NABL 229

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Specific Criteria for Accreditation of Biobank

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AMENDMENT SHEET

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i. Introduction

A biobank is a legal entity or part of a legal entity that performs bio-banking activity competently to provide confidence in the reliability of biological materials and their associated data. Biobank is integral to many different scientific disciplines and refers to all the processes from collection and/or acquisition to storing biological materials as well as associated data.

Note: Multiple names can be used for biobanks like biorepositories, repositories.

Biobank may hold millions of biological materials from multicellular organisms (e.g., humans, animals, fungi and plants) or microbes. The purpose of these are mainly to help the scientific community to develop everything from crop production to personalized medicine. Biobanks vary widely in terms of the kind of biological material they hold, the activities they undertake, the services they provide and their location, size, and structure.

Accreditation of biobank enables consistency and reliability of biological materials for use in research and other applications. Whether a biobank is serving an internal need at a specific organization or providing resources to outside parties, it is crucial to uphold the expectation of quality in both banked materials and biobank practices.

NABL accreditation program for biobank is designed to improve the quality of biobank through assuring compliance with the requirements of international standard ISO 20387: 2018.

ISO 20387: 2018 does not apply to biological material intended for food/feed production, laboratories undertaking analysis of food/feed, and/or therapeutic use. Such biobank shall not apply for NABL accreditation of biobank.

1. Scope

The specific criteria describes specific requirements for the accreditation of Biobank in accordance with ISO 20387: 2018

The biobank activities to be covered under scope of accreditation shall include a minimum of three activities for defined biological material as well as associated data. The activities of biobank that shall be covered under scope of accreditation are acquisition (required), storage (required) and one or more among the following:

a) Collection
b) Preparation
c) Preservation
d) Testing
e) Analysis
f) Distribution

A laboratory accredited by NABL in accordance with ISO 15189 or ISO/IEC 17025 may also be a biobank and can apply for accreditation of biobank as per ISO 20387.

Biobank that additionally undertakes testing and analysis of stored biospecimen for research and development purposes can obtain NABL accreditation as per ISO 15189 or ISO/IEC 17025.

Where a biobank is not accredited as per ISO 20387, but is accredited to ISO/IEC 17025 or ISO 15189 for testing activities that support biobanking, then these activities alone are not equivalent to all of the processes involved in biobanking.

2. Normative reference

ISO 20387: 2018 “Biotechnology – Biobanking – General requirements for biobanking”

3. Terms and definitions

a) Accessioning/ logging

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

b) Acquisition

Act of obtaining possession and/or custody of biological material and/or associated data.

c) Associated data

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

d) Biobank

Legal entity or part of a legal entity that performs biobanking.

e) Biobanking

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

f) 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).

g) Biosafety

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

h) Biosecurity

Institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional/unintentional release of pathogens,

genetically modified organisms, toxin-producing organisms, or parts thereof, as well as such toxins that are held, transferred and/or supplied by the biobank.

i) Chain of custody

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

j) Dedicated area

Space containing the biological material kept by the biobank or where the biobank activities take place.

k) Distribution

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

l) Impartiality

Presence of objectivity.

m) Processing

Performing any activity on biological material and associated data during all stages of the biobanking life cycle.

n) Traceability

Ability to trace the history, application or location of an object.

o) Validation

Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

4. General Requirements (Cl. 4 of ISO 20387: 2018)

a) Biobank shall conduct risk assessment to identify risk associated with the biobanking activities & opportunities for improvement. The biobank shall identify risks to its impartiality on an on-going basis. The action shall be taken to mitigate or minimize the risks.

b) The biobank shall identify and describe the scope of biobank activities for which it wishes to obtain NABL accreditation in accordance with ISO 20387.

c) Biobank shall follow national, regional, local laws and regulations, as applicable.

d) The biobank shall comply with relevant regional, national, and international ethical principles for biological material and associated data.

5. Structural Requirements (Cl. 5 of ISO 20387: 2018)

a) Biobank shall submit the copy of any of the following documents in support of the legal entity status claimed:

Type of Legal Identity	Document(s) to be submitted
One Person Company	Registration certificate under The Companies Act, 2013
Limited Liability Partnership	Registration certificate under The Limited Liability Partnership Act, 2008
Company	Registration certificate under The Companies Act, 1956 or 2013
Societies/ Trust	Registration certificate under Societies Registration Act, 1860 / Registration under The Indian Trusts Act, 1882
Government	Gazette or Government Notification or self-Declaration on Letter head by the Head of the organization

b) The biobank shall have a course of action to define and address liabilities arising from its activities (one or more but not limited to the following eg. Sample security/protection, data, patient privacy, confidentiality etc.)

6. Resource requirements (Cl. 6 of ISO 20387: 2018)

a) General (Cl. 6.1 of ISO 20387: 2018)

i. A biobank shall document a strategy to address continued financial viability at least for 3 years. This can be through some of the following, but not limited to:
- a strategic plan;
- a business plan;
- an agreement between the biobank and its funders;
- a compendium of relevant needs; like the approval of Institutional Ethics committee and/or, Institutional Biosafety Committee (IBSC). (Ref: Review Committee on Genetic Manipulation (RCGM) document).
- a sustainability plan;
- extramural grant collaboration with clinical research organizations;
- budgets or financial plans;
- audited accounts and/or letters confirming solvency or other financial guarantees from a professional accountant.

ii. Biobank shall define the frequency to review this strategy.

b) Personnel (Cl. 6.2 of ISO 20387: 2018)

i. The biobank shall have staff with the appropriate competence including requirements of educational qualification, training, experience, knowledge and demonstrated skills for each function.

ii. Records of competence assessment as per biobank matrix to be maintained.

iii. All personnel of biobank having access to confidential data of the biobank shall be bound by agreement to maintain confidentiality. The biobank shall retain evidence of the same (eg. confidentiality agreement or non-disclosure agreement).

c) Facilities/dedicated areas and environmental conditions (Cl. 6.3 of ISO 20387: 2018)

i. The biobank facilities and environmental conditions shall include, but not limited to, structural and organizational components, such as buildings, utilities and workspaces used for biobank operations, equipment, required redundancies (e.g., back-up storage units, alternative energy supplies, etc.).

The above shall be assessed by NABL by taking the following into consideration during the assessment of the biobank:
- quality of the biological material and its associated data.
- health and safety of the personnel;
- facility management;
- information/data security;
- fire safety;
- chemical safety;
- biosafety/biosecurity *
- physical safety;
- environmental monitoring;
- risk analysis;

**For biosafety and biosecurity: The biobank shall have a procedure and records for disposal of sample as per current Biomedical Waste Management Guidelines and IBSC approval (Institutional Biosafety Committee).*

ii. The biobank shall have separation of incompatible activities, eg.:
- performing such activities in separate rooms or dedicated areas; (eg.: accession and processing area have to be physically separated.
- performing such activities at different time points with adequate preparation (e.g., cleaning, calibration, etc.);
- defining pathways that avoid crossing of incompatible biological material
- establishing a biosafety policy to indicate infectious risks, appropriate decontamination, sterility, and confinement regimes, etc.
- The autoclaves for sterile articles and decontamination placed separately with provision of exhaust.

The biobank shall ensure that tests and activities performed in sections that are not under accreditation, do not adversely influence the other activities or vice versa.

iii. Environmental condition:
- Biobank shall maintain ambient room temperature and relative humidity as per the requirement of the biobanking activity and biobank policy.
- Biobank shall take necessary steps to maintain a stable environment, minimizing the risk of fluctuations & humidity that can affect sample quality.
- Biobank shall Implement continuous monitoring systems with alarms to detect any deviations from the set ranges of temperature & humidity.
- Access to the storage area shall be restricted to reduce the risk of environmental changes due to frequent opening of doors.
- The record shall be maintained through data logging for temperature and humidity to track and manage the storage conditions over time.
- Biobank shall monitor the oxygen level by use of oxygen level monitor in liquid nitrogen handling areas where there is storage and constant supply of liquid nitrogen. For maintaining a safe environment, protecting personnel from asphyxiation risks, and ensuring compliance with safety standards, Oxygen monitor shall be installed at reasonable height.
- Openable glass panes or alternate equivalent arrangements to be installed in liquid nitrogen storage area.

iv. The biobank shall have adequate space for efficient functioning and conditions to avoid cross contamination between processes.

v. Biobank shall ensure that long-term adverse effects to staff are avoided by checking noise, chemical levels and ensuring ergonomics and avoiding physical injuries.

vi. The sections of the biobank processes which involves handling of hazardous chemicals like formalin, acid/alcohol should have exhaust systems capable of removing fumes from the work areas without compromising the environmental requirements. It is desirable to have a fume hood with exhaust for this purpose.

vii. The Biobank shall have adequate lighting, power supply arrangements and an uninterrupted power supply to ensure there is no compromise on biobank activity and

stored data. Extension boards without a fuse shall not be used for connecting equipment. Biobank shall verify electrical safety of all points in use once in six months.

viii. All computers, peripherals, equipment and communication devices shall be supported in such a way that service is not likely to be interrupted.

ix. The biobank shall have procedures in place to ensure the integrity of refrigerated and frozen samples / reagents / consumables in the event of a power failure.

x. Biobank using carbon-dioxide (CO_2) cylinders should ensure that the cylinders are properly secured and do not pose any safety hazard.

d) Equipment (Cl. 6.5 of ISO 20387: 2018)

i. Calibration: Policy on calibration and traceability of measurements shall be as per NABL 142. The equipment shall be calibrated from NPL, India or a calibration laboratory accredited by NABL, accredited for the specified scope. The maximum periods between successive calibrations of general equipment are illustrated in Table 1 below.

Calibration requirements

Table 1

Item	Recommended maximum period between successive calibration by NABL accredited laboratory	Remark
Autoclave	One year	Calibration of pressure gauge and temperature by thermal mapping. If an automated timer is present, it also shall be calibrated.
Balances and scales	One year	Balances with in-built calibration facility must be verified using calibrated weights once a day before use.
Biological safety cabinet	One year	Verification of differential pressure, particle count, air flow velocities and HEPA filter integrity.
Laminar flow	One year	Verification of differential pressure, particle count, air flow velocities and HEPA filter integrity.
Centrifuge	One year	Speed and timer to be calibrated. For refrigerated centrifuges, temperature measuring device to be calibrated.
Mass	Two years and can be extended up to three years if the mass is E1 Class (stainless steel)	OIML R111 Calibrated weight shall be kept in proper storage condition to avoid abnormal drift.
Pipettes and dispensers	One year	Variable volume pipettes shall be calibrated across the full range and at volumes that are most frequently used. For performance acceptability after calibration, refer to ISO 8655 for guidance.
Thermometers	One year	Calibration to include points of use
pH meter (Digital)	Once a year/as recommended by the manufacturer.	Verified each time before use with two standard buffer solutions appropriate to the expected pH of the sample being tested.

ii. All equipment including thermometers, pipettes and centrifuges must be calibrated by an NABL accredited laboratory before being put into service for the first time. A manufacturer's calibration certificate is not valid unless it contains an accepted procedure and traceability of measurement to SI unit (as per NABL 142). It must be stressed that these calibration intervals depend upon ruggedness of the equipment, frequency of use, quality & periodicity of maintenance. Laboratory may seek a compliance report for the equipment from the accredited calibration laboratory.

iii. All equipment must be calibrated following preventive maintenance, breakdown and repairs or more frequently as recommended by the manufacturers. At the time of installation of new equipment, the Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) shall be performed and documented.

iv. Periodic calibration shall be carried out to ensure the satisfactory performance of the equipment.

7. Process requirements (Cl. 7 of ISO 20387: 2018)

a) General (Cl. 7.1 of ISO 20387: 2018)

i. The biobank shall determine the critical activities and relevant parameters during the life cycle of each type of biological material that it handles.

ii. The biobank shall document the date & time of the critical life cycle for all type of biological materials that it handles.

iii. The biobank shall document the standard format of date & time, preferably dd-mm-yyyy & hh:mm:ss format for date & time respectively.

b) Collection of biological material and associated data (Cl. 7.2 of ISO 20387: 2018)

i. Ethical requirements shall specifically apply to biobanking of human biological material and associated data. Other relevant requirements can apply to the associated data, such as those related to privacy, confidentiality, and data protection as well as specific data, such as medical records, and 'genetic & genomic' data. All applicable international, national and local regulations shall be followed by the biobank.

ii. The biobank shall ensure the above through:

- ethics committee review(s) and approval(s);
- either informed consent from the patient/donor/legal representative, or a waiver of informed consent in certain circumstances defined in a biobank.
- policy for such waivers shall be defined by biobank and records of such waivers shall be maintained.

c) Reception and distribution of biological material and associated data (Cl. 7.3 of ISO 20387: 2018)

i. Agreements or legally binding documents shall be available between the dispatcher and recipient, which includes chain of custody during transport. The biobank shall ensure the availability of approvals from biosafety committee.

ii. The chain of custody during transport shall include transport within the biobank, shipping between the biobank and recipients, and receipt of biological material at the receiving biobank and shall include processes employed by relevant parties, including shippers.

iii. The information related to transport-related events and conditions as well as critical chain of custody records including deviations from previously defined parameters, shall be made available.

d) Transport of biological material and associated data (Cl. 7.4 of ISO 20387: 2018)

i. The biobank shall have procedure for receiving, accessioning, coding and archival of varied biospecimen at the temperature suitable for their long term storage.

ii. The biobank shall have procedure for shipment and receiving of biological material including appropriate conditions for the continued maintenance of integrity of biological material.

iii. 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.

e) Traceability of biological material and associated data (Cl. 7.5 of ISO 20387: 2018)

i. The biobank shall have procedure for receiving, accessioning, coding, and archiving various biospecimens at the temperatures suitable to ensure their long-term storage. It includes maintaining quality improvement records, sample storage records, sample access forms, and records related to sample destruction or disposal.

ii. The procedures shall address the disposal and transfer of biological material and/or data, both as a planned event and in response to emergencies.

iii. Any deviation in the procedure shall be identified, recorded and corrective action shall be taken.

f) Storage of biological material (Cl. 7.7 of ISO 20387: 2018)

The biobank shall have contingency plan in case of emergency / unforeseen challenges in maintaining the defined storage condition.

g) Quality Control of biological material and associate data (Cl. 7.8 of ISO 20387: 2018)

i. A biobank shall define, apply, and assess quality control (QC) indicators related to any internal processes and externally-provided processes.

ii. QC for each stage of the life cycle of the biological material and associated data shall be demonstrated through the following means:

- specifications for the biological material and associated data based on the intended use;
- QC protocols;
- assessment of QC indicators;
- maintain the traceability chain.
- Traceability of legacy biological material is acceptable through Material Transfer Agreements (MTA).

h) Validation (Cl. 7.9 of ISO 20387: 2018)

i. Validation can be through various means, including tests, peer-reviewed research, simulations, etc. to provide the required evidence for the achievement of the fitness for the intended purpose.

ii. The documented evidence of validation (example specification for assay parameters such as identity, yield, purity, amplification, accuracy, reproducibility, etc.) shall be retained.

i) Management of information and data (Cl. 7.10 of ISO 20387: 2018)

i. The biobank shall have MoU, Material Transfer Agreements (MTA) and Data Transfer Agreement (DTA) with their relevant stakeholders in case of legacy sample, as applicable.

ii. The biobank shall retain access to the appropriate data associated with the biological material, as per biobank policy.

8. Quality management system requirements (Cl. 8 of ISO 20387: 2018)

a) Internal audit (Cl. 8.8 of ISO 20387: 2018)

i. Person conducting the internal audit of the biobank shall be trained for the requirements of ISO 20387.
ii. If biobanking activities include testing and/or analyzing, internal auditors of the biobank should be familiar with the relevant requirements of ISO 15189 and/or ISO/IEC 17025, as applicable.
iii. The biobank shall perform internal audits at least once a year covering all the activities.
iv. When internal audits are conducted with other relevant management system standards (such as ISO/IEC 17025 or ISO 15189), the biobank shall ensure that all requirements relevant to the biobanking are audited and relevant evidence is maintained by the biobank.

b) Quality management review (Cl. 8.9 of ISO 20387: 2018)

i. The biobank shall conduct a quality management review at least once a year, by covering all the agenda points defined in ISO 20387.
ii. The record of quality management review & action taken shall be retained.

c) Biobank shall keep and maintain ISO 20387 latest version and make it accessible to all the relevant personnel of biobank for a ready reference.

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