ISO/TC 276/SC N

Date: 2016-09-26

ISO/CD 20387:2016(E)

ISO/TC 276/SC /WG

Secretariat: DIN

Biotechnology — Biobanking — General requirements for biobanking

Élément introductif — Élément central — Élément complémentaire

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Document type: International Standard
Document subtype:
Document stage: (30) Committee
Document language: E

C:\Users\krl\Desktop\ISOTC 276\4_ ISOTC276WG2 - Dublin\1_ISO 20387\ISO-TC276-WG2_ISO_Biobanking_Manuscript_version_19_20160925.docx STD Version 2.8f

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Foreword

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The committee responsible for this document is ISO/276.

Biotechnology — Biobanking — General requirements for biobanking

1 Scope

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

1.2 This document is applicable to all organizations performing biobanking activities, including biobanking of human, animal, plant and microorganism resources for research and development.

1.3 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.

1.4 This document does not apply to biological material intended for food production or therapeutic use.

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

2 Normative references

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

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

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:

— IEC Electropedia: available at http://www.electropedia.org/
— ISO Online browsing platform: available at http://www.iso.org/obp

Please note that the Terminology is still under discussion and by no means finalized in this NWIP! The Terminology will be revised and finalized, once the document's content is agreed on.

3.1
access
right to obtain or make use of or take advantage of something (as services or membership); the right to enter

3.2
accessioning
logging
…

3.3
acquisition
…

3.4
aliquot
portion of a homogenous sample which has been divided into separate parts at the same time under identical conditions

3.5
analyte
component represented in the name of a measurable quantity

EXAMPLE In the type of quantity "mass of protein in 24-hour urine", "protein" is the analyte. In "amount of substance of glucose in plasma", "glucose" is the analyte. In both cases the long phrase represents the measurand.

[SOURCE: ISO 17511:2003, 3.2]

3.6
anonymization
removal of identifiable personal information from samples and data

Note 1 to entry: Anonymization can be complete or refer to coding so that the identity of the donor is held by the biobank but is unknown to the recipient of the samples.

3.7
associated data
any factual information affiliated with a biological resource, including but not limited to research, phenotypic, clinical, epidemiologic, and biological resource procedural data

3.8
biobank
facility where biobanking is performed

3.9
biobanking
process of collecting and storing, as well as some or all of the following activities: processing, testing, analyzing and distributing defined biological materials from human, animal, plant and microorganisms as well as related information and data; it also includes service providers and repositories of biological materials

3.10
biological material
any material obtained or derived from one or more biological entities

Note 1 to entry: This includes specimens, samples, derivatives, aliquots etc.

3.11
biological material collection
…

3.12
biological resource
set of a biological material and its associated data

3.13
cataloguing
process of compiling a record for inclusion in one or more catalogues or indexes, which describes an entity and assists in its retrieval

[SOURCE: ISO 8459:2009, 2.11]

3.14
chain of custody
...

3.15
classification
...

3.16
collection
procurement
process of removing a portion, of a biological material

3.17
collection site
location where the collection is performed

3.18
competence
ability to apply knowledge, experience, and skills to achieve intended results

[SOURCE: ISO 17100:2015, 2.4.9]

3.19
complaints
expression of dissatisfaction other than appeal (ISO/IEC 17000 6.4,) by any person or organization to a biobank, relating to the activities or results of that biobank where a response is expected

[SOURCE: ISO/IEC 17000:2004, 6.5 — modified: *conformity assessment body* or *accreditation body* replaced by b*iobank* and added the term *results*.]

3.20
contractual document
contract, collaboration agreement, material transfer agreement, convention for biological resource provision or similar

3.21
derivative
sample which was physically and/or chemically processed

3.22
destruction
…

3.23
disposal
…

3.24
distribution
release
process that includes receipt of request for biological resources, selection of appropriate biological resources, and final inspection, in conjunction with subsequent shipment and delivery of biological resources to another biobank, biological resource collection center, laboratory or researcher/client

3.25
documented information
information required to be controlled and maintained by an organization and the medium on which it is contained

[SOURCE: ISO 9000:2015, 3.8.6]

3.26
examination
analytical phase
set of operations having the object of determining the value or characteristics of a property

Note 1 to entry: Processes that start with the isolated analyte and include all kinds of parameter testing or chemical manipulation for quantitative or qualitative examination

[SOURCE: ISO 15189:2012, 3.7, modified — The term and definition is used here without the original notes.]

3.27
fit for purpose
fitness for the intended purpose
…

3.28
impartiality
presence of objectivity

Note 1 to entry: Objectivity is understood to mean that conflicts of interest do not exist, or are resolved so as not to adversely influence the activities of the laboratory.

Note 2 to entry: Other terms that are useful in conveying the element of impartiality are independence, freedom from conflicts of interest, freedom from bias, freedom from prejudice, neutrality, fairness, open-mindedness, even-handedness, detachment and balance

[SOURCE: ISO/IEC 17021-1:2015, 3.2]

3.29
inter-laboratory 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/IEC 17043:2010, 3.4]

3.30
IT system
computer hardware, software, and access to IT networks where appropriate

3.31
labeling
process that permits the identification and characterization of the contents of a sample container by means of a written, printed, electronic or graphic matter affixed to the sample container

3.32
legacy biological resource
biological resource collected prior to the first adoption of this document

3.xx
life cycle
xxxxxxxxx

3.33
measurable quantity
quantity
attribute of a phenomenon, body or substance that can be distinguished qualitatively and determined quantitatively

[SOURCE: VIM:1993, 1.1]

Note 1 to entry: Properties that are expressed on a nominal scale are not measurable quantities.

Note 2 to entry: "Measurable quantity" is not to be confused with "analyte", see 3.1.

3.34
non-conforming biological resources
...

3.35
packaging
any material used for the containment, protection, handling, delivery, storage, transport and presentation of goods

[SOURCE: ISO 17364:2013, 4.5]

Note 1 to entry: Within this document "goods" are equivalent to biological resources.

3.36
personnel
all persons engaged in a given organization, including employer(s), employees, self-employed persons or sub-/contractors

3.37
pre-examination processes
preanalytical phase
preanalytical workflow
processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, surgical procedure, collection of the primary sample(s), temporary storage, transportation to and within the analytical laboratory, aliquotting, retrieval, isolation of analytes, and end when the analytical examination begins

[SOURCE: ISO 15189:2012, 3.15, modified — An additional term was added and more details were included.]

Note 1 to entry: The pre-examination phase includes preparative processes, which can influence the outcome of the intended examination.

3.38
preservation
use of chemical agents, alterations in environmental conditions or other means during processing to prevent or retard biological or physical deterioration of a biological resource

Note 1 to entry: Preservation is applicable for reproducible specimens.

3.39
primary sample
specimen
discrete portion of material obtained from one specific biological entity at a specific time

3.40
procedure
specified way to carry out an activity or a process

[SOURCE: ISO 9000:2015,3.4.5, modified — Term taken over without the note.]

3.41
process
set of interrelated or interacting activities that use inputs to deliver an intended result

[SOURCE: ISO 9000:2015, 3.4.1, modified — Term taken over without notes.]

3.42
processing
any procedure employed after specimen/sample collection but prior to its distribution, including preparation, testing, and releasing the biological material to inventory and labeling

3.43
product
…

3.44
proficiency testing
evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons

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 analysis; 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 17043:2010, 3.7 — modified: the reference to the Annex and the last sentence of note 2 deleted.]

3.45
pseudonymization
...

3.46
quality assurance
QA
planned and systematic actions necessary to provide adequate confidence that a process, measurement, or service satisfies given requirements for quality

[SOURCE: ISO 13304-1:2013, 2.6]

3.47
quality control
QC
part of quality management focused on fulfilling quality requirements

[SOURCE: ISO 9000:2015, 3.3.7]

3.48
quarantine
inspection performed by facility for their compatibility, adequacy, or suitability of legacy biological material and services

3.49
real costs
cost expressed as a value at the base date, including estimated changes in price due to forecast changes in efficiency and technology, but excluding general price inflation or deflation

[SOURCE: ISO15686-5:2008, 3.1.12]

3.50
reception
…

3.51
room temperature
temperature which is defined as 18 °C to 25 °C for the purposes of this document

Note 1 to entry: Local or national regulations can have different definitions.

[SOURCE: ISO/DIS 20166-2:2016, 3.22]

3.52
sample
one or more parts taken from a primary sample

[SOURCE: ISO 15189:2012, 3.24, modified — The example was not taken over.]

3.53
sampling
process of removing a portion, intended to be representative, of a biological material to produce a sample or group of samples

3.54
sampling method
process of selecting portions of the specimen to be collected with a specific collection method

Note 1to entry: Sampling methods are used for inhomogeneous and large specimens (e.g., environmental collections).

3.55
stability
ability of a biological material, when stored under specified conditions, to maintain a stated property value within specified limits for a specified period of time

[SOURCE ISO Guide 30:2015, 2.1.15, modified — The words “reference material” were replaced by “biological material"; the original note was not needed.]

3.56
standard operating procedure
SOP
authorized, documented procedure or set of procedures, work instructions and test instructions for production and control

[SOURCE: ISO 15378:2015, 3.4.27]

3.57
storage
maintenance of biological resources under specified conditions for future use

Note 1 to entry: Storage is applicable for non-reproducible biological resources.

3.58
transport
...

3.59
unique identifier
identifier which is different from any other identifier within the same organization

3.60
validation
confirmation, throughout the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The term "validated" is used to designate the corresponding status.

Note 2 to entry: Adapted from ISO 9000:2005, definition 3.8.5.

[SOURCE: ISO 15189:2012, 3.26]

3.61
verification
confirmation, through provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The term "verified" is used to designate the corresponding status.

Note 2 to entry: Confirmation can comprise activities such as:

- performing alternative calculations,
- comparing a new design specification with a similar proven design specification,
- undertaking tests and demonstrations, and
- reviewing documents prior to issue.

[SOURCE: ISO 9000:2005, 3.8.4]

3.62
workflow
series of activities necessary to complete a task

[SOURCE: ISO/DIS 20166-2:2016, 3.31]

Note 1 to entry: Within the context of this document "activities" can be understood as "processes".

4 General requirements

4.1 General

4.1.1 The biobank shall have documented standard operating procedures (SOPs) addressing biobanking of each type of biological resource held. This includes processes such as specific pre-examination processing, collection/procurement, acquisition and reception, labeling, accessioning/logging, cataloguing/ classification, examination processing, replicating, storing, data management, destruction, packaging as well as safeguarding, distribution and transportation.

4.1.2 Information relevant to activities biobanking processes and SOPs shall be documented in a comprehensible format. The documentation shall include relevant information generated from procedures pertaining to the management system as well as the management of premises and equipment.

4.1.3 The biobank shall comply with relevant regional, national and international ethical principles for biological resources and for their use in research and development. Compliance with ethical principles shall be reflected in all SOPs used by biobanks.

4.1.4 The biobank shall have documented SOPs that clearly delineate compliance with relevant biosecurity and biosafety requirements. The SOPs shall also address risk management.

4.1.5 The biobank shall maintain documented personnel files that provide evidence of appropriate professional competence and ongoing education.

4.1.6 The biobank shall deploy a mechanism to track the identity of persons performing specific activities. This encompasses all procedures as defined in 4.1.1.

4.2 Impartiality

4.2.1 Biobanking activities shall be undertaken impartially, structured and managed so as to safeguard impartiality. The biobank shall have procedures in place to demonstrate impartiality, if externally funded work is performed.

4.2.2 The biobank management shall be committed to impartiality.

4.2.3 The biobank shall be responsible for the impartiality of its biobanking activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.2.4 The biobank shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a biobank with a risk to impartiality.

NOTE A relationship that threatens the impartiality of the biobank can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new users, etc.

4.2.5 If a risk to impartiality is identified, the biobank shall be able to demonstrate how it eliminates or minimizes such risk.

4.3 Confidentiality

4.3.1 The biobank shall ensure the protection of its biological resources', providers' and users' confidential information and proprietary rights, including protecting the electronic storage and transmission of data.

4.3.2 The biobank shall be responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of biobanking activities. The biobank shall only release information regarding biological resources according to contractual agreements. Except for information that the original donor of the human biological resource or the provider of the non-human biological resource has consented for public release, all other information is considered proprietary information and shall be regarded as confidential.

4.3.3 When the biobank is required by law or authorized by contractual arrangements to release confidential information, the provider/user or individual concerned shall, unless prohibited by law, be notified of the information provided.

4.3.4 Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the biobank's behalf, shall keep confidential all information obtained or created during the performance of the biobanking activities, except as required by law.

5 Structural requirements

5.1 The biobank shall be a legal entity, or a defined part of a legal entity, that is legally responsible for all its activities.

NOTE For the purpose of this document a governmental biobank is deemed to be a legal entity on the basis of its governmental status.

5.2 The biobank shall have a course of action to address liabilities arising from its activities.

5.3 The biobank shall carry out its activities in such a way as to meet the requirements of this document, its contractual agreements, regulatory authorities and organizations providing recognition.

5.4 The biobank shall define and document the range of biobanking activities for which it conforms with this document. The biobank shall only claim conformity with this document for the range of biobanking activities, which excludes externally provided biobanking activities on an ongoing basis.

5.5 The biobank shall:

a) define the organization and management structure of the biobank, its place in any parent organization, and the relationships between management, technical operations and support services;

b) specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of biobanking activities.

5.6 The biobank shall have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;

b) identification of deviations from the management system or from the procedures for performing biobanking activities;

c) initiation of actions to prevent or minimize such deviations;

d) reporting to biobank management on the performance of the management system and any need for improvement; and

e) ensuring the required validity of biobanking activities.

5.7 Biobank management shall ensure that:

a) the integrity of the management system is maintained when changes to the management system are implemented;

b) communication takes place regarding the effectiveness of the management system;

c) the importance of meeting user and other requirements is communicated to the biobank personnel.

6 Resource requirements

6.1 General

The biobank shall have available personnel, infrastructure and environmental conditions, equipment, information system(s) and support services necessary to perform its biobanking activities.

6.2 Personnel

6.2.1 General

6.2.1.1 All personnel of the biobank, either internal or external, that could influence the biobanking activities, shall act impartially.

6.2.1.2 The biobank shall define and document the competence requirements for personnel involved in biobanking activities.

6.2.1.3 All personnel having access to confidential data of a biobank shall be bound to confidentiality (4.3).

6.2.1.4 The biobank shall have documented procedures for personnel management and maintain records to indicate compliance with relevant requirements.

6.2.1.5 The biobank shall have job descriptions that describe responsibilities, authorities and tasks for all personnel.

6.2.2 Personnel competence and competence assessment

6.2.2.1 The biobank shall ensure that all its personnel shall be competent on the basis of appropriate education, training, demonstrated skills and/or experience necessary to perform the tasks assigned.

6.2.2.2 Health and safety officer shall be appointed for all safety aspects. The level of safety training required shall be determined according to position related requirements based on a comprehensive risk assessment of the biological and chemical materials, processes and equipment being handled.

6.2.2.3 Persons appointed to perform processes shall be subject to personnel training (6.2.3) and competence assessment and shall have the applicable theoretical and practical background and experience.

6.2.2.4 Following training, the biobank shall assess the competence of each person to perform assigned managerial or technical tasks according to the biobank's established criteria.

6.2.2.5 Assessment of competence shall take place at planned intervals. Retraining shall occur when necessary.

6.2.3 Personnel training

6.2.3.1 Each member of personnel shall receive appropriate and relevant training (internal and/or external training) with regular updates to acquire and retain the necessary competence. The training shall be documented.

6.2.3.2 The biobank shall provide training for all members of personnel which includes the following areas:

1. quality management;
2. assigned work processes and procedures;
3. applicable equipment and information system(s);
4. ethics;
5. confidentiality of donor / biological material information;
6. data management;
7. local emergency response plan including biosecurity, health and safety including the prevention or containment of the effects of adverse incidents and disaster management created for the biobank and associated infrastructure, if applicable.

All personnel shall have access to appropriate and relevant documentation.

For other personnel, all or part of this training shall be provided, based upon a documented risk-based approach with respect to the scope of activities performed.

6.2.3.3 Personnel undergoing training shall be supervised until the biobank confirms the personnel as competent to perform assigned tasks.

6.2.3.4 The aim and content of the education and training programme shall be periodically reviewed by the biobank.

6.3 6.2.3.1 A reception policy for the integration of new personnel members shall be implemented. New personnel shall be provided with appropriate orientation to the biobank.Infrastructure

6.3.1 The biobank shall determine, provide and maintain the infrastructure with the conditions needed to achieve conformity to the requirements for the biological resource(s), biosafety and biosecurity.

NOTE Infrastructure can include:

a) buildings, associated utilities and workspace used for biobank specific operation with biological resources;

b) equipment including hardware and software;

c) transportation;

d) information and communication technology;

e) security services (condition monitoring, control and recording access, remote control etc.).

6.3.2 Where necessary, effective separation between areas shall be in place, e.g., to avoid contaminations.

6.4 Environmental conditions

The biobank shall monitor, control and record environmental conditions, as required or where they can influence the quality of the biological material, results, and/or the health of personnel.

6.5 Control of externally provided processes, products and services

6.5.1 General

6.5.1.1 The biobank shall:

1. determine procedures and requirements for the externally provided processes, products[1)] and services;

2. document and communicate these procedures and requirements to the external provider;

3. retain relevant information about such communication;

4. ensure that the externally provided processes, products and services conform to the established procedures and requirements.

6.5.1.2 The biobank shall determine the controls to be applied to externally provided processes, products and services when:

1. products and services from external providers are intended for the biological material processing, preservation and/or authentication; as well as for information management, workflow control and monitoring of environmental conditions;

2. a biological resource or material is supplied directly to the user by external providers on behalf of the biobank;

3. a process, or part of a process, is provided by an external provider as a result of a decision by the biobank.

6.5.1.3 The biobank shall determine and apply criteria for the selection, evaluation, monitoring and re-evaluation of performance of external providers based on their ability to provide processes or products and services in accordance with requirements. The biobank shall retain documented information of these activities and any necessary actions arising from the evaluations.

6.5.1.4 When the biobank decides to utilize externally provided preservation and/or authentication process, or part of these, the biobank shall ensure that the process(es), and all the inter-related processes, are validated and documented according to this document provisions.

6.5.1.5 The biobank shall determine which externally provided processes, or part of these, shall be communicated to the users. When long-term storage of the preserved biological material is externally provided users shall be informed.

6.5.2 Type and extent of control

6.5.2.1 The biobank shall ensure that externally provided processes, products and services do not adversely affect the biobank's ability to consistently preserve and supply authenticated biological resources. The biobank shall determine the risks of externally provided processes, products and services to the

1) In this clause, the term "product" encompasses critical products used in biobank processes except the biological material to be preserved.

conformity of the biological material preservation and authentication and, when necessary, take measures to avoid negative effects.

6.5.2.2 The biobank shall determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet the biobank's requirements.

6.5.2.3 When the biobank decides to utilize externally provided preservation, storing and/or authentication activities, it shall ensure that:

1. the process and all the inter-related processes are validated according to the provisions of this document;

2. internal audits to these processes are planned and performed, at least, once a year (see also ISO 19011);

3. relevant documented information related to the above mentioned activities is retained.

6.6 Equipment

6.6.1 The biobank shall be furnished or have controlled access to all items of processing, measurement and test equipment required for the correct performance of the biobanking activities provided.

6.6.2 Using a risk-based approach, the biobank should categorize all equipment with respect to its direct or indirect impact on the quality of the biological material ensuring that critical equipment is clearly recognized.

NOTE For example, storage equipment such as freezers and refrigerators have a direct impact on sample quality, while equipment used to monitor and control storage conditions has an indirect impact on sample quality.

6.6.3 A register or a database containing a list of equipment defined under 6.7.1 and 6.7.2 including their categorization, performance, maintenance, verification and, if applicable, validation shall be maintained. Each item of equipment and its software shall, when practicable, be uniquely identified.

6.6.4 The biobank shall verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned.

6.6.5 The critical equipment and its software shall be capable of achieving the accuracy required and shall comply with specifications relevant to the processing or test methods concerned.

6.6.6 The biobank shall establish, document and implement procedures for controlled implementation, safe handling, transport, storage and planned maintenance of all equipment, including procedures for calibration, as necessary.

NOTE Typical procedures to demonstrate that equipment complies with specifications are Installation Qualification (IQ), Operational Qualification (OQ), Performance Qualification (PQ) and Performance Verification (PV).

6.6.7 The biobank shall have instructions on the use and operation of all relevant equipment.

6.6.8 Records for each critical equipment shall be maintained. These records shall include at least the following:

1. the identity of the item of equipment and its software;

2. the manufacturer’s name, type identification, and serial number or other unique identification;

3. checks that equipment complies with specifications;

4. the current location, where appropriate;

5. the manufacturer's instructions, if available, or reference to their location;

6. the dates, results and copies of reports and certificates of calibrations, adjustments, acceptance criteria and the due date of next calibration;

7. the maintenance plan, where appropriate, and maintenance carried out to date;

8. any damage, malfunction, modification or repair to the equipment;

9. the backup equipment, such as freezers for transformation and maintenance of biological material in emergency state.

6.6.9 Critical equipment and its software shall be safeguarded from adjustments, which would invalidate the process output.

6.6.10 To ensure measurement traceability, calibration of equipment, shall be performed according to documented procedures.

6.6.11 Equipment that has been subject to overloading or mishandling, gives suspect results/process output, or has been shown to be defective or outside of specification limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The biobank shall examine the effect of the defect or departure from specified limits on previously processed or tested samples and shall institute the "control of non-conforming work" procedure.

6.7 Principles of access

6.7.1 The principles governing access to and provision of biological resources shall be defined, documented and published. The biobank shall ensure that these principles comply with the contractual requirements established with the stakeholders, including in the event of competing interests.

6.7.2 The biobank shall establish a contractual document that includes the conditions governing the provision and use of biological resources (see also Annex A). Any usage other than that intended is prohibited.

6.7.3 When providing samples to end-users, a document shall be enclosed containing predefined information about the samples, including information on biosafety and biosecurity as appropriate.

6.8 Financial sustainability

6.8.1 The biobank shall have a documented strategy to safeguard its continued financial viability for the expected lifetime of the biological resource's storage and handling activities.

6.8.2 The biobank shall develop a breakdown of the real costs associated with the collection, identification, processing, storage and distribution of biological resources.

7 Process requirements

7.1 Biological material collection

7.1.1 Collection information

Biobanks shall define and document information related to the collection of the biological material. This shall include taxonomic information, time, date, place and procedure of collection, and any other information relevant according Annex A.

7.1.2 Pre-analytical steps

Biobanks shall document pre-analytical steps that can affect the properties of the biological material and provide elements to assess its fitness for purpose. For further details refer to Annex A.

7.1.3 Collection procedure

7.1.3.1 The collection of biological material shall be carefully planned with relevant and qualified personnel and users, if applicable.

7.1.3.2 The collection procedure shall be selected according to the requirements of the biological material and the required quality and quantity for the subsequent purpose.

7.1.3.3 The collection of biological material from human shall be performed by qualified personnel.

7.1.3.4 For biological material requiring clinical assessment or diagnosis, such as tumors or brain tissue, the preparation/dissection of the biological material, evaluation of the pathology and sampling shall be done under supervision or responsibility of a medically qualified (e.g., board certified) person.

7.2 Transport

7.2.1 Transport from and to the biobank (shipment)

7.2.1.1 The biobank shall establish, document and implement a policy and procedures for the shipment and receiving of shipped biological resources (air, sea and land).

7.2.1.2 The organization shall have procedures for safe handling, packaging, transport and reception depending on the classification and type of the biological resources.

NOTE Different packaging, labeling and transport arrangement apply depending on the biological material, whether they are infectious substances, genetically modified organism (GMO) or exempt substances. The requirements of various regulatory bodies are based on the United Nations Recommendations on the Transport of Dangerous Goods Model Regulations which are adopted by International Air Transportation Association (IATA) and many national regulations.

7.2.1.3 Transport conditions, such as temperature and time limit shall be defined to maintain the required biological material properties.

7.2.1.4 Only biobank personnel trained in shipping procedures shall prepare documentation for shipments, pack shipments and arrange shipment of biobank biological resources. Where required, personnel responsible for shipments shall hold relevant authorizations or have documented competence.

7.2.1.5 The biobank shall make arrangements for biological resource reception and distribution with relevant parties prior to the biological resource transfer.

7.2.1.6 The biobank shall maintain chain of custody records for all biological resources/material from point of shipment dispatch to shipment receipt. Each shipping event shall be tracked and monitored for those elements pertinent to biological material integrity, e.g., timeliness, temperature, humidity and light as appropriate to the biological material. The chain of custody records shall detail any deviations from specified parameters.

NOTE Typical elements tracked in the chain of custody are:

1. shipment/invoice ID;
2. custom invoice, if applicable;
3. source/sender;
4. destination (including name of person indicated as recipient);
5. date shipped and date received;
6. courier name;
7. package tracking record;
8. unique identifier for the biological material;
9. type(s) and description for the biological material;
10. quantity of biological material sent and received;
11. study name and number or requested reference, if applicable;
12. name(s) of key investigator(s) or responsible person;
13. confirmation of consignee receiving the biological resource/s;
14. shipping conditions (e.g., dry ice, room temperature);
15. name/signature of individual receiving the shipment;
16. biosafety and biosecurity specification regarding the biological material and/or the preservatives including disposal measures and measures to take in case of spillage;
17. any discrepancy between the shipping manifest and the actual shipment and any indication that biological material has been compromised.

7.2.2 Transport within the biobank

7.2.2.1 The biobank shall establish, document and implement procedures to regulate any internal biobank transfer of biological resources or of disposal material. Chain of custody records for all biological resources from point of dispatch to receipt of such transfers shall be maintained.

NOTE Specific attention should be given that biological material is not left unattended.

7.2.2.2 Each transfer shall be performed under conditions ensuring biological material integrity, e.g., timeliness, temperature, humidity, mechanical forces and light as appropriate to the biological material (see also Annex A). Any deviations from specified parameters shall be treated as non-conforming according to 7.9.

7.2.2.3 Chain of custody records for internal transfers may include all or part of the elements enumerated in section 7.2.1.7 as applicable.

7.3 Reception and distribution of biological resources

7.3.1 Reception of biological resources (accession/logging procedure)

7.3.1.1 The biobank shall establish, document and implement procedures for each biological resource reception process (e.g., produced within the biobank, purchased, or deposited).

7.3.1.2 When bringing a biological resource in the biobank, the biological resource shall be segregated to prevent final storage until ethical and legal compliance of the biological resource is cleared.

7.3.1.3 The records associated with each biological resource shall allow the receiving biobank to be confident that all biological resource related processes which occurred prior to the reception were conducted to comply with relevant legal and ethical requirements.

7.3.1.4 The recipient biobank shall obtain information about the biological resource, including biosafety, intellectual property and patent information.

7.3.1.5 Where possible, the identity and characteristics of biological material should be confirmed after receipt by a competent person (employed or contracted by the biobank or its parental organization).

7.3.2 Distribution of biological resources

7.3.2.1 The distribution and any exchange of biological resources shall take place in accordance with the biobank's access principles (6.8) and in compliance with regulatory requirements.

7.3.2.2 The biobank shall establish, document and implement processes for the preparation and distribution of biological resources ensuring that only agreed biological resources are distributed, fulfilling the conditions of the contractual document concluded with the recipient.

7.4 Traceability of biological resources

7.4.1 The biobank shall ensure that there is traceability of each biological resource from collection to long-term storage, processing, distribution, and/or destruction. That means that:

1. Biological resources shall be labeled appropriately so that identification is maintained throughout its life cycle under the custody of the biobank. Special attention shall be focused on persistent labelling of biological material through the use of unique identifiers. The biobank shall have a labeling SOP that is also compliant with regulatory and environmental requirements, and different storage modalities.
2. Each biological resource shall be associated with a consent procedure (when applicable) that records the detail of permissions or restrictions associated with its use.
3. The acquisition of each biological resource shall be associated with the relevant version of collection, processing, long-term storage, and distribution SOPs.
4. An inventory or tracking system shall allow for the annotation and query of relevant information associated with any handling SOP, including collection, packaging, transportation, processing, storing, and distribution procedures. This system should allow the flagging of any deviation in biobanking protocol(s).
5. A logical link between biological material and associated data shall be established and maintained, which guarantees unambiguous traceability of the information.

6. It shall be possible to identify the location of any biological resource at all times, as well as identifying those that have been distributed to end-users or disposed of.

7.4.2 The information should be easily accessible to allow querying the data as needed, e.g., upon receiving complaints or inquiries about distributed biological material.

7.5 Processing of biological resources

7.5.1 The biobank shall ensure that the life cycle of each biological resource in the biobank is identified and properly defined to ensure biological resource fit for purpose and not affecting negatively preanalytical values. A graphical workflow scheme shall describe the chain of custody of the biological resource within the biobank, followed by detailed SOPs for each process (e.g., identification, preservation, long-term storage, quality control, transport, discarding). All SOPs shall be specific for the biological resource.

7.5.2 Biobanks in partnership with, e.g., clinical and surgical departments shall establish a processing protocol (e.g., SOP) for each biological resource upon receipt.

7.5.3 All instructions and processes shall be kept up to date and shall be made readily available to personnel.

7.5.4 All processes shall be conducted in compliance with the relevant SOP and each processing step shall be individually documented.

7.5.5 The date and time of the each processing step shall be documented for all biological resources in a clear format in the study specific documentation or data management system (e.g., LIMS).

7.6 Preservation and long-term storage of biological material

7.6.1 Key parameters of the preservation procedure shall be recorded and monitored. Each preservation step shall be individually documented.

7.6.2 The date and time of each preservation step shall be documented for all biological material.

7.6.3 The method(s) of preservation shall be defined according state-of-the-art or according to documented methods. The preservation technique(s) used shall be able to withstand the storing conditions.

7.6.4 The biological material shall be preserved using environmental parameters to stabilize its properties and to avoid exogenous contaminants.

7.6.5 Alternative safeguarding should be planned as 'disaster' protection measure and to avoid accidental loss of biological material (e.g., duplicated stocks of relevant biological material maintained in separate locations).

7.6.6 Traceability shall be maintained during long-term storage. The biobank shall have documented SOPs in place for the long-term storage of biological material including at least:

a) the type of container and infrastructure for the biological material long-term storage;

b) the labelling information containing at least the identification of the biological material.

7.6.7 The date and time of the beginning of the long-term storage and personnel accessing it shall be documented for each biological material in a clear format in the study specific documentation or data management system (e.g., LIMS).

7.6.8 Containers and labels used for long term storage shall be validated for the relevant temperature and duration.

7.6.9 The biobank shall document and verify the long-term storage location of all biological. Traceability of each biological material and each storage transaction shall be assured consistently.

7.6.10 Long-term storage areas and processes shall be designed to minimize contact any contamination, and to ensure maintenance of maximized biological material integrity permitting repeated or equivalent examination. Such controls are extended to areas of packaging and transport.

7.6.11 The storage conditions shall be continuously monitored according to 6.4.

7.6.12 The biobank should verify the biological material inventory on an annual basis.

7.6.13 The biobank shall establish, document and implement SOPs related to the withdrawn consent to biobank storage and research and on how the biological materials shall be removed from the biobank or destructed; including processes to verify that the SOP was followed and mechanisms for annotating that a discontinuation event occurred.

7.7 Quality control of biological material and data

7.7.1 General

7.7.1.1 The biobank shall identify the critical processing steps having an impact on the quality of the biological resources, and establish, document and implement quality control (QC) procedures applying at least to these critical steps.

7.7.1.2 The biobank shall provide biological resources fit for the intended purpose. The biobank shall define a minimum set of QC tests to be performed on the biological resource.

7.7.1.3 These QC tests shall be defined according to the state of the science and regularly updated and ensure that user requirements are met where relevant. Exceptions can be justified for rare or legacy biological resources and QC procedures which lead to biological material elimination. The QC of biological resources shall be reviewed and approved by the biobank.

7.7.1.4 The biobank can also perform complementary tests upon request. The biobank shall have a procedure to prevent the release of biological resources in the event of non-conforming QC results.

7.7.2 Process-related quality control

7.7.2.1 The biobank shall establish, document and implement procedures specifying QC activities, including QC criteria according to pre-defined specifications, which ensure the fitness for the intended purpose of the biological resources throughout the biobanking processes.

7.7.2.2 The QC activities shall be performed according to planned intervals. Results of QC activities shall be documented and records shall be kept.

7.7.2.3 QC data shall be analyzed and where found to be outside pre-defined criteria, planned actions shall be taken to correct the problem, and to prevent incorrect data to be reported and/or non-compliant biological resources to be distributed. The organization shall ensure that identified limitations are clearly documented and communicated to the user. During the biological resource's distribution process, it is the user’s responsibility to decide on the acceptance of receiving biological resources with documented and communicated limitations.

7.7.2.4 The biobank shall ensure that information of QC results is provided to the user as specified by contractual requirements.

7.7.2.5 QC results shall be periodically analyzed for trends and used as input for the continuous improvement process.

7.7.2.6 Depending on the scope of provided services, the biobank's QC procedures shall refer to Annex A.

7.7.2.7 The biobank shall document all process related data (see Annex A).

7.7.2.8 As part of the QC system, the biobank should have appropriate QC materials. QC materials shall be periodically examined in order to assess important quality characteristics of the biological material, including the biological material stability, the performance of the biological material preparation method and the accuracy/precision of the QC testing method.

7.7.2.9 To allow comparability, the biobank shall participate in an external quality assessment (EQA) program or proficiency testing program appropriate to the scope of its processing and testing methods performed on biological materials and their intended use, when such programs are available. Whenever such inter-laboratory testing program is not available, the biobank shall develop other approaches and provide objective evidence for determining the acceptability of biological material quality (the processing or testing output). The biobank should integrate inter-laboratory testing samples into the routine workflow in a manner that follows, as much as possible, the processing or testing of biological material.

7.7.2.10 The biobank shall not communicate with other participants in the inter-laboratory comparison program(s) about biological material data until after they have submitted the data.

7.7.2.11 The biobank shall monitor the results of the inter-laboratory comparison program(s) and perform and document corrective actions when pre-determined performance criteria are not fulfilled.

7.7.2.12 Whenever possible, the biobank shall utilize appropriate materials for the external quality assessment (EQA) program. Examples of such materials are:

1. certified reference materials;

2. samples previously examined;

3. samples previously shared with other biobanks;

4. control materials that are tested regularly in EQA programs.

7.7.3 Data specific quality control

7.7.3.1 The biobank shall identify the critical data (see Annex A) having an impact on the quality of the biological resource/s, and establish, document and implement QC procedures applying at least to these critical data.

7.7.3.2 The biobank shall ensure that requirements for biological material associated data are defined.

7.7.3.3 The biobank shall make every effort to support interoperability of associated data.

7.7.3.4 QC shall focus on accuracy, completeness and consistency of data. QC shall be performed at random, on a regular basis.

7.7.3.5 For more detailed information and requirements see Annex A.

7.8 Validation and verification of methods

7.8.1 General

7.8.1.1 The biobank shall use appropriate validated and/or verified methods, procedures and instructions according to 7.8.2 and 7.8.3 at all stages of the biological material life cycle (e.g., for equipment, collection, accession, identification, preservation, transport, long-term storage, discarding and quality control) to ensure that the biological material consistently meet the requirements within its scope.

NOTE Appropriate methods can have external sources (e.g., published in International Standards or guidelines, or by reputable technical organizations, or national or regional regulations or in relevant scientific texts or peer-reviewed journals, or as specified by the manufacturer of the equipment) and can be developed or adopted by the biobank.

7.8.1.2 All methods, procedures and instructions shall be implemented through an appropriate design, analysis and control process. This process shall be appropriately documented to meet the needs of the biological material, the intended use of the biological material and the given application or field of application of the biobank. All records shall be maintained.

7.8.2 Validation

7.8.2.1 The biobank shall validate all non-standard and modified standard methods as well as biobank-designed/developed methods in order to fulfil the requirements for a specific intended use. The biobank shall record the results obtained, the procedure used for the validation, and a statement as to whether the method, procedure or instruction is fit for the intended use.

7.8.2.2 Validation should be performed according to ISO 21899.

7.8.3 Verification

7.8.3.1 The biobank shall verify all standard methods, procedures and instructions in accordance with specified requirements. All verification related records shall be maintained for a defined period of time.

7.8.3.2 Verification should be performed according to ISO 21899.

7.9 Information technology and data management

7.9.1 A computer-based system shall be in place to track the location and the data for biological materials in the biobank and shall meet the data needs and specific requirements of the biobank. Each computer-based system shall have the ability to integrate with other electronic systems and local applications to permit linkage of datasets and to control access.

7.9.2 Associated data shall be defined by those responsible for the curation of the biobank's biological resources.

7.9.3 Allowance for future capacity to address further data of biological material shall be addressed.

7.9.4 An SOP for implementation, modification and use of computer system software, hardware, and database shall be in place. The SOP shall at least include data integrity, security controls and back-up system to prevent loss or corruption of data. 7

7.9.5 The biobank shall have access to the data and information needed to provide a service that meets the needs and requirements of the user.

7.9.6 The biobank shall provide the stakeholders with access to a catalogue of available biological resources.

7.9.7 The biobank shall store data associated with the biological material for at least the lifetime of the biological material.

7.10 Non-conforming biological resources, work and information

7.10.1 General

7.10.1.1 The biobank shall establish, document and implement a policy with respect to non-conforming biological resources as well as those collected prior to the first adoption of this document.

7.10.1.2 The biobank shall establish, document and implement policies and procedures to deal with situations in which processing activities do not conform with established standard operating procedures or the requirements agreed with the user.

7.10.2 Biological resources in legacy biological resource collections (LBRCs)

7.10.2.1 The biobank shall identify biological resources collected prior to the first adoption of this document.

7.10.2.2 The biobank shall document the legal, ethical and quality related information of biological resources in LBRCs. Biological resources from LBRCs not satisfying the defined quality criteria of the biobank shall be reprocessed (if indicated) and marked accordingly. Non-compliance shall be analyzed and documented and the impact on the further utilization of the biological resources shall be communicated to the relevant parties, including any future unavailability or destruction of the biological material.

7.10.2.3 When bringing biological resources in from external collections, the biological resources shall be held in quarantine until its quality and documentation status has been assessed. The recipient biobank shall obtain copies of all available records associated with the adopted biological resources, including copies of the protocols and operating procedures used by the external collector. The records associated with such adopted biological resources shall allow a recipient to be confident that the biological material has been collected legally and ethically for the intended use. The biobank shall undertake appropriate quality control measures to evaluate representative biological resources from the adopted collection prior to release from quarantine.

7.10.2.4 Reasonable efforts shall be made by the biobank to prevent the users from a breach of current laws and relevant ethical guidelines.

7.10.3 Control of non-conforming work, biological material and data

7.10.3.1 The biobank shall establish a non-conformance procedure to identify, report, document and analyze non-conformities in the processing activities, biological resources, data and services and to take measurements for implementation of corrective and preventive actions. Remedial actions shall be taken within defined limits (see also 8.7).

7.10.3.2 The biobank shall determine responsibilities and mitigate the impacts of non-conformance and prevent their reoccurrence in proportion to the risks presented by the respective non-conforming work, biological resource or data. The biobank shall keep all records and review the effectiveness of corrective actions taken (see also 8.7).

7.10.3.3 The biobank shall communicate the non-conformance to relevant parties in the following cases:

1. the nonconformity cannot be remedied for technical reasons;

2. the non-conforming biological materials, work and information will be continued because the remedy of the nonconformity cannot be considered as economically reasonable.

7.10.3.4 The decision on recall of biological material and data shall be taken in a timely manner to limit the use of non-conforming materials and data by users.

7.11 Complaints

7.11.1 The biobank shall have a documented process to receive, evaluate and make decisions on complaints.

7.11.2 A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the biobank shall confirm whether the complaint relates to biobanking activities that it is responsible for and, if so, shall deal with it. The biobank shall be responsible for all levels of the handling process for complaints.

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

1. description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;

2. tracking and recording complaints, including actions undertaken to resolve them;

3. ensuring that any appropriate action is taken.

7.11.4 The biobank receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.

7.11.5 Whenever possible, the biobank shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.

7.11.6 The outcome to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original biobanking activities in question.

7.11.7 Whenever possible, the biobank shall give formal notice of the end of the complaint handling to the complainant.

7.12 Disposal and transfer of biological material

The biobank shall establish, document and implement policies and SOPs for the disposal and transfer of biological material and/or data, both as a planned event and as an emergency. The plan for such actions as well as implemented policies and SOPs shall be regularly evaluated and updated.

8 Management requirements

8.1 Options

8.1.1 General

The biobank shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this International

Standard and assuring the quality of biobanking. In addition to meeting the requirements of clauses 4 to 7 of this document, the biobank shall implement a management system in accordance with option A or option B.

8.1.2 Option A

As a minimum the management system of the biobank shall address the following:

1. management system documentation (see 8.2);
2. control of management system documents (see 8.3);
3. control of records (see 8.4);
4. actions to address risks and opportunities (see 8.5)
5. improvement (see 8.6);
6. corrective action (see 8.7);
7. internal audits (see 8.8);
8. management review (see 8.9).

8.1.3 Option B

A biobank that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfillment of the requirements of clauses 4 to 7 of this International Standard also fulfills at least the intent of the management system section requirements (8.2 - 8.9).

8.2 Management system documentation (Option A)

8.2.1 The biobank management shall establish, document, and maintain policies and objectives for the fulfillment of the purpose of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the biobank.

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the biobank.

8.2.3 The biobank management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

8.2.4 All documentation, processes, systems, records, etc. related to the fulfillment of the requirements of this document shall be included, referenced, or linked to the management system.

8.2.5 All personnel involved in biobanking activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Control of management system documents (Option A)

8.3.1 The biobank shall control the documents (internal or external) that relate to the fulfillment of this document.

NOTE In this context “document” could be policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, whether hard copy or digital.

8.3.2 The biobank shall ensure that:

1. documents are approved for adequacy prior to issue by authorized personnel;

2. documents are periodically reviewed and updated as necessary;

3. changes and the current revision status of documents are identified;

4. relevant versions of applicable documents are available at points of use and where necessary their distribution is controlled;

5. documents are uniquely identified and;

6. the unintended use of obsolete documents is prevented, and suitable identification applied to them, if they are retained for any purpose.

8.4 Control of records (Option A)

8.4.1 The biobank shall establish and maintain legible records to demonstrate fulfillment of the requirements in this document.

8.4.2 The biobank shall implement the controls needed for the identification, long-term storage, protection, back-up, archive, retrieval, retention time, and disposal of its records. The biobank shall retain records for a period consistent with its contractual and legal obligations. Access to these records shall be consistent with the confidentiality arrangements and records shall be readily available.

8.5 Actions to address risks and opportunities (Option A)

8.5.1 The biobank shall consider the risks and opportunities associated with the biobanking activities in order to:

1. give assurance that the management system can achieve its intended results;

2. enhance opportunities to achieve the purpose and objectives of the biobank;

3. prevent, or reduce, undesired impacts and potential failures in the biobanking activities; and

4. achieve improvement.

8.5.2 The biobank shall plan:

1. actions to address these risks and opportunities;

2. how to:
   a) integrate and implement the actions into its management system;

   b) evaluate the effectiveness of these actions.

8.5.3 Actions taken to address risks and opportunities shall be proportionate to the potential impact on and the validity of biobanking.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the biobanking activities, addressing new users, using new technology and other possibilities to address user needs.

8.6 Improvement (Option A)

8.6.1 The biobank shall identify and select opportunities for improvement and implement any necessary actions.

NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, risk assessment, analysis of data, and proficiency-testing results.

8.6.2 The biobank shall seek feedback, both positive and negative, from its users. The feedback shall be analyzed and used to improve the management system, biobanking activities and user service.

NOTE Examples of the types of feedback include user satisfaction surveys and review of reports with users.

8.7 Corrective action (Option A)

8.7.1 When a nonconformity occurs, the biobank shall:

1. react to the nonconformity and, as applicable:
    a) take action to control and correct it;
    b) deal with the consequences;
2. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
    a) reviewing and analysing the nonconformity;
    b) determining the causes of the nonconformity;
    c) determining if similar nonconformities exist, or could potentially occur;
    d) implement any action needed;
    e) review the effectiveness of any corrective action taken;
    f) update risks and opportunities determined during planning, if necessary;
    g) make changes to the management system, if necessary.

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The biobank shall retain records as evidence of:

1. the nature of the nonconformities, cause(s) and any subsequent actions taken;
2. the results of any corrective action.

8.8 Internal audits (Option A)

8.8.1 The biobank shall conduct internal audits at planned intervals to provide information on whether the management system:

1. conforms to:

   — the biobank's own requirements for its management system, including biobanking activities;

   — the requirements of this document;

2. is effectively implemented and maintained.

8.8.2 The biobank shall:

1. plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the biobanking activities concerned, changes affecting the biobank, and the results of previous audits;

2. define the audit criteria and scope for each audit;

3. ensure that the results of the audits are reported to relevant management;

4. implement appropriate correction and corrective actions without undue delay;

5. retain records as evidence of the implementation of the audit programme and the audit results.

NOTE ISO 19011 provides guidance for internal audits.

8.9 Management reviews (Option A)

8.9.1 The biobank management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfillment of this document.

8.9.2 The inputs to management review shall be documented and shall include information related to the following:

1. changes in internal and external issues that are relevant to the biobank;

2. fulfillment of objectives;

3. suitability of policies and procedures;

4. status of actions from previous management reviews;

5. outcome of recent internal audits;

6. corrective actions;

7. assessments by external bodies;

8. changes in the volume and type of the work or in the range of biobanking activities;

9. user feedback;
10. complaints;
11. effectiveness of any implemented improvements;
12. the adequacy of resources;
13. results of risk identification;
14. outcomes of the quality control;
15. other relevant factors, such as monitoring activities and training.

8.9.3 The outputs from the management review shall record decisions and actions related to:

1. the effectiveness of the management system and its processes;
2. improvement of the biobanking activities related to the fulfillment of the requirements of this document;
3. provision of required resources;
4. any need for changes.

Annex A
(normative)

Quality control

A.1 Quality control procedures

A.1.1 The following scheme defines the critical processing steps and data having an impact on the quality of the biological resources. These shall be part of the documentation of the biological resources in the biobank and of the quality control procedures as applicable according to the biological resources (see 6.8, 7.1.1, 7.7.1, 7.7.2 and 7.7.3):

⇨ Insert Excel table after finalization

A.2 Quality control of data

A.2.1 The creation of a bibliography (or dictionary) of all annotated data variables recorded shall be part of the quality control system of the biobank and will enable users to determine fitness for purpose.

A.2.2 The Biobank shall ensure that data comply with the following requirements:

⇨ Insert requirements after finalization

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