TECHNICAL REPORT

ISO/TR 22758

First edition
2020-05

Biotechnology — Biobanking — Implementation guide for ISO 20387

Biotechnologie — Biobanking — Guide de mise en oeuvre de l'ISO 20387

Reference number
ISO/TR 22758:2020(E)

© ISO 2020



COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

 © ISO 2020 – All rights reserved

Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 Background information for the development of ISO 20387 ..... **1**
4.1 General 1
4.2 Intended audience for ISO 20387 and this document 2
4.3 Implementation of ISO 20387 2

5 Fitness for the intended purpose (FIP) (ISO 20387:2018, 3.24) in biobanking **3**
5.1 General 3
5.2 Fitness for the intended purpose and biological material and/or associated data (BMaD) life cycle 3
5.3 Factors affecting fitness for the intended purpose 4
5.4 Determination of the pre-arranged requirements for FIP 5
5.5 Decision whether the biological material and associated data is truly fit for an intended purpose 5

6 Process landscape **5**

7 Conformity with ISO 20387 ..... **7**
7.1 Scopes of Conformity 7
7.1.1 General 7
7.1.2 Determination of the scope of conformity 7
7.2 Conformity Assessment (CA) Practices (General aspects and applicability for biobanks) 8

8 Guidance on the interpretation of selected ISO 20387:2018 text parts **8**
8.1 General Requirements (ISO 20387:2018, Clause 4) 8
8.1.1 General 8
8.1.2 Impartiality (ISO 20387:2018, 4.2) 9
8.1.3 Confidentiality (ISO 20387:2018, 4.3) 9
8.2 Structural requirements (20387:2018, Clause 5) 9
8.2.1 General 9
8.2.2 ISO 20387:2018, 5.1 9
8.2.3 ISO 20387:2018, 5.3 9
8.2.4 ISO 20387:2018, 5.5 9
8.2.5 ISO 20387:2018, 5.7 10
8.2.6 ISO 20387:2018, 5.8, a) 10
8.2.7 ISO 20387:2018, 5.9 10
8.3 Resource requirements (ISO 20387:2018, Clause 6) 11
8.3.1 General 11
8.3.2 ISO 20387:2018, 6.1.2 11
8.3.3 ISO 20387:2018, 6.2.1.2 12
8.3.4 ISO 20387:2018, 6.2.1.4 12
8.3.5 ISO 20387:2018, 6.2.2.1 12
8.3.6 ISO 20387:2018, 6.2.2.3 12
8.3.7 ISO 20387:2018, 6.2.3 12
8.3.8 ISO 20387:2018, 6.2.3.3 12
8.3.9 ISO 20387:2018, 6.3 12
8.3.10 ISO 20387:2018, 6.3.2 13
8.3.11 ISO 20387:2018, 6.3.3 14
8.3.12 ISO 20387:2018, 6.3.5 14
8.3.13 ISO 20387:2018, 6.3.7 14
8.3.14 ISO 20387:2018, 6.4.1.1 14

© ISO 2020 – All rights reserved

8.3.15 ISO 20387:2018, 6.4.1.5 14
8.3.16 ISO 20387:2018, 6.4.1.6 15
8.3.17 ISO 20387:2018, 6.5.1 15
8.3.18 ISO 20387:2018, 6.5.3 15
8.3.19 ISO 20387:2018, 6.5.6 15
8.3.20 ISO 20387:2018, 6.5.10 15
8.3.21 ISO 20387:2018, 6.5.11 15
8.3.22 ISO 20387:2018, 6.5.12 15
8.4 Process requirements (ISO 20387:2018, Clause 7) 16
8.4.1 General 16
8.4.2 ISO 20387:2018, 7.1.1 16
8.4.3 ISO 20387:2018, 7.2.1.1 16
8.4.4 ISO 20387:2018, 7.2.3.4 16
8.4.5 ISO 20387:2018, 7.3.1.1 16
8.4.6 ISO 20387:2018, 7.3.2.4 17
8.4.7 ISO 20387:2018, 7.3.2.5 17
8.4.8 ISO 20387:2018, 7.3.3.2 18
8.4.9 ISO 20387:2018, 7.4.2 18
8.4.10 ISO 20387:2018, 7.4.5 18
8.4.11 ISO 20387:2018, 7.6.2 18
8.4.12 ISO 20387:2018, 7.7.1 18
8.4.13 ISO 20387:2018, 7.7.3 19
8.4.14 ISO 20387:2018, 7.7.5 19
8.4.15 ISO 20387:2018, 7.7.7 19
8.4.16 ISO 20387:2018, 7.8.1.2 19
8.4.17 ISO 20387:2018, 7.9.1.1 20
8.4.18 ISO 20387:2018, 7.10.5 20
8.4.19 ISO 20387:2018, 7.12.2.1 20
8.4.20 ISO 20387:2018, 7.13.2 20
8.5 Quality management system requirements (ISO 20387:2018, Clause 8) 20
8.5.1 General 20
8.5.2 ISO 20387:2018, 8.1.1, 8.1.2 and 8.1.3 20
8.5.3 ISO 20387:2018, 8.3.1 21
8.5.4 ISO 20387:2018, 8.4.1, 8.4.2 and 8.4.3 21
8.5.5 ISO 20387:2018, 8.5.1, 8.5.2 and 8.5.3 22
8.5.6 ISO 20387:2018, 8.6.1 22
8.5.7 ISO 20387:2018, 8.8.1 and 8.8.2 22

Bibliography **23**

 © ISO 2020 – All rights reserved

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2020 – All rights reserved

Introduction

This document is intended to be a supplement to, rather than a substitute for, ISO 20387; as such, it is not a stand-alone document. It can be helpful for the reader to first review ISO 20387, and refer to this technical report in parallel or thereafter.

The following is noted in regards to the contents of this document:

— A technical report, by definition, contains no requirements. For this reason, the language is intentionally non-prescriptive to avoid the introduction of new requirements.

— This document does not address those clauses and subclauses of ISO 20387 which are considered to be self-explanatory (e.g. ISO 20387:2018, Clauses 1, 2, and 3, and Annexes A, B, and C, etc.).

— Clauses 4, 5, 6 and 7 of this document address some general concepts that underlie the requirements of ISO 20387.

— Clause 8 of this document addresses a selection of the specific requirements in ISO 20387, as noted above.

— Examples are provided throughout the text of this document, and are used to illustrate a non-exhaustive list of possibilities.

— Acronyms are used to simplify the text:

1) BMaD: ISO 20387 defines *biological material* (ISO 20387:2018, 3.7) and *associated data* (ISO 20387:2018, 3.3). For the purpose of this document the terms are combined as "biological materials and/or associated data" (BMaD). There are places where references are made to either biological material or associated data. The term is spelled out in these cases.

2) FIP: *Fit for purpose* or *fitness for intended purpose* (ISO 20387:2018, 3.24) is also defined by ISO 20387. For the purpose of this document this term is denoted by FIP.

The term biobank has been previously defined in a number of ways and no single definition has yet been universally accepted by the scientific community.

ISO 20387 defines a *biobank* (ISO 20387:2018, 3.5) as *a legal entity or part of a legal entity that performs biobanking*, and the term *biobanking* (ISO 20387:2018, 3.6) as *the process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data*. For the purposes of this document, the term *biobank* includes the personnel performing biobanking activities on behalf of the biobank, as well as the entity itself.

Biobanks can vary widely in:

— domains that are managed, e.g., human, animal, fungus, microbial, and/or plant, etc. or a multiple of these;

— types of biological material and data in the biobank, e.g. nucleic acids, tissue, etc.;

— activities being performed;

— types of organizations that are involved; and

— structure, governance, oversight, and operation.

At the time of acquisition, biobanks can perform acquisition, processing and storage of BMaD for not-yet-identified future use(s). In these cases, the biobank can acquire the BMaD according to standard operating procedures (SOPs) appropriate for the projected end-use(s). Alternatively, biobanks can acquire BMaD in response to a request from a user. The user can specify criteria for the BMaD and/or SOPs developed or applied for that specific use.

© ISO 2020 – All rights reserved

Biobanks can acquire BMaD for investigators studying new methods of collecting, storing, or processing biological materials and the effects of these new methods on various analytes. In these cases, the biobank can tailor the procedures to specifically meet the investigator's needs rather than following widely-accepted SOPs for handling of the BMaD.

Biobanks vary in the types of activities they perform. They can either perform the full range of activities included in the definition of biobanking in ISO 20387, i.e. collecting/acquisitioning, preparing, preserving, testing, storage, analysing and distributing BMaD or a subset of these activities for example collecting/acquisitioning and distributing.

Biobanks can involve different types of organizations. They can be independent legal entities or reside within governmental entities, academic institutions, hospitals, non-profit or commercial organizations.

Biobanks can include multiple sites of operation and can sometimes involve parties at multiple institutions or organizations. In addition, they can involve sites of operations within different regions or sometimes even different countries.

It is up to the biobank to identify the scope of biobank activities for which it wants to implement ISO 20387.

© ISO 2020 – All rights reserved

Biotechnology — Biobanking — Implementation guide for ISO 20387

1 Scope

This document provides guidance to biobanks on how to implement the quality management, management, and technical requirements of ISO 20387. It expands on aspects of ISO 20387 and provides examples for illustration purposes. The aim of this document is to assist biobanks to address competency of personnel and appropriate quality of biological material and data collections. This document is equally applicable to newly established and existing biobanks.

This document is applicable to all organizations performing biobanking, including biobanking of biological material from multicellular organisms (e.g., human, animal, fungus and plant) and microorganisms for research and development.

This document does not apply to biological material intended for feed/food production, laboratories undertaking analysis for food/feed production and/or therapeutic use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387 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 http://www.electropedia.org/

4 Background information for the development of ISO 20387

4.1 General

ISO 20387 was developed to benefit biobanks of all sizes, types, resources and levels of maturity and/or complexity as covered by the scope.

The motivation for the development of ISO 20387 was to enable robustness and reliability of research undertaken with these BMaD, supporting quality and reproducibility in research and development. This in turn can contribute to increased and broader utilization of biological materials and associated data. It is intended that conformity to ISO 20387 can help demonstrate a commitment to professionalism within biobanking, promoting trust for key stakeholders, such as the public, donors, patients, users, or funders. Benefits such as increased efficiency of biobank operations and interoperability among biobanks, and improved marketability can result from a commitment to ISO 20387. These benefits can also facilitate sustainability at a time of increasing complexity of research requirements.

© ISO 2020 – All rights reserved