ISO 20387:2018

training for assessors

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2020

Introduction

INTERNATIONAL STANDARD

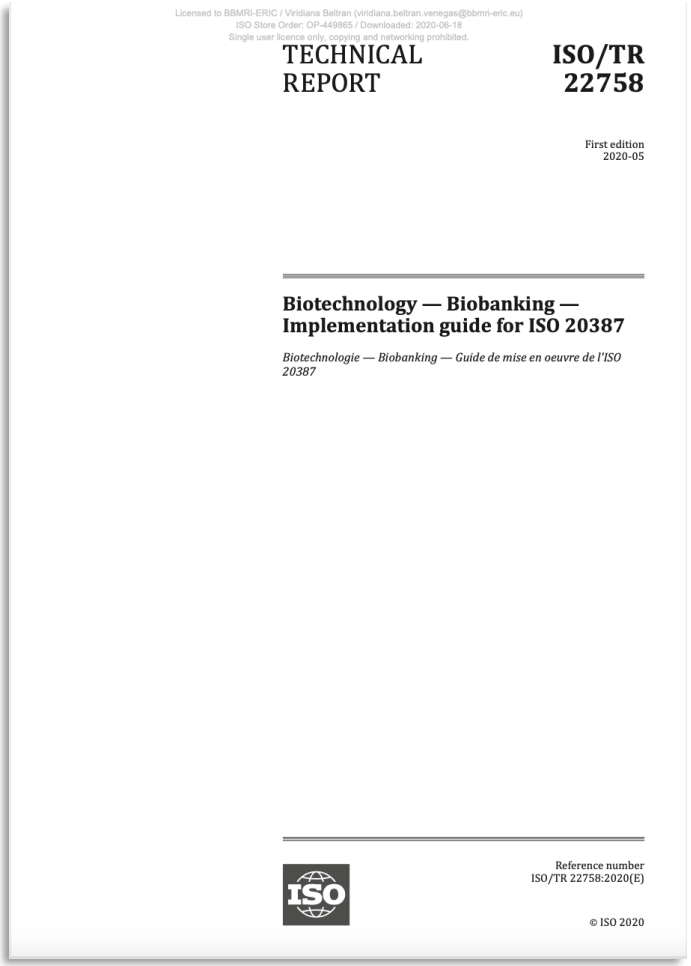
ISO 20387

First edition
2018-08

Biotechnology — Biobanking — General requirements for biobanking

Biotechnologie — «Biobanking» — Exigences générales relatives au «biobanking»

Reference number
ISO 20387:2018(E)



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 20387:2018 Requirements

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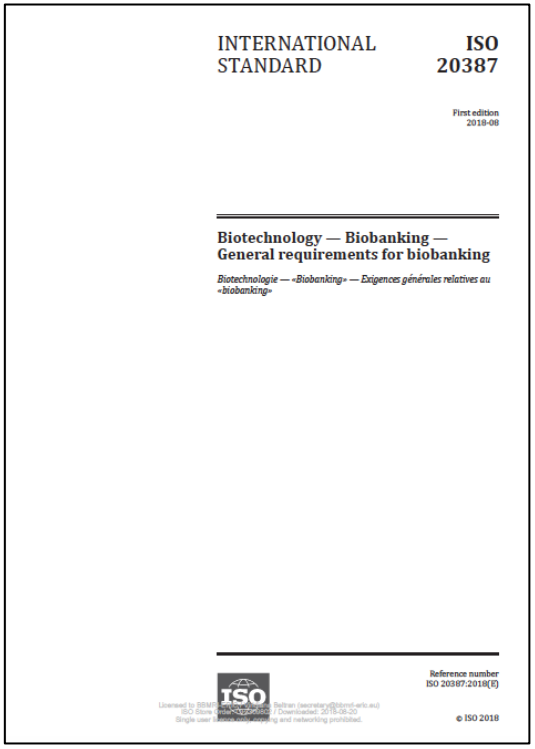
INTERNATIONAL STANDARD

ISO 20387

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Biotechnology — Biobanking — General requirements for biobanking

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ISO 20387:2018 Requirements

1 SCOPE

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

- applicable to all organizations performing biobanking activities, including biobanking of **human, animal, plant and microorganism** resources for research and development.

  - **does not apply** to biological material intended for food production or therapeutic use.

ISO 20387:2018 Requirements

1 SCOPE

To be used by Biobank users, regulatory authorities, organizations and schemes using peer-assessment, accreditation bodies and others for confirming or recognizing the competence of biobanks.

International, national or regional regulations or requirements can apply to specific topics of ISO 20387.

For entities handling human materials procured and used solely for diagnostic and treatment purposes ISO 15189 and other clinical standards apply first and foremost.

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

ISO 20387:2018 Requirements

3. Terms and definitions

- **Biobank**

  legal entity or part of a legal entity that performs biobanking

- **biobanking**

  process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analyzing and distributing defined biological material as well as related information and data

- **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)

- **fit for purpose, fitness for the intended purpose**

  in line with prearranged requirements for an intended use

  Note : The definition of such requirements can take place within the biobank itself and/or in collaboration with users and should consider analytical and other relevant criteria.

ISO/TR 22578:2020

Process landscape model

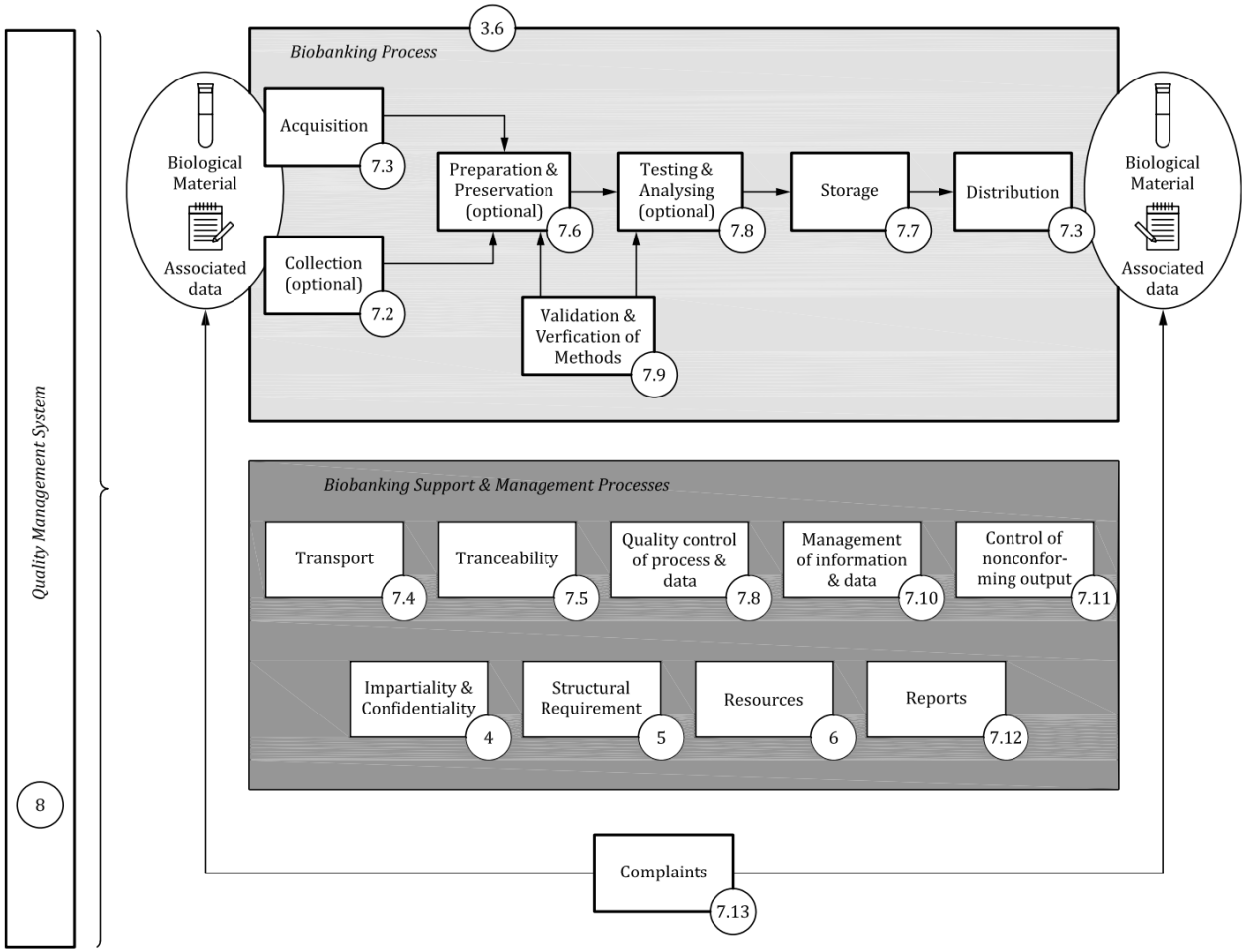

Figure 2 — Components of the biobanking process and its related support and management processes, with encircled numbers corresponding to Clauses of ISO 20387:2018

ISO 20387:2018 Requirements

4.1 General requirements

Summary of the standard requirement – no specific requirements defined

- collecting/procuring and/or acquiring and receiving, tagging, accessioning/logging, cataloguing/classifying, examining, preparing, preserving, storing, managing data, destroying, packaging, safeguarding, distributing and transporting.
- procedures to ensure compliance with relevant biosecurity and biosafety requirements.
- address risks and opportunities using a risk assessment
- ensure that biological material and associated data are handled in a way to enable reproducible research.

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Requirements

4.2 Impartiality

➢ **Examples**

- Declaration of impartiality
- Regular review / identification of risks to its impartiality
- Identified risk to impartiality / demonstration of elimination / minimization

➢ Transparent policies

➢ Transparent access procedures

➢ Oversight by advisory boards

➢ Obersight by access committees

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Requirements

4.3 Confidentiality

➢ **Examples**

- How is confidential information / sample / data and proprietary rights of sample providers / donors, recipients and users protected?
- What kind of agreements are in place?
- Legal and ethical duties of the biobank

➢ Contractual agreements

➢ Legally binding documents

➢ Ethical approvals

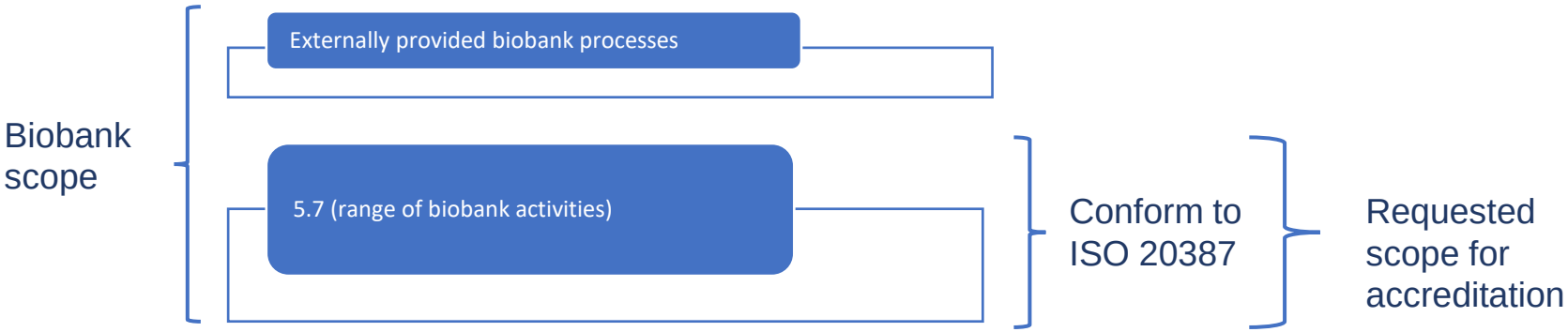
➢ Confidentiality agreement (personnel)

➢ non-disclosure agreement (personnel)

ISO 20387:2018 Requirements

5 Structural requirements

- The biobank legally identifiable
- Top management defined
- Responsibilities clearly defined
- Defined scope claiming conformity to ISO 20387 (5.7)
- (permanent) Externally provided processes excluded from scope
- Description of biobank structure including personnel



ISO 20387:2018

Requirements

6 Resource requirements

➢ **Examples**

- Documented strategy enabling continued financial viability
- Periodically reviewed

➢ Strategic plan
➢ Business plan
➢ Agreement between biobank and funders
➢ Sustainability plan

➢ Cost recovery strategy / plan
➢ Diversifying funding sources
➢ Review scope of biobank activities, risk assessment

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Requirements

6.2 Personnel

➢ **Examples**

- Documented procedures personnel management
- Documented information about personnel management
- Job descriptions
- Health and safety requirements
- Training

➢ Risk assessment for biological / chemical materials / processes / equipment

6.2 Personnel - Competence

- Personnel competence defined and documented
- Based on education, training, demonstrated skills, experience / criteria
- Regularly documented assessment of competence (require / maintain competence)

6.2 Personnel - Training

- Personnel receive appropriate and relevant (re-)training, documented (internal / external)
- Regular updates and retrain competences
- Personnel undergoing training – supervised until confirmed competent for tasks
- Introduction policy for new personnel, appropriate orientation to the biobank

6.3 Facilities / dedecated areas and enviromental conditions

- Securing biomaterials
- Requirements defined, monitored and documented
- Assessment is subject-specific to be assessed by the expert assessor
- Different types of biobanks have different measures to take
- QC, fitness for intended purpose, biosafety and biosecurity of biological material and data
- Facilities / areas defined and monitored
- Not adversely affect fitness for purpose of biomaterial and data, and personnel health and safety

ISO 20387:2018 Requirements

6.3 Facilities / dedecated areas and enviromental conditions

- Control of environmental conditions / temperature, cross contamination, access…
- Controlled access of external providers / Technicians, Logistics, IT, Cleaning?

- ➢ Legal basis available / contract, confidentiality, data protection
- ➢ Evidence of implementation in QM System / documentation
- ➢ Training / occupational safety and health protection / hygiene / dangerous goods (assessment is no substitute for official surveillance)

6.3 Facilities / dedecated areas and enviromental conditions

- Contingency plan / disaster plan
- Based on risk assessment

- ➢ Legal basis available / contract, confidentiality, data protection
- ➢ Evidence of implementation in QM System / documentation
- ➢ Training / occupational safety and health protection / hygienie

6.4 Externally provided processes, products and services

The term “product” encompasses items used in biobank processes, except the biological material

- List of service providers / overview from merchandise management system
- Criteria for the selection of service providers and suppliers defined (documented) and communicated
- Make sure that the requirements are met. Checking and verification / initial approval of suppliers
- Supplier evaluation - evaluation of performance: define processes, criteria for poor evaluations - actions, documentation

6.4 Externally provided processes, products and services

- Interaction between procurement and QM
- Definition of which information must be transmitted to the user of the biobank
- Risk assessment of the influence on materials and data
- Corresponding measures have demonstrably been taken

6.4 Externally provided processes, products and services

Externally provided preservation, storing and / or authentication activities:

- Processes and interrelated processes are validated
- Internal audits of these processes are performed regularly (risk-based approach) by external provider
- Documented information is retained

6.5 Equipment

The term “equipment” encompasses items of equipment and associated software when applicable

- Controlled access conditions to biobanks
- Documented procedures for controlled implementation of safe handling, transport, storage and maintenance of all equipment, including calibration if necessary
- Categorized quality relevant equipment, critical for biobanking (risk-based approach)

6.5 Equipment

Documentation of critical equipment contains at least:

- equipment and software identity
- the manufacturer’s name, type identification, and serial number or other unique identification
- checks that equipment complies with specifications
- the current location, where appropriate
- the manufacturer’s instructions, if available, or reference to their location

6.5 Equipment

- results, reports, and certificates of calibrations, adjustments, acceptance criteria, and associated date(s) [documented in a standard format preferably according to ISO 8601
- the due date of next calibration (documented in a standard format preferably according to ISO 8601, YYYYMMDD))
- the maintenance plan, where appropriate, and maintenance carried out to date
- any damage, malfunction, modification, or repair to the equipment

6.5 Equipment

- Metrological traceability (where applicable - measuring equipment) must be ensured with an applicable reference

- applicable reference: national and international standards, if calibration is not in SI units, certified reference materials, agreed methods and / or standards based on mutual consensus
- Metrological traceability can be done by the Biobank or by a competent external service provider (external service provider / subcontractor list)
- The procedures, tolerance ranges as well as calibration and adjustment intervals must be determined by the biobank itself, as they depend on the manufacturer's specifications, the individual use of the reference standard, the stability of the measurement, etc.

6.5 Equipment

Equipment shall be taken out of service if:

- it is subject to overloading or mishandling
- it generates potentially compromised process output/results
- it has been shown to be defective or outside of specification limits

- isolated to prevent use or clearly labelled or marked as being out of service until repaired and shown by calibration or test to perform correctly
- examine the effect of any defect or departure from specifications using appropriate measures

ISO 20387:2018 Requirements

7 Process requirements

➢ **Examples**

- The life cycle stages of the biological material and associated data in the biobank shall be identified

➢ **ISO/TR 22578:2020 Example**

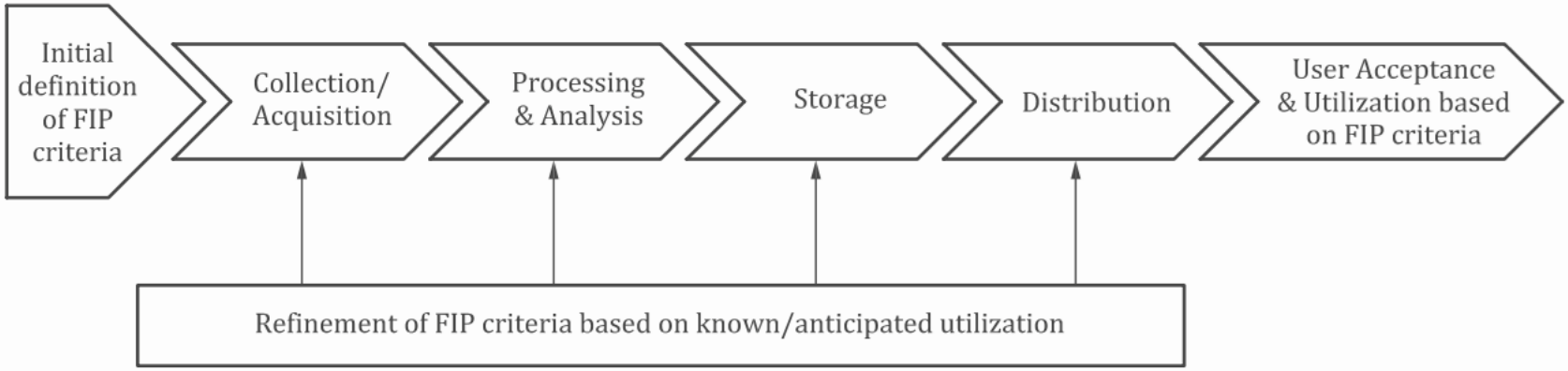

Figure 1 — The progression of BMaD and associated FIP criteria over its life cycle

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7 Process requirements

- A workflow shall describe these stages followed by detailed procedures for each relevant process
  - Collection
  - Accession
  - Acquisition
  - Identification
  - Preservation
  - Long-term storage
  - Quality control
  - Transport
  - Disposal
- All procedures must be specific, documented and implemented. Critical activities are to be identified and documented

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Requirements

7 Process requirements

- All procedures and processes kept up to date
- readily available to the personnel

➢ **Examples**

➢ Document management system

➢ Approval / distribution

➢ Training

➢ Update / change control

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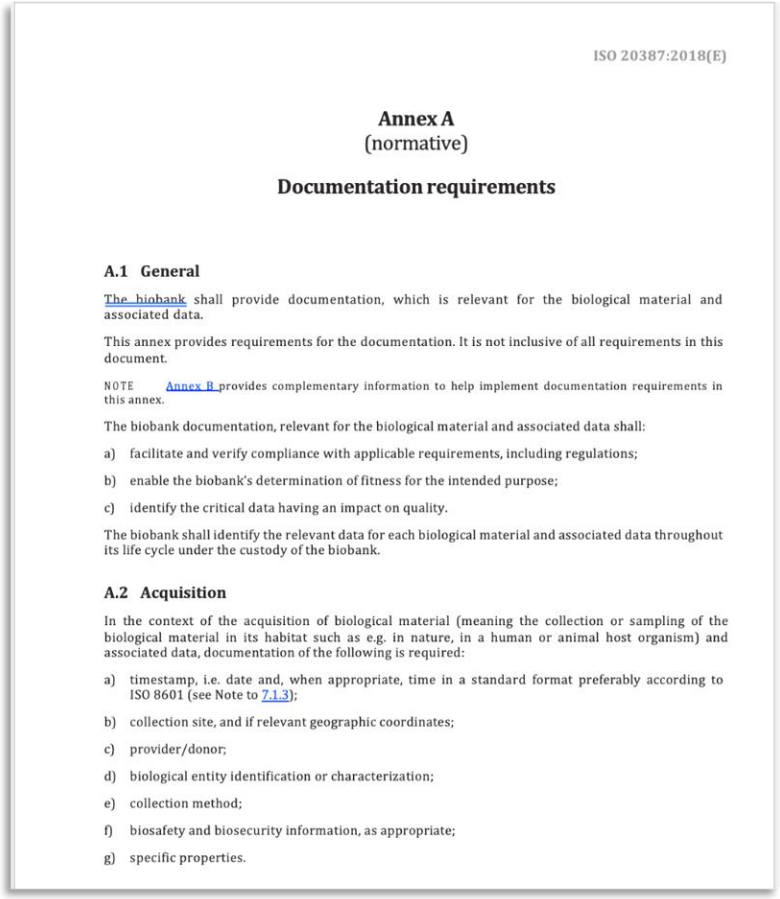
Requirements

7 Process requirements

➢ Examples



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Annex A
(normative)

Documentation requirements

A.1 General

The biobank shall provide documentation, which is relevant for the biological material and associated data.

This annex provides requirements for the documentation. It is not inclusive of all requirements in this document.

NOTE Annex B provides complementary information to help implement documentation requirements in this annex.

The biobank documentation, relevant for the biological material and associated data shall:

a) facilitate and verify compliance with applicable requirements, including regulations;

b) enable the biobank's determination of fitness for the intended purpose;

c) identify the critical data having an impact on quality.

The biobank shall identify the relevant data for each biological material and associated data throughout its life cycle under the custody of the biobank.

A.2 Acquisition

In the context of the acquisition of biological material (meaning the collection or sampling of the biological material in its habitat such as e.g. in nature, in a human or animal host organism) and associated data, documentation of the following is required:

a) timestamp, i.e. date and, when appropriate, time in a standard format preferably according to ISO 8601 (see Note to 7.1.3);

b) collection site, and if relevant geographic coordinates;

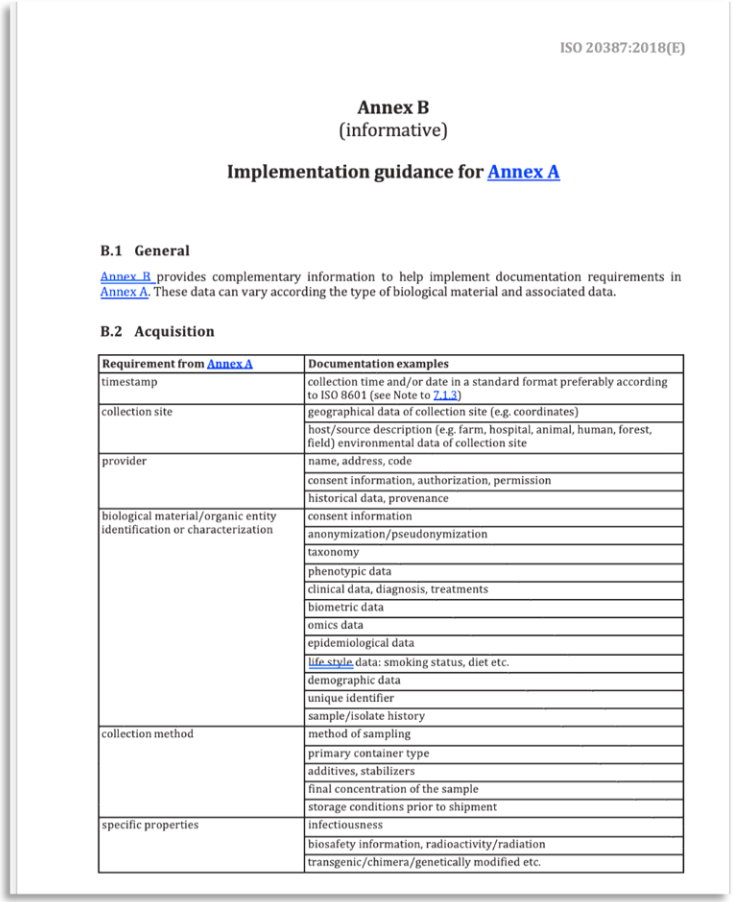
c) provider/donor;

d) biological entity identification or characterization;

e) collection method;

f) biosafety and biosecurity information, as appropriate;

g) specific properties.



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Annex B
(informative)

Implementation guidance for Annex A

B.1 General

Annex B provides complementary information to help implement documentation requirements in Annex A. These data can vary according the type of biological material and associated data.

B.2 Acquisition

Requirement from Annex A	Documentation examples
timestamp	collection time and/or date in a standard format preferably according to ISO 8601 (see Note to 7.1.3)
collection site	geographical data of collection site (e.g. coordinates)
	host/source description (e.g. farm, hospital, animal, human, forest, field) environmental data of collection site
provider	name, address, code
	consent information, authorization, permission
	historical data, provenance
biological material/organic entity identification or characterization	consent information
	anonymization/pseudonymization
	taxonomy
	phenotypic data
	clinical data, diagnosis, treatments
	biometric data
	omics data
	epidemiological data
	life style data: smoking status, diet etc.
	demographic data
	unique identifier
	sample/isolate history
collection method	method of sampling
	primary container type
	additives, stabilizers
	final concentration of the sample
	storage conditions prior to shipment
specific properties	infectiousness
	biosafety information, radioactivity/radiation
	transgenic/chimera/genetically modified etc.

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7 Process requirements

Collection of biological material and associated data

Documented information requirements

When the biobank is responsible for collection of biological material, it shall define, and document information related to the collection of the biological material.

- Date
- Place
- procedure of collection / information relevant to accomplish the objectives of the biobank (e.g. taxonomic information
- time of the collection of the biological material

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7 Process requirements

Collection of biological material and associated data

Pre-acquisition information

the biobank shall document and/or retain information related to stages prior to the reception of the biological material that can affect the properties of the biological material to allow the assessment of its fitness for the intended purpose.

- Annex A
- Annex B

ISO 20387:2018 Requirements

7 Process requirements

Collection of biological material and associated data
Pre-acquisition information
Annex A Documentation requirements

In the context of the acquisition of biological material (meaning the collection or sampling of the biological material in its habitat such as e.g. in nature, in a human or animal host organism) and associated data, documentation of the following is required:

- timestamp, i.e. date, when appropriate, time
- collection site, and if relevant geographic coordinates
- provider/donor
- biological entity identification or characterization
- collection method
- biosafety and biosecurity information, as appropriate
- specific properties

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7 Process requirements

Collection of biological material and associated data

Collection procedure

The collection procedure shall be defined either by the biobank and/or the recipient/user,

- according to the intended use of the biological material
- proven techniques
- relevant standards (7.2.3.2 e.g. ISO 20166-1, ISO 20166-2 and ISO 20166-3, ISO 20184-1 and ISO 20184-2, ISO 20186-1, ISO 20186-2 and ISO 20186-3, ISO/TS 20658)
- Qualified and authorized personnel

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7 Process requirements

Collection of biological material and associated data

Collection procedure

- **relevant standards (7.2.3.2)**

ISO 20184-1 frozen tissue – Part 1: Isolated RNA
ISO 20184-2 frozen tissue – Part 2: Isolated proteins

ISO 20166-1, FFPE tissue – Part 1: Isolated RNA
ISO 20166-2, FFPE tissue – Part 2: Isolated proteins
ISO 20166-3, FFPE tissue – Part 3: Isolated DNA

ISO 20186-1, venous whole blood - Part 1: Isolated cellular RNA
ISO 20186-2, venous whole blood - Part 2: Isolated genomic DNA
ISO 20186-3, venous whole blood – Part 3: Isolated circ. cell-free DNA from plasma

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7 Process requirements

Collection of biological material and associated data

Collection procedure

The collection of biological material and/or data for research shall never adversely affect patient care and diagnosis, or donor wellbeing.

The collection of human biological material shall be performed in accordance with relevant ethical requirements (e.g. relevant ethical approvals or waiver of consent of the patient/donor, etc.)

7 Process requirements

Reception and distribution of biological material and associated data

Access principles

The principles governing **access to** and **distribution of** biological material and associated data shall be defined, documented and, where relevant, published.

The biobank shall ensure that documented requirements established with interested parties comply with these principles.

ISO 20387:2018 Requirements

7 Process requirements

Reception and distribution of biological material and associated data

Reception

The biobank shall have documented procedures for receiving samples, which defines

- Acceptance criteria for biomaterial
- Covers the legal basis and requirements biological security / data protection / IPR
- Safe handling, packaging (transport organization, trained / qualified personnel)
- Fulfils integrity according to the requirements of the biological material and purpose
- Verified upon acquisition / reception according to the defined acceptance criteria
- Procedures for segregation to prevent final storage until legal, ethical, documentation, and quality compliance has been assessed and managed.

7 Process requirements

Reception and distribution of biological material and associated data

Distribution

The distribution and any exchange of biological material and associated data in accordance with the

- biobank's access principles
- reporting specifications
- compliance with other relevant requirements (e.g. material transfer agreement (MTA), data transfer agreement (DTA))
- documented agreement or legally binding document (e.g. contract, written and signed commitment, binding online acceptance of terms and conditions)

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7 Process requirements

Reception and distribution of biological material and associated data

Distribution

- Conditions governing the provision and use of biological material and/or associated data, are used
- Any changes to it are documented
- Distributing biological material and/or associated data to a recipient/user predefined information be provided (Report requirements)
    - unless the biobank has valid reasons for not doing so, such as data protection compliance.

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7 Process requirements

Transport of biological material and associated data

The biobank shall have documented procedures for shipping and receiving biological material, including appropriate conditions for the continued maintenance of biological material integrity in place.

Document and implement procedures for shipping and receiving data. The transfer of data shall be designed to ensure integrity and prevent breach of data privacy.

Prior to the transfer of data, arrangements shall be made for data reception and/or distribution with relevant parties.

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7 Process requirements

Transport of biological material and associated data

- procedures for safe handling, packaging, transport and reception relevant to the biological material concerned
- biological material not be left unattended, unless in designated custody zones as indicated by relevant procedures
- Only competent personnel prepare biological material for shipment
- arrangements be made for biological material distribution and reception with relevant parties.

➢ Training, competence check

➢ Access control

ISO 20387:2018 Requirements

7 Process requirements

Transport of biological material and associated data

- Approved transport procedures / qualified transport services
  - Direct transport to the entrance (central lab)
  - Pneumatic tube
  - Courier
  - Post
  - IATA e.g. UN 3373..

- Process validation / qualified equipment / qualified personnel
- Annex A
- Annex B

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7 Process requirements

Transport of biological material and associated data

Annex A Transport

In the context of the internal and external transport of biological material, the transport conditions are documented, when relevant and appropriate, and include:

- mode of transportation/shipment specifications
- temperature during transport
- temperature or temperature range at reception
- transport start and end time and date for external transport in a standard format preferably according to ISO 8601
- specific requirements, if applicable

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7 Process requirements

Traceability of biological material and associated data

The biobank shall ensure traceability of biological material and associated data

from collection (where relevant), acquisition or reception

to distribution, disposal or destruction mode of transportation/shipment specifications

- Appropriately tagged
- identification is maintained throughout the life cycle under the custody
- Persistent tagging through the use of unique identifiers

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7 Process requirements

Traceability of biological material and associated data

documented tagging procedure compliant with environmental requirements including relevant storage conditions

- linked to the documented information with detail of permissions or restrictions associated for its use
- inventory or tracking system shall allow for the annotation and query of relevant information associated with any handling procedure, including collection, packaging, transportation, preparation, preservation, storing, and distribution procedures
- any deviation in biobanking procedure(s) to be flagged
- link between biological material and associated data shall be established and maintained for unambiguous traceability

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7 Process requirements

Traceability of biological material and associated data

- Tracking of location / identify the location
- Monitoring / tracking of distribution
- information accessible by personnel to allow querying the data as needed
- Documented procedures for the disposal and transfer of biological material and/or data as planned event and as a result of an emergency (Routine – Emergency)

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7 Process requirements

Preparation and preservation of biological material

The method(s) of preparation and/or preservation shall be defined according to an evidence- based documented processing method (e.g. an International Standard) or as specified in agreement with the provider/recipient/user.

Critical activities of the preparation and/or preservation procedure

- be monitored and the relevant parameters documented. Each preservation step individually documented. Annex A4
- The date of each preparation and/or preservation step documented in a standard format for all biological material.
- The time of each related step should be documented in a standard format (ISO8601).

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7 Process requirements

Storage of biological material

The biobank shall demonstrate

documented procedures for the storage and tracking of biological material

The biobank should have

A disaster protection plan with use of alternative methods of safeguarding to avoid loss of biological material

7 Process requirements

Storage of biological material

documented procedures for the storage and tracking of biological material including at least:

- tagging information containing the unique identifier
- the type of container and environmental conditions
- mechanism(s) for traceability
- a short-term back-up plan for maintaining accurate storage conditions/temperatures in the case of emergency challenges in maintaining defined storage conditions

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7 Process requirements

Storage of biological material

During the execution of critical activities performed during storage, relevant processing parameters shall be measured, monitored and documented.

- Documentation of critical activities with date / where necessary, the time
- Appropriate conditions of environmental and premises
- Access control
- Traceability of any storage activity, anytime
- Minimize risk of contamination
- Safeguard the integrity of material

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7 Process requirements

Storage of biological material

- verify the biological material inventory at planned intervals by a defined procedure

When applicable, the biobank shall establish, document and implement procedures supporting the patient/donor right to withdraw consent for storage and use of biological material and associated data.

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7 Process requirements

Storage of biological material

- verify the biological material inventory at planned intervals by a defined procedure

When applicable, the biobank shall establish, document and implement procedures supporting the patient/donor right to withdraw consent for storage and use of biological material and associated data.

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7 Process requirements

Quality control of of biological material and associated data

The biobank shall demonstrate

- Identification critical activities having an impact on the quality of the biological material and associated data
- establish, document and implement quality control (QC) procedures related to such activities
    - Exceptions can be justified for rare or legacy biological material and associated data and QC procedures which lead to biological material elimination.

“Legacy biological material and associated data” refers to the biological material and associated data acquired or received by the biobank before the biobank has implemented ISO 20387

7 Process requirements

Quality control of of biological material and associated data

The QC measures shall

- be defined according to proven techniques and fitness for the intended purpose
- be regularly updated
- ensure that provider/recipient/user requirements are met where possible

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7 Process requirements

Quality control of of biological material and associated data

Quality control of processes

- document and implement procedures specifying QC activities throughout the biobanking processes, including QC criteria corresponding to predefined specifications, to demonstrate fitness for the intended purpose
- The QC activities performed according to planned intervals
- retain documented information of QC activities and results
- QC data shall be analysed / predefined criteria are not met, actions to be taken to control reporting of invalid data and/or distribution of non-compliant biological material and associated data
- identified limitations are clearly documented and communicated to the recipient/user. It is the user's responsibility to (not) accept non conformities

ISO 20387:2018 Requirements

7 Process requirements

Quality control of of biological material and associated data

Quality control of processes

- QC results shall be periodically analysed for trends and used as input for the continuous improvement process (presentation e.g. in management review)
- Documentation in accordance with Annex A
- QC materials employed by the biobank periodically examined to assess important quality characteristics of the biological material,
  - stability
  - performance of the processing methods
  - accuracy/precision of the QC procedures.

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7 Process requirements

Quality control of of biological material and associated data

Quality control of processes

- Provide objective evidence to demonstrate the comparability of biological material quality (the processing or testing output), where available and appropriate
- External quality assessment (EQA) programs, proficiency testing programs, interlaboratory comparisons
- The biobank may develop its own approaches, including the use of:
  - certified reference materials, where available, produced by a reference material producer fulfilling the requirements of ISO 17034
  - samples previously examined
  - samples previously shared with other biobanks
  - control materials that are tested regularly in EQA programs
- Participation in EQA / monitoring of results / perform document corrective actions

ISO 20387:2018 Requirements

7 Process requirements

Quality control of of biological material and associated data

Quality control of data

- Identify the critical data, and establish, document and implement QC procedures applying at least to these critical data
- Define the type and frequency of the QC performed
- QC focus on accuracy, completeness and consistency of data

ISO 20387:2018 Requirements

7 Process requirements

Validation and verification of methods

The biobank shall demonstrate

- Use validated and / or verified procedures
- Ensure fitness for the intended purpose
- Define the period of validity
- Document the results achieved / procedures used
- Demonstrate the usability of the procedures
- Demonstrate objective evidence of performance characteristics
- Assess the impact of changes

ISO 20387:2018 Requirements

7 Process requirements

Validation and verification of methods

Validation

The validation shall be as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use have been fulfilled

When changes are made to a validated method, the impact of such changes is documented and, when appropriate, a new validation be carried out

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7 Process requirements

Validation and verification of methods

Verification

Validated methods used without modification shall be subject to verification by the biobank before being used

The verification by the biobank shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the set criteria for the method have been met

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7 Process requirements

Validation and verification of methods

Verification

Validated methods used without modification shall be subject to verification by the biobank before being used

The verification by the biobank shall confirm, through obtaining objective evidence (in the form of performance characteristics) that the set criteria for the method have been met

- Documented the procedure used for the verification and the results obtained
- Process descriptions
- Process depiction appropriate level of details
- Systemic analysis of risks in the process (FMEA)
- Derivation of measurable performance criteria

7 Process requirements

Management of information and data

- Define the required information and data related to biological material
- Tracking system in place
- Introduce reasonable efforts to support interoperability of information and data
- Address future expansion of its capacity to allow further addition and/or processing of data associated with biological material
- A procedure for implementation, modification and use of computer system software, hardware, and database(s) in place, when used for biobanking.
- The procedure shall at least include
  - data integrity
  - security controls and backup system to prevent loss or corruption of data

ISO 20387:2018 Requirements

7 Process requirements

Management of information and data

- Access to the data and information needed to provide a service specified by contractual agreements
- Provide interested parties with access to a catalogue of available biological material and associated data
- Retain access to the appropriate data associated with the biological material, as necessary for research purposes and/or in compliance with applicable requirements and 7.3.3.2 Distribution

ISO 20387:2018 Requirements

7 Process requirements

Nonconforming output

The Biobank shall demonstrate

documented and implemented procedures for management of output that does not conform to

- the predefined requirements of the biobank
- the agreement with the recipient/user
- the agreement with the provider

By

- Identification of nonconformities
- disclose information about nonconforming output to relevant parties
- take appropriate corrective action

7 Process requirements

Nonconforming output

The procedures for nonconforming output shall address:

- responsibilities and authorities
- Impact analysis
- decision for measures
- persistence of nonconforming output, when
  - remedy of the nonconformity is impossible
  - remedy of the nonconformity is considered impractical
  - the output can have an impact on the results produced by third parties
- communication of nonconforming output and the authorization for acceptance by the recipient/user.

ISO 20387:2018 Requirements

7 Process requirements

Nonconforming output

Control of nonconforming output

The biobank shall demonstrate

- the mitigation of the impacts of nonconformity
- implement corrective actions in proportion to the risk(s) presented by nonconforming output and prevent recurrence
- Remedial actions appropriate to the effects taken within defined limits and controlled when nonconforming output is corrected

7 Process requirements

Report requirements

The biobank shall provide

- a report at least as specified in 7.12.2 Content of the report
- including the required information as agreed upon in the documented agreement or other legally binding document with the recipient/user
    - Reports are sometimes called certificates
- issued as hard copy or by electronic data transfer or by an electronic data entry in an accessible database
- Disclaimer specifying that the report shall not be reproduced except in full
- responsible for all the information provided in the report, except when information is provided by the provider/recipient/user
- biobank has not been responsible for collection or sampling, the report shall state it

7 Process requirements

Report requirements

Content of the report

- a title (e.g. “Quality report” or “Material certificate”)
- the name and address of the biobank, and the location where activities referred to in the report were carried out, if different from the address of the biobank
- the date of issue of the report in a standard format according to ISO 8601
- unique identification of the report (such as a serial number), with an identification on each page to ensure that the page is recognized as a part of the report, and a clear identification of the end of the report
- biological material identification or specific properties
- relevant quality information of the biological material and associated data

7 Process requirements

Report requirements

Content of the report

- method(s) used for identification or characterization of the biological material
- testing results with, where appropriate, the units of measurement
- method(s) used for testing
- method(s) used for collection/acquisition, preparation and/or preservation, as applicable
- storage conditions
- the name(s), function(s) of person(s) authorizing the report

ISO 20387:2018 Requirements

7 Process requirements

Complaints

The biobank shall demonstrate

- documented and implemented procedures to receive, evaluate and make decisions on complaints
- a description of the handling process for complaints be made available upon request. Upon receipt of a complaint, the biobank shall confirm whether the submitted complaint relates to activities for which it is responsible and, if so, shall address it
- responsibility for all levels of complaint handling

7 Process requirements

Complaints

The process for handling complaints shall include at least the following elements and methods:

- description of the process for receiving, accepting, investigating the complaint, and deciding what actions are to be taken in response to it
- tracking and recording complaints, including actions undertaken to resolve them
- ensuring that any appropriate action is taken

ISO 20387:2018 Requirements

8 Quality management system requirements

The biobank shall establish, document, implement and maintain a quality management system that is capable of supporting and demonstrating the consistent achievement of the requirements of ISO 20387 and assuring the quality of biobanking.

- meeting the requirements of Clauses 4 to 7
- implement a quality management system in accordance with **option A or option B**.

ISO 20387:2018 Requirements

8 Quality management system requirements **Annex C** informative

Option A

lists the minimum requirements for implementation of a quality management system in a biobank. Care has been taken to incorporate all those requirements of ISO 9001 that are relevant to the scope of biobanking that are covered by the quality management system. Biobanks that comply with Clauses 4 to 7 and implement Option A of Clause 8 will therefore also operate generally in accordance with the principles of ISO 9001.

Option B

allows biobanks to establish and maintain a quality management system in accordance with the requirements of ISO 9001, in a manner that supports and demonstrates the consistent fulfilment of Clauses 4 to 7. **Biobanks that implement Option B** of Clause 8 will therefore also operate in accordance with ISO 9001. **Conformity of the quality management system within which the biobank operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the biobank to produce technically valid data and outputs. This is accomplished through compliance with Clauses 4 to 7.**

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

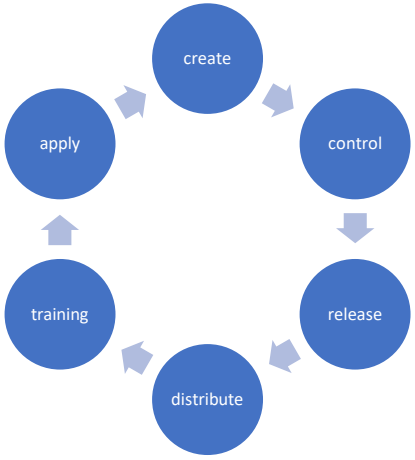
Documented information for the quality management system

- Documented QMS
  - Demonstrate that relevant documents are identified / created / controlled
  - Policies / objectives are documented / maintained / implemented / improved
  - Accessible for all personnel involved in biobanking

8 Quality management system requirements A

Control of quality management system documents

- Documented QMS
  - Demonstrate that relevant documents are identified / created / controlled
  - Policies / objectives are documented / maintained / implemented / improved
  - Accessible for all personnel involved in biobanking



- Approved by authorized personnel
- Periodically reviewed / updated as necessary
- Current revision status identified
- Available at points of use
- Uniquely identified
- Control of outdated versions

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

Control of records

The biobank shall demonstrate

- legible records to demonstrate fulfilment of the requirements ISO 20387
- controls needed for the identification, storage, protection, back- up, archive, retrieval, retention time, and disposal of its records
- retain records for a period consistent with its contractual and legal obligations
- Access to these records consistent with the confidentiality arrangements and records / readily available

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

Actions to address risks and opportunities

The biobank shall demonstrate

- Considerations of the risks and opportunities associated with its biobank activities
  - assurance that the quality management system can achieve its intended results
  - enhance opportunities to achieve the purpose and objectives of the biobank
  - prevent or reduce undesired impacts and potential failures in biobanking, including discontinuation of operations of the biobank
  - continuous improvement

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

Actions to address risks and opportunities

The biobank shall demonstrate documented information:

- action plan(s) to address these risks and opportunities
- action plan(s) to safeguard biological material and associated data in the event of a disaster
- action plan(s) to address discontinuation of operations in particular handling of concerned biological material and associated data (e.g. legacy plan)

approach(es) to:

- integrate and implement these actions into its QMS
- evaluate the effectiveness of these actions
- handle the end of business in case of the biobank's closure

Actions taken proportionate to the potential impact on and the validity of biobanking

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

Improvement

- identify and select opportunities for improvement
- implement any necessary actions
  - review of the operational procedures, policies, overall objectives, audit results, corrective actions, management review, risk assessment, analysis of data, and proficiency-testing results

- seek feedback from provider(s)/ recipient(s)/ user(s)
  - analysed / improve the QMS, biobanking services

ISO 20387:2018 Requirements

8 Quality management system requirements A

Corrective action for nonconforming output

The biobank shall demonstrate

- reacts to the nonconforming output and, as applicable:
  - take action to control and correct it
  - deal with the consequences
- cause analysis
- impact analysis
- corrective action
- effectiveness of any corrective action
- retain documented information as evidence

ISO 20387:2018 Requirements

8 Quality management system requirements A

Internal audits

The biobank shall demonstrate

- Audit programm (plan, determine, maintain)
  - frequency, methods, responsibilities, planning requirements, including pre-audit measures, reporting
  - definition of audit scopes
  - reported to the management (management review)
  - implement corrective actions without undue delay
  - retain records

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

Internal audits

The biobank shall demonstrate

- Conducting audits
  - planned intervals
  - provide evidence / reports of conform to QMS to its own requirements
  - provide evidence / reports of conform to ISO 20387
  - Effectively implemented and maintained

ISO 20387:2018 Requirements

8 Quality management system requirements A

Quality management reviews

- top management shall review its quality management system at planned intervals
- ensures its continuing suitability
- adequacy and effectiveness
- stated policies and objectives related to the fulfilment of ISO 20387

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

Quality management reviews

Documented input to the reviews

- changes in internal and external issues that are relevant to the biobank
- fulfilment of objectives
- suitability of policies and procedures
- status of actions from previous management reviews
- outcome of recent internal audits
- corrective actions
- assessments by external bodies
- changes in the volume and type of work or in the range of the biobank's activities

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

Quality management reviews

Documented input to the reviews

- provider/recipient/user feedback
- complaints
- effectiveness of any implemented improvements
- adequacy of biological material and associated data
- results of risk identification
- outcomes of the quality control
- other relevant factors, such as monitoring activities and training

ISO 20387:2018 Requirements

8 Quality management system requirements **A**

Quality management reviews

Documented output of the reviews

Output from the review: recorded decisions and actions to be implemented

- the effectiveness of the quality management system and its processes
- improvement of the activities related to the fulfilment of the requirements of ISO 20387
- provision of required biological material and associated data
- any need for change

Thank you for your attention

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