



BSI Standards Publication

Biotechnology — Biobanking — General requirements for biobanking

National foreword

This British Standard is the UK implementation of EN ISO 20387:2020+A11:2024. It is derived from ISO 20387:2018. It supersedes BS EN ISO 20387:2020, which is withdrawn.

The start and finish of text introduced or altered by amendment A11 is indicated in the text by tags. Tags indicating changes to CEN/CENELEC text carry the number of the CEN/CENELEC amendment. For example, text altered by CEN/CENELEC amendment A11 is indicated by A11 A11.

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© The British Standards Institution 2024
Published by BSI Standards Limited 2024

ISBN 978 0 539 32670 3

ICS 07.080

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 August 2018.

Amendments/corrigenda issued since publication

Date	Text affected
31 October 2020	This corrigendum renumbers BS ISO 20387:2018 as BS EN ISO 20387:2020
31 July 2024	Implementation of CEN/CENELEC amendment A11:2024

English version

Biotechnology - Biobanking - General requirements for biobanking (ISO 20387:2018)

Biotechnologie - "Biobanking" - Exigences générales relatives au "biobanking" (ISO 20387:2018)

Biotechnologie - Biobanking - Allgemeine Anforderungen an Biobanking (ISO 20387:2018)

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European foreword

The text of ISO 20387:2018 has been prepared by Technical Committee ISO/TC 276 "Biotechnology" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 20387:2020 by Technical Committee CEN/CLC/JTC 1 "Criteria for conformity assessment bodies" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2021, and conflicting national standards shall be withdrawn at the latest by March 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 20387:2018 has been approved by CEN as EN ISO 20387:2020 without any modification.

European foreword to Amendment A11

This document (EN ISO 20387:2020/A11:2024) has been prepared by Technical Committee CEN/CLC/JTC 1 “Criteria for conformity assessment bodies” the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 20387:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2025, and conflicting national standards shall be withdrawn at the latest by January 2025.

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This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

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A11 Annex ZA
(informative)

Relationship between this European Standard and the requirements of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 aimed to be covered

This European Standard has been prepared under Commission Implementing Decision C(2021)9277 of 17.12.2021 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards accreditation and conformity assessment in support of Regulation (EC) No 765/2008 of the European Parliament and of the Council (M/580), to provide one voluntary means of conforming to Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 [OJ L 218].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding requirements of that Regulation, and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93 [OJ L 218]

Requirement of Regulation (EC) 765/2008	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
Article 8(10)	4 General requirements 5 Structural requirements 6 Resource requirements 7 Process requirements 8 Management system requirements	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard. **A11**

Contents

	Page
Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	8
4.1 General.....	8
4.2 Impartiality.....	9
4.3 Confidentiality.....	9
5 Structural requirements	9
6 Resource requirements	10
6.1 General.....	10
6.2 Personnel.....	11
6.2.1 General.....	11
6.2.2 Competence and competence assessment.....	11
6.2.3 Training.....	11
6.3 Facilities/dedicated areas and environmental conditions.....	12
6.4 Externally provided processes, products and services.....	12
6.5 Equipment.....	13
7 Process requirements	14
7.1 General.....	14
7.2 Collection of biological material and associated data.....	15
7.2.1 Documented information requirements.....	15
7.2.2 Pre-acquisition information.....	15
7.2.3 Collection procedure.....	15
7.3 Reception and distribution of biological material and associated data.....	15
7.3.1 Access principles.....	15
7.3.2 Reception.....	15
7.3.3 Distribution.....	16
7.4 Transport of biological material and associated data.....	16
7.5 Traceability of biological material and associated data.....	17
7.6 Preparation and preservation of biological material.....	18
7.7 Storage of biological material.....	18
7.8 Quality control of biological material and associated data.....	19
7.8.1 General.....	19
7.8.2 Quality control of processes.....	19
7.8.3 Quality control of data.....	20
7.9 Validation and verification of methods.....	20
7.9.1 General.....	20
7.9.2 Validation.....	20
7.9.3 Verification.....	20
7.10 Management of information and data.....	21
7.11 Nonconforming output.....	21
7.11.1 General.....	21
7.11.2 Control of nonconforming output.....	22
7.12 Report requirements.....	22
7.12.1 General.....	22
7.12.2 Content of the report.....	22
7.13 Complaints.....	23
8 Quality management system requirements	24
8.1 Options.....	24

8.1.1	General	24
8.1.2	Option A	24
8.1.3	Option B	24
8.2	Documented information for the quality management system (Option A)	24
8.3	Control of quality management system documents (Option A)	25
8.4	Control of records (Option A)	25
8.5	Actions to address risks and opportunities (Option A)	25
8.6	Improvement (Option A)	26
8.7	Corrective action for nonconforming output (Option A)	26
8.8	Internal audits (Option A)	27
8.9	Quality management reviews (Option A)	27
Annex A (normative) Documentation requirements		29
Annex B (informative) Implementation guidance for Annex A		31
Annex C (informative) Quality management system options		34
Bibliography		35

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.

Introduction

This document has been developed with the objective of promoting confidence in biobanking. It contains requirements to enable biobanks to demonstrate competent biobank operation and the ability to provide biological material 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 covering the life cycle of biological materials and their associated data. The use of this document facilitates cooperation, fosters exchange, and assists in the harmonization of practices among biobanks, researchers and other parties.

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.

Further details can be found in the ISO/IEC Directives, Part 2.

Biotechnology — Biobanking — General requirements for biobanking

1 Scope

This document specifies general requirements for the competence, impartiality and consistent operation of biobanks including quality control requirements to ensure biological material and data collections of appropriate quality.

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.

Biobank users, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies, and others can also use this document in confirming or recognizing the competence of biobanks.

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

NOTE 1 International, national or regional regulations or requirements can also apply to specific topics covered in this document.

NOTE 2 For entities handling human materials procured and used for diagnostic and treatment purposes ISO 15189 and other clinical standards are intended to apply first and foremost.

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 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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/>

3.1 accessioning logging

documenting the addition of a new biological material and/or associated data to a biobank

3.2 acquisition

act of obtaining possession and/or custody of biological material and/or associated data

3.3

associated data

any information affiliated with biological material including but not limited to research, phenotypic, clinical, epidemiologic, and procedural data

3.4

authentication

process by which biological material is characterized to a defined level of specification using appropriate technology/documentation to establish a conclusive basis for accepting the material as genuine

3.5

biobank

legal entity or part of a legal entity that performs *biobanking* (3.6)

3.6

biobanking

process of *acquisition* (3.2) 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

3.7

biological material

any substance derived or part obtained from an organic entity such as a human, animal, plant, microorganism(s) or multicellular organism(s) that is(are) neither animal nor plant (e.g. brown seaweed, fungi)

3.8

biosafety

containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release

[SOURCE: Laboratory Biosafety Manual, third edition, WHO, 2004]

3.9

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

3.10

catalogue

systematically arranged list or record often including descriptive information

3.11

cataloguing

act of creating and maintaining a systematically arranged list or record often including descriptive information

3.12

chain of custody

responsibility for or control of materials and associated data as they move through each step of a process

3.13

competence

ability to apply knowledge, experience, and skills to achieve intended results

[SOURCE: ISO 17100:2015, 2.4.9]

3.14 complaint

expression of dissatisfaction other than appeal by any person or organization to a *biobank* (3.5), relating to the activities, products or results of that biobank where a response is expected

Note 1 to entry: The wording “activities, products or results” includes biological material and/or associated data.

Note 2 to entry: “Appeal” is defined in ISO/IEC 17000:2004, 6.4.

[SOURCE: ISO/IEC 17000:2004, 6.5 modified — “conformity assessment body or accreditation body” has been replaced by “biobank”, the words “products or results” have been added, Note 1 to entry and Note 2 to entry have been added]

3.15 conformity fulfillment of a requirement

Note 1 to entry: In English the word “conformance” is synonymous but deprecated. In French the word “compliance” is synonymous but deprecated.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

[SOURCE: ISO 9000:2015, 3.6.11]

3.16 critical

having a potential impact on the fitness for the intended purpose of biological material and/or associated data

3.17 dedicated area

space containing the biological material kept by the *biobank* (3.5) or where the biobank activities take place

3.18 destruction

process of eliminating biological material and/or deleting associated data, beyond any possible reconstruction

3.19 disposal

act of removing a biological material and/or associated data usually for scrapping, destruction or returning to provider/donor

3.20 distribution

process of providing selected biological material and/or associated data to recipient(s)/user(s)

3.21 documented information

information required to be controlled and maintained by an organization and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

- the management system, including related processes;
- information created in order for the organization to operate (documentation);