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Biotechnology — Biobanking of microorganisms —

Part 1: Bacteria and archaea

Biotechnologie — Biobanque des microorganismes —

Partie 1: Bactéries et archées

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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*.

A list of all parts in the ISO 24088 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

Many countries around the world have microbial biobanks that perform biobanking activities according to their own guidelines. Microbial biobanks face challenges such as the genetic mutation of strains, microbial contamination, misidentification and loss of viability. These challenges can impact users' research results with consequent serious socio-economic losses, affecting the bioindustry, society in general and other stakeholders. It is imperative that internationally standardized operational and management requirements address these common problems.

This document has been developed to promote confidence in microbial biobanking. It contains the requirements to enable biobanks to demonstrate their competent operation and the ability to provide authenticated microbial materials and associated data of appropriate quality for research and development.

This is intended to be achieved by the planning and implementation of policies, processes and procedures relevant to the life cycle of microbial material and associated data within the scope/control of the microbial biobank.

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 microorganisms —

Part 1: Bacteria and archaea

1 Scope

This document specifies requirements for the biobanking of bacteria and archaea. It includes management of microbial material associated data as well as biosafety and biosecurity requirements.

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

This document does not apply to processing methods for microbial materials intended for food/feed production, laboratories undertaking food/feed analysis or therapeutic use.

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

WHO. *Laboratory biosafety manual*. Fourth edition. World Health Organization, 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 terminological 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
associated data
any information affiliated with *microbial material* (3.12) including *biosafety* (3.2) conditions but not limited to collection, taxonomic, deposit history, specific authorization and provider data

3.2
biosafety
practices and controls that reduce the risk of unintentional exposure or release of biological materials

[SOURCE: ISO 35001:2019, 3.22]

3.3
biosecurity
institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional/unintentional release of pathogens, genetically modified organisms, toxin-producing organisms, or parts thereof, as well as such toxins that are held, transferred and/or supplied by the biobank

[SOURCE: ISO 20387:2018, 3.9]

3.4
catalogue
systematically arranged list or record, often including *associated data* (3.1)

Note 1 to entry: This catalogue can be printed and/or available online.

[SOURCE: ISO 20387:2018, 3.10, modified — "associated data" has replaced "descriptive information" and Note 1 to entry has been added.]

3.5
deposit
process of transferring possession and/or custody of *microbial material* (3.12) and/or *associated data* (3.1) from a *provider* (3.15) to a *microbial biobank* (3.11)

3.6
distribution stock
microbial material (3.12) for distribution to recipients or users

[SOURCE: OECD. *Best practice guidelines for biological resource centres*, 2007[11]]

3.7
genomic stability
conditions produced by the absence of molecular evolution in a microbial culture

3.8
master stock
microbial material (3.12), used to produce the *distribution stock* (3.6)

3.9
material accession agreement
MAA
material acquisition agreement
documented agreement governing the transfer of *microbial material* (3.12) and *associated data* (3.1) between a *microbial biobank* (3.11) and another/other party/parties such as a *provider* (3.15)

Note 1 to entry: An MAA documents basic data, such as place and date of sampling, in a standardized format, and specifies the role, rights and duties of each party.

Note 2 to entry: MAA is a synonym of material deposit agreement (MDA). It is normally put in place by a microbial biobank.

Note 3 to entry: The definition was derived from ISO 21710:2020, 3.13, with the change that an MAA is not always a contractual document.

3.10
material transfer agreement
MTA
documented agreement governing the transfer of *microbial material* (3.12) and *associated data* (3.1) between a *microbial biobank* (3.11) and a recipient

Note 1 to entry: All the documents can be designated as MTA as long as they contain information about the *in situ* origin or the source of the microbial material and associated data, information about the *provider* (3.15) and recipient, and information that defines the limits of the use of the microbial material and associated data.

Note 2 to entry: An MTA can include requirements for the microbial material being deposited, e.g. to meet the need of the provider country or country of origin, particularly those that are the parties of the Convention of Biological Diversity (CBD) and Nagoya Protocol (NP).

Note 3 to entry: The definition was derived from ISO 21710:2020, 3.19, with the change that an MTA is not always a contractual document.

3.11
microbial biobank
MRC
microbial resource centre
microbial biological resource centre
microbial BRC
microbial culture collection
legal entity or part of a legal entity that performs biobanking with *microbial material* (3.12) and *associated data* (3.1)

[SOURCE: ISO 21710:2020, 3.18, modified — "microbial biobank" has replaced "MRC" as the preferred term and the term "microbial culture collection" has been added.]

3.12
microbial material
microorganism itself or any substance(s) or part(s) obtained from a microorganism, and any complexes or associations between microorganisms

Note 1 to entry: This comprises all prokaryotes (archaea and bacteria), some eukaryotic organisms (fungi, algae, protozoa), any association between the latter (e.g. lichens), non-cellular entities (e.g. viruses), their replicable parts and other derived materials (e.g. genomes, plasmids, cDNA). It also includes some viable but not yet culturable microorganisms.

[SOURCE: ISO 21710:2020, 3.17, modified — "microorganism itself or any substance(s) or part(s)" has replaced "any substance(s) derived or part" in the definition and "yeasts" have been deleted from the note.]

3.13
minimum data set
MDS
collection of technical and scientific data digitized in specific fields of a database, which is necessary to distinguish unambiguously a particular *microbial material* (3.12) and provides a minimum amount of information available for each accession in a *microbial biobank* (3.11)

Note 1 to entry: Microbial materials for which this information is not available cannot be inserted into the *catalogue* (3.4) since they lack some essential data.

[SOURCE: ISO 21710:2020, 3.15, modified — "a microbial biobank" has replaced "an MRC" and the Note to entry has been reworded.]

3.14
passage number
number of serial subcultures that an isolate has been grown from the original isolation

3.15
provider
depositor
person or entity from whom/which a *microbial material* (3.12) and/or *associated data* (3.1) is received or acquired for biobanking

[SOURCE: ISO 20387:2018, 3.41, modified — "a microbial" has replaced "the biological" and Note 1 to entry has been deleted.]

3.16
purity
absence of impurity or contaminants in a substance

3.17
recommended data set
RDS
collection of data that includes useful information for an improved description of the functions and properties of a *microbial material* (3.12)

Note 1 to entry: This includes optional data fields for use by the *microbial biobank* (3.11) in the *catalogue* (3.4), when available.

3.18
safe deposit
service for long-term preservation of microorganisms with distributing restriction(s) at the discretion of the *provider* (3.15)

Note 1 to entry: *Microbial biobanks* (3.11) maintain the biological strain(s) and ensure their *viability* (3.19) but the authenticity of those strain(s) is the provider's responsibility. All information related to a safe deposit is treated as confidential. Access to this type of strain is granted only on written request of the provider.

Note 2 to entry: Culture collections with International Depository Authority status have the possibility to *deposit* (3.5) microorganisms as a part of a patenting process according to the Budapest Treaty[8].

3.19
viability
ability to survive or live successfully

4 General requirements

4.1 General

The microbial 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.

Microbial biobanks that manage microorganisms shall identify the processes necessary for the microbial biobank operating system and determine the criteria and methods used to check the operational status appropriate to the characteristics of each microbial cohort.

4.2 Legal requirements

The microbial biobank shall retain documented information that is relevant to comply with national and international legislation. This can include:

— evidence of compliance with applicable health and safety requirements;

— microorganism risk classification;

— quarantine requirements;

— intellectual property rights;

— international treaties;

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

4.3 Health and safety

4.3.1 General

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

The microbial biobank shall define the biosafety level in accordance with the WHO's *Laboratory Biosafety Manual* and shall manage facilities and activities accordingly.

Personal protective equipment (PPE) required to mitigate the risk according to the relevant biosafety level shall be used when collecting, transporting and/or processing samples of microbiological origin.

NOTE Appropriate measures for each biosafety level and for each dangerous pathogen are given in Reference [9].

4.3.2 Chemical safety

The microbial biobank shall establish, document and implement policies and procedures concerning the storage, handling, use and disposal of chemicals, taking into account the relevant regulations of each country or region in which the microbial 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 microbial biobank shall be prominently displayed or readily available.

4.3.3 Biosafety and biorisk

The biobank should conform to ISO 35001 or the WHO's *Laboratory Biosafety Manual* 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.

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

Biosafety in the microbial biobank shall conform to ISO 45001:2018, Clause 7.

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

Waste management procedures for microbial materials shall be documented including spent culture, waste storage, packaging, transportation and decontamination.

NOTE More information about biosafety can be found in Reference [9].

4.3.4 Personal protective equipment

4.3.4.1 General

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

The microbial 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. Access to emergency equipment including fire extinguishers, safety showers, eye washers and first aid kits shall be maintained.

The microbial biobank shall establish, document and implement policies and procedures concerning the storage, handling, use and disposal of compressed gas, taking into account the relevant regulations of each country or region.

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 relevant requirements of each country or region.

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

4.4 Biosecurity and access

4.4.1 General

The microbial biobank shall determine appropriate risk control measures and requirements for biosecurity for each distinct area.

Microbial materials shall be handled and stored by authorized personnel in areas with relevant biosecurity requirements. The same treatment should be assigned to the associated data once information by itself can also represent a threat. It is recommended that the microbial biobank assesses the potential for dual use research of concern (DURC) and for malicious use of microorganisms and determines the biosecurity risk.

The biosecurity risk should be re-evaluated when new circumstances or information arises which affect the original assessment. For the assessment of potential malicious use, the following can be considered: technology and knowledge, infectivity, pathogenicity, mortality rate, transmission of infectious diseases, availability, cloning, dispersion, environmental viability, countermeasures and economic importance.

NOTE 1 DURC refers to life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products or technologies that can be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material or national security[10].

NOTE 2 Relevant information on biosecurity risk assessment can be found in Reference [11].

The microbial biobank shall establish, document and implement a chain of custody for the transport of microbial material that presents a moderate or high biosecurity risk.

NOTE 3 More information can be found in Reference [11].

NOTE 4 More information for animal pathogens can be found in Reference [12].

NOTE 5 More information for zoonoses can be found in Reference [13].

NOTE 6 More information for human pathogens can be found in the WHO's *Laboratory Biosafety Manual* and ISO 15190.

NOTE 7 More information for plant pathogens can be found in Reference [14].

4.4.2 Access to biosecure area(s)

The microbial biobank shall establish and document requirements for personnel access to biosecure area(s) to ensure that only authorized personnel have access to microorganisms that are pathogenic or toxic. Security devices and/or systems shall be used. Such devices/systems can include restricted entry, and the presence of security personnel and/or a security circuit.

All personnel in the microbial biobank shall carry identification which indicates the maximum level of security access, except in circumstances where doing so would present a risk (see 4.4.2, NOTE). The microbial biobank shall retrieve the identification upon termination of the employment/work/visit.

NOTE Exceptions are situations in which a person cannot carry identification, such as when wearing a biohazard suit.

4.5 Relocation of microbial materials

ISO 20387:2018, 6.5.2, 6.5.5, 6.5.6, 7.7.1, 7.7.2, 7.7.4, 7.5, 7.11, 8.5 and 8.7, shall be followed.

The microbial biobank shall establish, document and implement procedures when relocation of microbial material is necessary, e.g. due to expansion, reduction or in response to an emergency.

Movement/relocation shall be carefully planned and executed to maintain suitable conditions for microbial material during transport.

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.

Critical activities shall be performed by competent and authorized personnel.

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

The microbial biobank shall ensure that all personnel are regularly trained on how to follow the disaster protection plan (see ISO 20387:2018, 7.7.1) and to take appropriate action in case of a security breach.

6 Facilities

6.1 General

ISO 20387:2018, 6.3, shall be followed.

The microbial biobank shall take appropriate measures to prevent contamination such as assigning dedicated areas for specific activities such as acquisition, media and reagents preparation, sterilization, inoculation, culturing, testing, storage, disposal and cleaning.

The microbial biobank shall use appropriate signage to indicate the relevant biohazard level(s).

NOTE Details about signage can be found in ISO 7010.

The design of the facility should meet the biosafety, biosecurity and biorisk objectives of the biobank, e.g. the use of negative pressure to prevent the unwanted release of hazardous microbial materials.

6.2 Biosafety cabinets

The microbial biobank shall use biosafety cabinets with appropriate ventilation systems to prevent the environmental contamination and exposure of personnel to hazardous microbial materials. Consideration (e.g. direction of airflow, cabinet design) shall be given to the integrity of microbial materials being handled within the cabinet.

6.3 Back-up storage facilities

The microbial biobank or the legal entity of which it is a part should establish a disaster protection plan with use of alternative methods of safeguarding, e.g. dual locations, to avoid loss of master stocks.

7 Critical equipment for microbial 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 microbial materials shall be appropriately disinfected.

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 microorganisms requiring non-atmospheric gaseous culture 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, anaerobic condition, illumination, CO_2).

7.4 Refrigerators

When a refrigerator is used for storage of microbial materials, the internal temperature shall be maintained at an appropriate temperature, preferably from 2 °C to 8 °C.

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 microbial 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 microbial 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 ensure stable storage temperatures to sustain long-term viability of preserved microorganisms (e.g. storage below melting point of cryopreserved materials).

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

7.7 Freeze dryer

Freeze drying can be used for long-term preservation of microbial materials (see ISO 20387:2018, 6.5.3).

The risk of environmental and personnel contamination due to the freeze dryer vacuum (used to draw air and moisture from within the vials) shall be assessed and avoided in case of hazardous microbial materials.

7.8 Automated storage systems

When used, automatic storage systems should maintain the storage temperature required for microbial materials while minimizing temperature changes. The temperature of incoming microbial materials should be decreased gradually or step by step until the storage temperature is reached. The automated storage system should be capable of various temperature settings (e.g. 15 °C to 25 °C, −20 °C, −80 °C, −130 °C).

The microbial biobank should select microbial material storage containers appropriate to the automatic storage system. Each container used for microbial material shall have a unique identifier (e.g. barcode, RFID).

7.9 Autoclave

The microbial biobank shall establish, document and implement validated sterilization procedures to suit microorganisms relevant to the biobank at quiescent and growth phases.

Sterilization time and temperature can vary depending on the classification of microorganism, concentration, quantity, container material and degree of contamination of the sterilized items. High-pressure steam sterilization is typically conducted at 121 °C and 15 Pa for 15 min; however, the most

effective sterilization time should be selected to suit each condition and microorganism (i.e. ≥ 20 min for spore-forming bacteria, etc.).

Biological indicators (e.g. endospores) should be used periodically to measure the efficacy of autoclave.

8 Process requirements

8.1 Acquisition or deposit

8.1.1 General

ISO 20387:2018, 7.3.1, 7.3.2 and 7.5, shall be followed.

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

8.1.2 Review of requests to deposit material(s)

The microbial biobank shall communicate to the provider all relevant conditions for the microorganism to be deposited. Biobanks shall confirm and document the distribution conditions when providers request to deposit microorganisms.

NOTE To protect assigned intellectual property rights, deposit conditions can be defined in, for example, an MAA.

Before accepting requests to deposit microbial materials, the microbial biobank shall:

a) confirm the authenticity of the provider;

   1) all microbial material deposits, including those refused, shall be documented and records shall be retained;

b) perform a biosafety risk assessment;

   1) where microbial material is accompanied by a biosafety assessment methodology, this and the results thereof may be used to assist the microbial biobank in completing its own biosafety risk assessment;

c) confirm that the biosafety risk level of the microbial material in question is within the biosafety containment level of the microbial biobank;

d) confirm that, at minimum, the following information about the microbial material is provided:

   1) name or other identifier, or both;

   2) name and contact information of the provider;

   3) identification and data relating to the source, substrate and host;

   4) description of the microbial material including the geographical origin (the minimum requirement is the country of origin or the provider of the source, substrate or host) and relevant dates (e.g. date of collection for sampling or date of creation for recombinant plasmids);

   5) culturability;

   6) provider's microbial material number or additional collection number(s), if deposited elsewhere;

   7) growth media and conditions;

   8) cell preservation or storage conditions, when known;

9) biosafety risk assessment and results;

10) distribution conditions (i.e. accessibility of the deposit);

11) phenotypic characteristics (e.g. serotype, toxin producing), if available;

12) intended purpose, if applicable;

13) intellectual property rights, if applicable;

14) biomolecular information and metadata (e.g. whole genome sequence), if available;

15) relevant literature, if available.

If microbial material is received for safe deposit, the microbial biobank shall define the applicable required information given in d) above based on the contractual document or negotiation with the provider.

The microbial biobank shall document/collect and retain records related to the requests. The microbial biobank should ensure the validity of the information it receives. If the microbial biobank cannot fulfil the request, an alternative microbial biobank can be recommended.

8.1.3 Decision regarding requests to deposit materials

The microbial biobank shall decide to accept or reject requests to deposit materials based upon verification of the information provided. The decision shall be communicated to the requester. If the deposit request is rejected, the microbial biobank should document the interaction and provide the reason for rejection.

NOTE In special cases, a legacy microbial material can be received and stored until authenticated.

8.1.4 Confirmation of materials and associated data

The microbial biobank shall establish, document and implement procedures for receipt and storage appropriate to the type of microbial materials. All packages containing microbial material should be opened under appropriate environmental containment (e.g. microbiological safety cabinet) with facilities for safe handling and disposal of microbial material waste.

8.2 Authentication

The microbial biobank shall establish, document and implement procedures for authentication for each microbial material type. The microbial biobank can rely upon internal and/or external authentication methods. These can include viability, phenotypic, genotypic and omics characterizations and should be selected for each type of microorganism.

Purity of the microorganism shall be confirmed where required. For mixed cultures which cannot be purified, appropriate procedures are necessary for authentication.

The microbial biobank shall ensure authentication of the microorganism(s) and that the microbial material is free from contamination. If misidentification or contamination is detected, the microbial biobank should ask the provider to provide a new sample.

8.3 Purity and passage control

8.3.1 General

Only pure culture should be accepted for storage unless otherwise specified (e.g. for cyanobacteria). Microbial biobanks shall develop and implement a microbial contamination detection plan.

8.3.2 Contamination with other microorganisms

If contamination is detected in a microbial culture, the microbial culture should be evaluated for rejection or removal.

Each culture typically yields an expected colony appearance when cultured on solid medium. If an unexpected (non-predicted) colony variation is observed, the purity shall be checked with an appropriate method (e.g. 16S rRNA sequencing).

When purification from the contaminated culture is not possible, the culture should be re-established from its master stock or from newly obtained material from the provider.

NOTE Some bacteria with stringent culture condition such as cyanobacteria can require co-culturing with other strains.

8.3.3 Passage control

The microbial biobank shall take measures to limit the passage number of each microbial culture and retain subculture records.

8.4 Preparation, preservation and storage

8.4.1 General

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

Preservation methods shall be validated for each type of microorganism to ensure viability of the microorganism recovered from storage.

Each microorganism should be preserved using at least two different preservation methods. The viability of preserved organisms should be checked periodically, especially for cases where stability is known to be problematic, such as fastidious microorganisms (e.g. *Campylobacter* spp., *Helicobacter* spp., *Vibrio* spp.).

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

8.4.2 Preparation of distribution stock and master stock

8.4.2.1 General

The microbial biobank shall establish, document and implement procedures for the preparation and management of the distribution and master stocks of bacteria/archaea.

The biobank can use the following methods, depending on suitability for each bacteria/archaea undergoing preservation:

a) cryopreservation/use of freezer (see 8.4.2.2);

b) cryopreservation/use of liquid nitrogen (see 8.4.2.3);

c) freeze drying (lyophilization) (see 8.4.2.4);

d) liquid-drying (see 8.4.2.5);

e) subculture/continuous culture (see 8.4.2.6).

Stock of each microbial material except derivatives (e.g. DNA, RNA, proteomes) should be prepared with at least two different methods and kept at separate locations.

The microbial biobank shall determine the number of aliquots for both the distribution stock and the master stock. Frequently distributed microbial materials require a large number of aliquots depending on the ease of culture or the anticipated demand. The microbial biobank should determine the minimum number of aliquots remaining prior to stock re-establishment.

8.4.2.2 Freezing

Microorganisms collected after growth in liquid or solid medium can be dispersed into an appropriate liquid preservation medium and stored at temperatures from −20 °C to −80 °C.

8.4.2.3 Cryopreservation/use of liquid/vapour nitrogen

Bacteria and archaea collected after growth in a liquid culture medium or from colonies grown on a solid culture medium are dispersed in a liquid preservation medium and mixed with sterile cryoprotectant stock (e.g. glycerol), making a final concentration appropriate for each species, generally 10^8 CFU/ml to 10^{10} CFU/ml. The resulting aliquots are stored in ultra-low temperature freezers set at the higher temperature limits ≤ −70 °C, or in liquid/vapour nitrogen (i.e. ≤ −135 °C). However, a controlled cooling rate can be required before finally transferring the aliquots into ultra-low temperature storage. The cooling protocol shall be documented, validated and/or verified in accordance with ISO 20387:2018, 7.9.

8.4.2.4 Freeze drying (lyophilization)

Where used, the microbial biobank shall establish, document and implement procedures for freeze drying relevant microorganisms. The following can be considered for inclusion:

a) harvesting after growth in a liquid culture medium or from colonies grown on a solid culture medium;

b) choice of excipient appropriate to both the freeze-drying method and the particular microorganism;

c) choice of vials appropriate for rapid freezing (e.g. snap freezing in a dry ice/methanol bath, liquid nitrogen) and for freeze drying (e.g. at ultra-low temperature under vacuum);

d) number of freeze-drying rounds (see 8.4.2.5 for liquid-drying);

e) cryovial vacuum testing;

f) labelling and storage at a validated temperature (e.g. from 2 °C to 8 °C).

8.4.2.5 Liquid-drying

Where used (e.g. for bacteria that are particularly sensitive to the initial freezing stage of the normal lyophilization process), the microbial biobank shall establish, document and implement procedures for liquid-drying of relevant microorganisms. The following can be considered for inclusion:

a) harvesting after growth in a liquid culture medium or from colonies on a solid culture medium;

b) choice of excipient (e.g. sodium glutamate) appropriate to both the liquid-drying method and the particular microorganism;

c) concentration of the microbial suspension (e.g. approximately 10^{10} CFU/ml);

d) choice of tubes (e.g. glass) appropriate, for example, for vacuum drying and flame sealing;

e) vacuum hold time;

f) labelling and storage at a validated temperature (e.g. from 2 °C to 8 °C).

8.4.2.6 Subculture/continuous culture

The microbial biobank should take measures to avoid serial passage for the purpose of culture maintenance. However, in exceptional circumstances, such as when the organism cannot be preserved, the culture may be inoculated into new media at regular intervals and placed in conditions such as reduced temperature suitable to slow growth.

8.4.3 Preparation, preservation and storage of derivatives from microorganism(s)

The microbial biobank can extract genetic (e.g. DNA, RNA), metabolomic, proteomic material and/or bacteriophages, and aliquot and preserve these derivatives under appropriate conditions until used or distributed. Methods for extraction shall be validated, verified and documented.

NOTE For further information on the validation of the extraction method, see ISO 21899.

8.5 Distribution

8.5.1 General

ISO 20387:2018, 7.3.3, shall be followed.

8.5.2 Review and acceptance of distribution requests

The microbial biobank shall determine, document and implement procedures for the acceptance of distribution requests based on its access principles and the implemented access criteria.

Relevant policies/principles, procedures, required information and documents shall be provided to the user or recipient, preferably on the microbial biobank's website.

The microbial biobank shall acquire adequate information and documents that demonstrate the recipient's or user's and/or organization's competence for handling and receiving the requested microbial materials before distributing any microbial materials.

8.5.3 Distribution agreement

Distribution of a microbial material to a user or recipient shall be accompanied by a documented agreement or a legally binding document (e.g. contract, MTA) in accordance with ISO 20387:2018, 7.3.3.2.

The distribution agreement shall include, but is not limited to:

a) requirements in accordance with ISO 20387:2018, 7.3.3.4 and 7.12;

b) scope of transfer: including the provider and recipient, the microbial material and/or restrictions on the transfer of microbial material to other parties and/or other laboratories/locations;

c) benefit sharing: provide measures or procedures for benefit sharing;

d) intellectual property protection: provide protection of the intellectual property of contracting parties;

e) liability on quality: provide the microbial biobank's liability related to the quality of microbial materials;

f) safety and security: provide the responsibility of the recipient towards the safe and secure handling of microbial materials.

NOTE 1 Biological materials are permanently transferred to third parties only under terms and conditions consistent with those under which they were acquired and with copies of the documentation showing agreements with the providing country, where applicable, including prior informed consent (PIC), mutually agreed terms (MATs) or other relevant documents.