INTERNATIONAL STANDARD

ISO 24088-1

First edition
2022-07

Biotechnology — Biobanking of microorganisms —

Part 1: Bacteria and archaea

Biotechnologie — Biobanque des microorganismes —

Partie 1: Bactéries et archées

Reference number
ISO 24088-1:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.