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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

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Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 20387

Biotechnology — Biobanking — General requirements for biobanks

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This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

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Contents

Page

Foreword	v
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	10
4.1 General	10
4.2 Impartiality	11
4.3 Confidentiality	11
5 Structural requirements	12
6 Resource requirements	13
6.1 General	13
6.2 Personnel	13
6.2.1 General	13
6.2.2 Competence and training	14
6.3 Facilities/dedicated areas and environmental conditions	14
6.4 Externally provided critical processes and services (Outsourcing)	15
6.5 Externally provided products and services	15
6.6 Equipment	16
7 Process requirements	17
7.1 General	17
7.2 Collection of biological material and associated data	18
7.2.1 Documented information	18
7.2.2 Collection of biological material	18
7.3 Acquisition and reception of biological material and associated data	19
7.4 Transport of biological material and associated data	19
7.5 Traceability of biological material and associated data	20
7.6 Processing, testing and preservation of biological material	20
7.7 Storage of biological material and associated data	21
7.8 Retrieval of biological material and associated data	21
7.9 Distribution of biological material and associated data	22
7.10 Disposal of biological material and associated data	22
7.11 Quality control of biological material and associated data	22
7.11.1 General	22
7.11.2 Quality control of processes	23
7.11.3 Quality control of biological material	23
7.11.4 Quality assurance for biological material	23
7.11.5 Quality control of data	24
7.12 Validation and verification of methods	24
7.12.1 General	24
7.12.2 Validation	24
7.12.3 Verification	24
7.13 Management of information and data	25
7.14 Nonconforming output	25
7.15 Report requirements	26
7.15.1 General	26
7.15.2 Content of the report	26
7.15.3 Preparation of the report	28
7.15.4 Amendments to reports	29
7.16 Complaints	30
8 Management system requirements	30
8.1 General	30

ISO/DIS 20387:2025(en)

8.2	Documented information for the management system	31
8.3	Control of management system documents	31
8.4	Control of records	32
8.5	Actions to address risks and opportunities	32
8.6	Improvement	33
8.7	Corrective action for nonconforming output	33
8.8	Internal audits	34
8.9	Management reviews	34
Annex A (normative) Documentation requirements		36
Annex B (informative) Implementation guidance for Annex A		39
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 market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 aimed to be covered		42
Bibliography		43

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*.

This second edition cancels and replaces the first edition (ISO 20387:2018), which has been technically revised.

The main changes are as follows:

- update and clarification of terminology;
- addition of 4.1.10 regarding climate change;
- addition of [5.14](#) on collaborative activities;
- together with the addition of [5.10](#) and [5.11](#) regarding the range of performed and outsourced activities and the related conformity claim, [6.4](#) was updated to be more precise now about the obligatory biobanking processes;
- [6.2.2](#) and 6.2.3 were merged;
- [6.4](#) was split into [6.4](#) and [6.5](#) to separate externally provided critical processes and services from non-critical services and products;
- [7.2](#) and [7.3](#) were updated to include different cases of control over the collection, and putting acquisition and reception requirements within the same chapter as clear differentiation is not always possible;
- testing requirements were added in [7.6](#) and ;
- new clauses on retrieval ([7.8](#)), distribution ([7.9](#)) and disposal ([7.10](#)) were added;
- the QC clause was restructured;
- in the report requirements clause, subchapters for the preparation of the report and amendments to reports have been added;
- [Clause 8](#) was updated based on the latest ISO requirements;
- editorial update and clarification of wording.

ISO/DIS 20387:2025(en)

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.

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 biobanks

1 Scope

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

This document is applicable to all organizations performing biobanking. This can include biobanking of biological material:

- a) from multicellular organisms (e.g. human, animal, fungus and plant);
- b) from microorganisms;
- c) derived from sources such as environmental samples (e.g. soil, sediment, water, air).

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 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/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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 <https://www.electropedia.org/>

3.1 acquisition

set of activities to obtain possession and/or custody of *biological material* (3.6) and *associated data* (3.2), that includes some or all of the activities of *collection* (3.10) when the collection is performed by the *biobank* (3.4)

Note 1 to entry: Acquisition is also called procurement in some sectors.

3.2**associated data**

any information affiliated with *biological material* (3.6) including but not limited to research, phenotypic, genotypic, clinical, epidemiologic, and procedural data

3.3**authentication**

set of activities to characterize *biological material* (3.6) to a defined level of specification using appropriate technology/documentation to establish a conclusive basis for accepting the material as genuine

3.4**biobank**

legal entity (3.27) or part(s) of a legal entity that engage(s) in *biobanking* (3.5), which can include provision of support services for biobanking

Note 1 to entry: Examples for 'support services' are administrative and IT support, legal counsel, procurement, facility services etc.

3.5**biobanking**

set of activities aiming for *fit for purpose* (3.22) *biological material* (3.6) and *associated data* (3.2) including *acquisition* (3.1), *storage* (3.54) and *retrieval* (3.50) of defined biological material and associated data; with the potential inclusion of one or more of the following: *collection* (3.10), *processing* (3.39), *preservation* (3.36), *testing* (3.56), *distribution* (3.19), *destruction* (3.17), and *disposal* (3.18)

3.6**biological material**

organic entity or any substance derived or part obtained from:

- a) an organic entity, such as *microorganism(s)* (3.31) or multicellular organism(s) (e.g. human, animal, fungus, brown seaweed, plant); or
- b) an environmental sample (e.g. soil, sediment, water, air), that contains an organic entity of interest

3.7**biosafety**

practices and controls that reduce the risk of unintentional exposure to or release of *biological materials* (3.6)

Note 1 to entry: Biological materials or parts thereof handled in *biobanks* (3.4) can contain biological agents or toxins or biological agent vectors, such as arthropods, nematodes, and mites.

Note 2 to entry: For more details regarding biosafety, refer to ISO 35001.

[SOURCE: ISO 35001:2019, 3.22, modified — Two notes added; “to” added to definition.]

3.8**biosecurity**

practices and controls that reduce the risk of loss, theft, misuse, diversion of, or intentional unauthorized release of *biological materials* (3.6)

Note 1 to entry: Practices and controls can include but are not limited to institutional and personal security measures and *procedures* (3.37).

[SOURCE: ISO 35001:2019, 3.23, modified — Note added.]

3.9**chain of custody**

chronological record that tracks the control and responsibility for *biological material* (3.6) and *associated data* (3.2) moving through each step of a *process* (3.38)

Note 1 to entry: The chain of custody can help assess the integrity of biological material and associated data.

3.10
collection

set of activities to (physically) gather *biological material* (3.6) and *associated data* (3.2) from a source

Note 1 to entry: Collection can be part of the broader *process* (3.38) of *acquisition* (3.1).

3.11
competence

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

[SOURCE: ISO 17100:2015, 2.4.9]

3.12
complaint

expression of dissatisfaction other than appeal by any person or organization to a *biobank* (3.4), 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* (3.6) or *associated data* (3.2) or both.

Note 2 to entry: “Appeal” is defined in ISO/IEC 17000:2020, 8.6.

[SOURCE: ISO/IEC 17000:2020, 8.7 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]

3.13
confidentiality

property that information is not made available or disclosed to unauthorized individuals, entities, or *processes* (3.38)

[SOURCE: ISO/IEC 27000:2018, 3.10]

3.14
conformity

fulfilment of a requirement

Note 1 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, modified – Note 1 was deleted.]

3.15
critical

having a potential impact on the *fitness for the intended purpose* (3.22) of *biological material* (3.6) or *associated data* (3.2) or both

Note 1 to entry: Critical elements can vary depending on the intended purpose and the type of biological material and associated data. Peer consensus, *user* (3.59) requests, and a risk assessment can assist with identifying critical elements.

3.16
dedicated area

space containing the *biological material* (3.6) kept by the *biobank* (3.4) or where the biobank executes its activities

3.17
destruction

set of activities to eliminate *biological material* (3.6) and/or delete *associated data* (3.2), beyond any possible reconstruction

3.18

disposal

set of activities to remove a retrieved *biological material* (3.6) or *associated data* (3.2) or both from the *biobank* (3.4) if no longer useable or authorized for use; usually including discarding, *destruction* (3.17) or returning to the *provider* (3.42) or *donor* (3.21)

3.19

distribution

set of activities to provide selected *biological material* (3.6) or *associated data* (3.2) or both to *recipient(s)* (3.49)/*user(s)* (3.59)

3.20

documented information

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

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* (3.29), including related *processes* (3.38);
- information created in order for the organization to operate (documentation);
- evidence of results achieved.

Note 3 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.

[SOURCE: ISO 9000:2015, 3.8.6, modified – “required to be controlled and maintained by an organization” put at the end of the definition.]

3.21

donor

organic source such as a human, animal, plant etc. from which the *biological material* (3.6) or *associated data* (3.2) or both is collected for *biobanking* (3.5)

Note 1 to entry: A human donor can also be a *provider* (3.42).

3.22

fit for purpose

fitness for the intended purpose

aligned with prearranged requirements for an intended use

Note 1 to entry: The definition of such requirements can take place within the *biobank* (3.4) itself and/or in collaboration with *users* (3.59) and include analytical and other relevant criteria.

Note 2 to entry: These requirements correspond to the feasibility of the downstream intended use and the satisfaction of predefined performance criteria of the intended use.

Note 3 to entry: When the suitability for the intended purpose cannot be determined, the biobank indicates the range of applications for which the *biological material* (3.6) can be used (see 4.1.2).

3.23

governance

principles, policies and framework by which a *biobank* (3.4) is overseen, directed and controlled

[SOURCE: ISO 21505:2017, 3.1, modified – added ‘overseen’, ‘an organization’ replaced by “a biobank”]

3.24

impartiality

objectivity, neutrality and fairness along with the awareness of bias and reduction of prejudice

Note 1 to entry: It is important for impartiality that possible conflicts of interest are declared, resolved or do not exist.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “freedom from conflict of interests”, “freedom from bias”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

[SOURCE: ISO 21043-1:2018, 3.17, modified – Note 2 added.]

3.25

interlaboratory comparison

organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions

[SOURCE: ISO 13528:2022, 3.1]

3.26

interoperability

interoperability (of information and data)

ability of two or more systems or applications to exchange information and to mutually use the information that has been exchanged

[SOURCE: ISO/TR 14639-1:2012, 2.20, modified – additional term added]

3.27

legal entity

structure that is organized under the laws of any jurisdiction

[SOURCE: ISO 5009:2022, 3.2, modified - Deleted “Legal person”]

3.28

life cycle

consecutive and interlinked stages of *biological material* (3.6) and *associated data* (3.2) from start (e.g. *collection* (3.10), *acquisition* (3.1) or *reception* (3.48)) to finish (e.g. *distribution* (3.19), *disposal* (3.18) or *destruction* (3.17))

Note 1 to entry: This term refers to the *biobanking* (3.5) life cycle only.

3.29

management system

set of interrelated or interacting elements of an organization to establish policies and objectives, and *processes* (3.38) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines, e.g. *quality management* (3.45), financial management or environmental management.

Note 2 to entry: The management system elements establish the organization’s structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

Note 3 to entry: The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

[SOURCE: ISO 9000:2015, 3.5.3, modified – Note 4 was deleted.]

3.30

metrological traceability

property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

[SOURCE: ISO/IEC Guide 99:2007, 2.41, modified — The notes were deleted.]

3.31

microorganism

microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material

[SOURCE: ISO 15190:2020, 3.15]

3.32

nonconforming

deviating from a particular requirement

3.33

outsourcing

act of making an arrangement where an organization or entity external from the *biobank* (3.4) performs part of the biobank's service or *process* (3.38)

Note 1 to entry: An organization to which processes or services are outsourced to can be called process or service provider.

Note 2 to entry: While an external organization operates outside of the biobank's *management system* (3.29), any outsourced service or process remains under the *oversight* (see 6.4) of the biobank.

Note 3 to entry: Entities external to the biobank can belong to the same *legal entity* (3.27) as the biobank and can be or not be within the scope of the biobank's management system. In any case, the *oversight* (3.34) of the outsourced service or process remains within the scope of the biobank's management system.

3.34

oversight

ongoing and structured monitoring of the implementation of organizational and *governance* (3.23) policies, including monitoring of how associated tasks, services, and *processes* (3.38) are managed, to ensure they remain appropriate and responsive to internal and external circumstances

3.35

personnel

person(s) employed by or working for the *biobank* (3.4)

Note 1 to entry: Personnel can be either internal or external.

3.36

preservation

set of activities to prevent or to slow biological or physical deterioration of *biological material* (3.6)

3.37

procedure

specified way to carry out an activity or a *process* (3.38)

[SOURCE: ISO 9000:2015, 3.4.5]

3.38

process

set of interrelated or interacting activities that use inputs to deliver an intended result

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry 1, 2, 3, 4, 5 and 6 have been removed.]

3.39

processing

performing a set of activities on *biological material* (3.6) and *associated data* (3.2) to prepare them for downstream *life cycle* (3.28) stages

Note 1 to entry: Processing activities for biological material can include, centrifuging, homogenizing, purifying, fixing, stabilizing, replicating, filtering, sorting, culturing, cloning, vacuum drying, freeze drying, freezing and thawing, tissue sectioning, fractionating, dispensing/aliquoting, and cryopreserving.

Note 2 to entry: Processing activities for associated data can include, cleansing, structuring, formatting, anonymizing, filtering, sorting, aggregating, classifying, and statistical analysis^{[60][61]}.

3.40**processing method**

procedure (3.37), applied to *biological material* (3.6) or *associated data* (3.2) or both during *processing* (3.39), with potential to impact the intrinsic properties of the biological material or associated data or both produced as output

3.41**proficiency testing**

evaluation of participant performance against pre-established criteria by means of *interlaboratory comparisons* (3.25)

Note 1 to entry: For the purposes of this document, the term “proficiency testing” is taken in its widest sense and includes, but is not limited to:

- a) quantitative scheme — where the objective is to quantify one or more measurands of the proficiency test item;
- b) qualitative scheme — where the objective is to identify or describe one or more characteristics of the proficiency test item;
- c) sequential scheme — where one or more proficiency test items are distributed sequentially for testing or measurement and returned to the proficiency testing provider at intervals;
- d) simultaneous scheme — where proficiency test items are distributed for concurrent testing or measurement within a defined time period;
- e) single occasion exercise — where proficiency test items are provided on a single occasion;
- f) continuous scheme — where proficiency test items are provided at regular intervals;
- g) sampling — where samples are taken for subsequent testing; and
- h) data transformation and interpretation — where sets of data or other information are furnished and the information is processed to provide an interpretation (or other outcome).

Note 2 to entry: Some providers of proficiency testing in the medical area use the term “External Quality Assessment (EQA)” for their proficiency testing schemes, or for their broader programs, or both.

[SOURCE: ISO/IEC 17043:2023, 3.7, modified — Note 1 to entry has been deleted and a new Note 1 and Note 2 have been added.]

3.42**provider**

depositor

person or entity from whom/which the *biological material* (3.6) or *associated data* (3.2) or both is received or acquired for *biobanking* (3.5)

Note 1 to entry: *Proficiency testing* (3.41) providers and external providers are not included.

3.43**pseudonymization**

processing (3.39) of data in such a manner that these data can no longer be attributed to a specific data subject without the use of additional information

Note 1 to entry: Additional information is kept separately and is subject to technical and organizational measures to ensure that the individual data are not attributed to an identified or identifiable subject.

Note 2 to entry: Pseudonymization is a particular type of de-identification.

3.44**quality control**

part of *quality management* (3.45) focused on fulfilling quality requirements

[SOURCE: ISO 9000:2015, 3.3.7]