, periodical tests should be performed and treatment of infected personnel should be provided.

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

Biosafety in the biobank shall be in accordance with ISO 45001:2018, Clause 7.

The biobank shall have material SDSs for at least internationally recognized hazardous parasites and/or hazardous derivatives handled in the biobank and should ensure that they are prominently displayed or readily available.

Waste management procedures for biological material shall be documented including waste storage, packaging, transportation and decontamination.

NOTE More information about biosafety can be found in the CDC 6th guideline[25].

The safety rating of pathogens is classified as follows:

a) Class 1: Parasites that are non-pathogenic and have been used for a long time, which may cause opportunistic infection, or require caution in excessive or long-term contact.

b) Class 2: Parasites that are likely to infect but can be prevented from infecting, and there are treatment measures when they infect humans.

c) Class 3: Direct handling of parasites at the hospital requires considerable care. Parasites can be prevented from infecting humans, and there are treatment measures when they infect humans.

d) Class 4: Parasites that cannot be prevented from infecting, and there is no treatment when they infect humans

4.3.4 Personal protective equipment (PPE)

4.3.4.1 General

The biobank shall provide appropriate PPE according to the biosafety level of the helminth being handled and those of the equipment and materials being used.

The biobank shall ensure that all PPE is working properly, free of contamination before use and available in a place that is easily accessible.

4.3.4.2 Physical safety

Facilities for compressed gas shall be provided in accordance with ISO 15190:2020, 9.1. In addition, access to emergency equipment including fire extinguishers, safety showers and eye washers, and first aid kits shall be maintained.

4.3.4.3 Liquid nitrogen safety

In order to safely handle, store and use liquid nitrogen, appropriate facilities and securing devices in accordance with ISO 15190:2020, 9.1, shall be provided, taking into account the applicable requirements of each country or region.

Oxygen monitoring devices and alarm systems should be installed in areas where liquid nitrogen is stored or handled.

5 Personnel

ISO 20387:2018, 6.2, shall be followed. ISO/TR 22758:2020, 8.3.7 and 8.3.8, can be consulted for further information.

The personnel shall demonstrate competence for using the technique(s) of distinguishing helminth eggs (under microscopy) or larva from the medium, the technique(s) of separating parasites from the host (animal or human) body or organ(s).

NOTE Critical activities include but are not limited to biological material acquisition, handling, preservation, identification, characterization, distribution, quality control tests and associated data management.

6 Facilities

6.1 General

ISO 20387:2018, 6.3, ISO 15190:2020, 4.2, ISO 35001:2019, 8.1 shall be followed.

NOTE WHO 4th guideline[26],3.3, 4.3 and 5.3 and CDC 6th guideline[25], Section 3 and 4 provide applicable guidelines.

The biobank shall evaluate the risks arising from the handling of biological material, and shall establish and operate facilities according to the biosafety class.

The facilities according to the biosafety level are as follows:

a) Class 1: A washbasin shall be provided in the laboratory and the laboratory shall be divided into a space for handling biological resources and other work spaces. The suitable biological safety cabinets (BSCs) shall be prepared to protect the operator, the laboratory environment and work materials from exposure to infectious aerosols and splashes.

b) Class 2: The laboratory shall be equipped with an anteroom and automatic closing doors and shall be equipped with faucet for easy use of eye wash water around the sink.

c) Class 3: There should be a hands-free or automatically controlled sink for washing hand, foot or elbow and eye wash near the exit. Clean air shall be continuously supplied to prohibit recirculation of exhaust air and to prevent potential contamination in the laboratory and also, all penetrations in laboratory shall be sealed. Controlled ventilation system shall be installed to monitor directional airflow available.

d) Class 4: The laboratory shall be in a separate building or in an isolated restricted area within the same building. The laboratory shall have dedicated supply and exhaust air lines, vacuum lines, and decontamination systems.

NOTE Details about the biosafety level can be found in WHO 4th guideline[26] Clause 5 and CDC 6th guideline[25] Section 3 and 4.

6.2 Breeding facilities

The parasite breeding or management and animal breeding facility shall be clean, where the temperature and humidity suitable for the breeding of the parasite's host animal are maintained and no specific pathogen exists.

For breeding host animals infected with parasites, the laboratory shall be equipped with facilities with biosafety Class 2 or higher.

6.3 Sample storage room

ISO 20387:2018, 7.7, shall be followed.

In the sample storage room of the biobank an appropriate temperature and humidity to prevent deformation and damage to the sample shall be maintained.

The sample storage room shall be designed so that illumination and shading can be adjusted to prevent changes in the colour and shape of the sample.

The sample storage room shall be equipped with ventilation facilities and hoods for discharging chemical preservatives (e.g. formalin, xylene) and other contaminants used in immersion samples.

7 Critical equipment for parasite biobanking

7.1 General

ISO 20387:2018, 6.5, shall be followed.

NOTE For other laboratory safety requirements, see IEC 61010-1.

Contaminated equipment exposed to biological material(s) shall be appropriately disinfected.

Safety of electrical equipment for laboratory shall be in accordance with IEC 61010-1.

The equipment needed by the biobank includes steam sterilizer(s) (i.e. autoclave), freezer(s), refrigerator(s), incubator(s), biosafety workstation(s), liquid nitrogen storage system(s), ultra-low temperature electrically powered storage(s), microscope(s), and microtome(s). All necessary equipment except microtome(s) to produce extremely thin slices of cells and tissues shall be maintained and managed in accordance with Clause 7.

The laboratory shall be equipped with a biological safety workstation (Class 2 [see 6.1, (b)]).

7.2 Calibration

For the equipment calibration/test, ISO 20387:2018, 6.5.2, 6.5.8 f) and g), 6.5.10, 6.5.11, 6.5.12, shall be followed. ISO/IEC 17025:2017, 6.4 and 6.5, can be used.

7.3 Incubators

Incubators shall be monitored for conditions or defects that can adversely affect their functionality.

Incubators shall be monitored for incubation temperature with suitable temperature recording systems.

Incubators intended for organisms requiring non-atmospheric gaseous environments should have monitoring and alarm systems that measure and provide an alert in the event of deviation in atmospheric composition (e.g. temperature, humidity, illumination, CO_2).

7.4 Refrigerators

When a refrigerator is used for storage of biological material, the internal temperature shall be maintained at an appropriate temperature, preferably from 2 °C to 8 °C. Refrigerators shall be cleaned and checked for their temperature periodically, and any broken materials shall be carefully stored or removed.

Temperature and power monitoring systems should be installed to alert personnel when the temperature of the refrigerator is outside the set range or in the event of a power outage.

7.5 Ultra-low temperature electrically powered storage

Ultra-low temperature electrically powered storage should be used to safely store biological materials for a long period of time. It is recommended to use ultra-low temperature electrically powered storage with enhanced safety features, such as a dual compressor system, dry ice or liquid nitrogen providing backup capability.

Measures should be taken to avoid unnecessary exposure of biological material cryovials to temperatures outside the recommended temperature range. For example, when a cryovial container needs to be accessed for long periods, it should be transferred to a suitable temporary container.

7.6 Liquid nitrogen storage system/liquid nitrogen supply

Measures should be taken to avoid unnecessary exposure of biological material cryovials to temperatures outside the recommended temperature range. For example, leaving vessel lids open can impact the viability of many of the stored biological materials and result in contamination of the vessel, and should be avoided.

8 Process requirements

8.1 General

The biobank can acquire helminths by deposition or collection. The procedure for collecting helminth and associated data shall be in accordance with ISO 20387:2018, 7.2, 7.3.1, 7.3.2 and 7.5. An overview of the process of helminths management is provided in Annex A.

Receipt of biological material shall be in accordance with the acceptance criteria of the biobank and with other relevant requirements (e.g. MAA).

Helminths are present in living animals and humans, animal carcasses, and animal or human excrement or tissue, urine, blood, sputum and are classified as adult, larva, and egg according to the growth stage.

When a host for collecting parasites is secured, the practitioner shall document the following information including, but not limited to:

a) the date and place of securing the host;

b) the scientific name of the infected host;

c) the infected area.

8.2 Collection

8.2.1 Adult worms

Adult worms can be collected from the host's organs, feces and sputum. When separating helminths from the host animal, the presence or absence of parasite outside the animal's body shall be checked. If ectoparasites exist outside the body, they should be carefully separated with a tweezer or removed with other suitable methods.

The infected area (eyes, airways, lungs, heart, liver, gastrointestinal tract, etc.) in the animal preferred by helminths shall be separated to check for parasite infections and then the parasite(s) shall be collected.

Adult worms in feces shall be either:

a) collected directly from the surface of the feces; or

b) collected after being filtered by a sieve (250 µm to 500 µm) in saline or tap water 1,5 times volume of the amount of feces.

8.2.2 Larvae

Larvae shall be collected from the host's organs, muscles, biopsized samples, blood or feces using a stereoscopic or light microscope and pipette or collecting tools.

8.2.3 Eggs

Eggs should be collected from the host's organs, feces, urine, tissue or sputum using a concentration method such as floatation or sedimentation techniques).

8.3 Pre-treatment according to the preservation form of biological material

8.3.1 Immersion samples

For morphological observation of parasites, large-sized parasites such as cestodes should be washed with water and immersed in warm formalin (e.g. between 40 °C and 80 °C) to relax their shapes.

Small-sized parasites such as nematodes should be immersed in sterile saline at 70 °C to 80 °C to relax their shape, and be immersed in formalin or ethanol.

For the fixation for molecular usages, parasites should be stored in ≥ 70 % ethanol.

8.3.2 Slide samples

If parts of the helminth are needed, the tissue of the parasite shall be cut with a sterile sharp blade or scissors.

Samples should be fixed, e.g. in alcohol-formalin-acetic acid (AFA) fixative or in formalin at room temperature, and mounted on a glass slide after staining or being rendered transparent to identify parasites, eggs, or sacs under a microscope.

Cestodes and trematodes should be stained (with Semichon's acetocarmine, H&E stain, etc.) after being fixed.

Monogenoids can be stained with Gomori's trichromic (see [13], [16]) or Eosin/Orange G (see [14], [17]) before being fixed.

Nematodes should be made transparent generally with lactophenol or phenol. Large worms should be cut into several slices with a blade to fit on a glass slide.

8.3.3 Pre-treatment for freezing tissue and DNA, RNA, protein isolation

For DNA, RNA, protein isolation or sampling of parasitic resources, the following shall be done:

a) The tissue of the parasite shall be cut with a sterile sharp blade.

b) Afterwards, the tissue of the parasite shall be placed in a suitable container and stored at ≤ −80 °C.

Tissue for DNA isolation should be stabilized by immersing it in 70 % ethanol.

8.4 Characterization and identification

For the classification of parasitic organisms, morphology analysis of parasitic resources shall be performed. This enables the anatomical observation of the parasite life cycle and their characteristic forms at each stage.

NOTE Annex B gives morphological details, including six parasite figures (Figures B.1 to B.6) in Table B.1, for all growth stages of various parasite groups that can be used for the morphology analysis.

Molecular biological characterization by DNA sequencing should be performed:

a) when epidemiological investigations are necessary;

b) when morphological identification is difficult;

c) for the medical diagnosis and application;

d) for the classification between closely related species.

The biobank shall conduct morphological tests and molecular biological characterization for the identification of helminths. Through this, the taxonomy or identity of the helminth can be confirmed.

8.5 Preparation, preservation and storage

ISO 20387:2018, 7.6 and 7.7, shall be followed.

The biobank shall determine the methods of preservation and storage, the unit of preservation, and the container for preservation according to the characteristics, stability, and usability of the parasitic organism(s).

Biological materials can be preserved as immersion samples, slide samples, frozen tissue, paraffin blocks, and DNA extracts. The biobank shall preserve or store the parasitic material in separate places, classifying them for long-term preservation, inspection and management, and for distribution.

Preservation methods shall be validated for each type of parasite to ensure the viability of the sample recovered from storage, where necessary.

Each sample should be preserved using at least two different preservation methods. The viability of preserved sample should be checked periodically, especially for cases where stability is known to be problematic.

Furthermore, duplicate or multiple samples should be stored separately (e.g. location, freezer) in the interest of emergency preparedness.

Information on the preserved biological material identified by the characterization shall be catalogued. The catalogue shall specify requirements for the distribution of biological material (e.g. applicable regulations to prevent contagious disease transmission).

8.6 Distribution and disposal

ISO 20387:2018, 7.3.3, A.7 and A.8, shall be followed.

The biobank shall be able to distribute all biological material listed in the catalogue. The biobank can decide whether or not to distribute the biological material (s) after checking the bio-safety level of the user.

The biobank shall dispose of any of the following biological material:

a) contaminated parasites;

b) parasites for which the results of quality control and characteristic inspection are nonconforming;

c) parasites for which storage management is not possible or duplicate storage is not worthwhile.

The disposal of a biological material shall be carried out by appropriate disinfection or sterilization in a manner that completely kills the parasite(s) and inactivates any associated toxins.

8.7 Transport of helminths and associated data

ISO 20387:2018, 7.4, shall be followed.

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

The biological material shall be labelled and placed in a safe container. This container should be further packaged as appropriate for the transport (e.g. tertiary packaging).

Packages of immersion specimens shall be carefully packed to prevent leakage of stored liquid.

Packaging of frozen tissue shall be packaged with dry ice or ice packs to maintain the temperature during transportation. Instructions for identification and use of parasitic resources shall be enclosed when packing.

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.

9 Complaint management

Complaints shall be managed in accordance with ISO 20387:2018, 7.13 and 8.9.2.

10 Management of information and data

10.1 Information system requirements

10.1.1 General

The information system shall meet ISO 20387:2018, 7.3, 7.5, 7.10, and ISO 21710:2020, 5.4.

10.1.2 Biological material identification and tracking system

The biobank shall record and manage the data relating to each biological material in the information system. The biobank shall establish identifiers/numbers for biobank accession, production lot and location for each biological material.

10.1.3 Data management

Data management of biological material is divided into minimum data set (MDS) and recommended data set (RDS).

An MDS of the biological material shall be available, including the following data fields: accession number, organism type, status, biosafety and biosecurity, any known restrictions and history of deposit in accordance with ISO 21710:2020, 4.2.2.

The MDS should be documented in accordance with ISO 21710:2020, 5.3.3.

The RDS of biological materials shall contain data fields other than the information required for the MDS, in particular: collection, cultivation, conservation and maintenance information.

Examples for RDS can be found in ISO 21710:2020, Annex A.

10.1.4 Biobank accession number

The biobank shall assign a unique accession number to each newly registered biological material. The biobank accession number shall be a persistent identifier for the biological materials.

For each sample derived, produced or replicated from the original source biological material, a unique identifier shall be generated and linked to the identifier of the source biological material. A registration date shall be documented for each accession. The registration date is the date on which the biobank registers the biological material in the material information system.

Date and time documentation should be formatted in accordance with ISO 8601-1.

10.1.5 Location

The location of each biological material within the biobank shall be documented. Records shall be updated when the location is altered. The preservation device, shelf, preservation box and storage area can be considered for the designated location.

10.2 Inventory management

ISO 20387:2018, 7.5.1 c) and 7.7, shall be followed.

Inventory management can be verified when the biobank receives an application for distribution of biological material(s).

11 Quality control, validation and verification

11.1 General

The biobank shall conduct quality control (QC), validation and/or verification of methods in accordance with ISO 20387:2018, 7.8 and 7.9.

11.2 Contamination inspection of biological material accompanying QC

11.2.1 Immersion samples

The contamination of biological material in an immersion sample should be determined through observation of contamination of the sample bottle (glass product) and the preservation solution. Parasites preserved in immersion solution should be tested for contamination by molecular biological tests with DNA isolation and sequencing.

11.2.2 Slide samples

A slide sample of a biological material shall be inspected for defects, damage and contamination in order to observe the form of slide breakage, filler defect, sample maintenance, etc. to check the preservation status of the slide.

11.2.3 DNA

A randomly collected DNA sample should be subjected to a molecular biological test to determine whether or not it is contaminated by checking the sequence, or to measure the ultraviolet (UV) absorbance of DNA to check the concentration and purity of DNA.

11.2.4 RNA

A randomly collected RNA sample should be subjected to a molecular biological test to determine whether or not it is contaminated by checking the sequence, or to measure the UV absorbance to check the concentration and purity of RNA.

11.2.5 Protein

A randomly collected protein sample should be subjected to quantitation and purity.

12 Reporting

ISO 20387:2018, 7.12, shall be followed.

Annex A
(informative)

Process of helminths management

1. Acquisition

Collection	or	Deposit	
Pre-treatment Characterization and Identification Morphological examination Molecular biological characterization		Authentication for reception Check the biosafety level Identity test	
		Acceptance Identification Acceptance criteria Assignment of a unique identifier	or Rejection of deposit

2. Preparation/preservation/storage

Master stock
Distribution stock including distribution stock culture
Quality control
Contamination test
Identification
(Preservation method) at least two different methods
(Storage location) at least two different rooms
NOTE Depending on the type of helminth, it can be impossible to respond to these.

3. Publishing helminth materials and associated information

Recording in information system
Categorization of information disclosed to recipient

4. Distribution

Review of distribution request Accept distribution request Package and transportation	or	Rejection of deposit

5. Complaint management