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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