1. INTRODUCTION

In 2018, the International Organization for Standardization (ISO) published the standard titled **"ISO 20387:2018 Biotechnology – Biobanking – General requirements for biobanking."** This standard defines the requirements that biobanks must meet in terms of competence, impartiality, quality assurance, and overall operational integrity to ensure that biological materials (biological samples) and/or associated data are collected, stored, and distributed under appropriate conditions.

The standard applies to all organizations engaged in biobanking activities for research and development purposes. It includes biobanks that handle biological materials obtained from multicellular organisms (such as humans, animals, fungi, and plants) as well as microorganisms.

ISO 20387:2018 does not apply to laboratories that perform analyses for food/feed production or for diagnostic and therapeutic purposes using biological samples.

The purpose of this guidance is to support biobanks during the accreditation process and to provide accreditation assessors with information on evaluating the conformity of biobanks with the requirements of ISO 20387:2018.

The assessment of biobanks is planned to cover all operations both at the facility and in the field. These operations may include: the collection/procurement, acquisition, testing, labeling, logging, cataloguing, examination, preparation, preservation, storage, data management, disposal, packaging, securing, distribution, and transportation of biological samples and/or associated data, particularly for R&D purposes.

2. RELATED DOCUMENTS

ISO 20387:2018 General requirements for biobanking
ISO 22758 Guidance for the implementation of ISO 20387:2018
ILAC P10 ILAC Policy on the Traceability of Measurement Results
PR.017-NAC Procedure for the Accreditation of Conformity Assessment Bodies
PR.019-NAC Procedure for Proficiency Testing and Interlaboratory Comparison Programs
GL.016-NAC Guidelines on Metrological Traceability
GL.007-NAC Guideline on the Use of the NAC Accreditation Mark

3. IMPLEMENTATION

Organizations conducting biobanking activities for research and development (R&D) purposes—including the biobanking of multicellular organisms (such as humans, animals, fungi, and plants) and microorganisms—may apply to NAC for accreditation.

Organizations that handle human-derived samples obtained and used for diagnostic and therapeutic purposes must apply for accreditation under the ISO 15189 standard.

Applicants must complete their accreditation requests via the NAC System by following the relevant steps.

The PR.017-NAC outlines how applications submitted by Conformity Assessment Bodies (CABs) will be reviewed, assessed, and finalized by NAC. This procedure also covers the accreditation of biobanks under the ISO 20387:2018 standard.

Section 3.1.3 of PR.017-NAC describes the application and evaluation process. In addition to this section, the following requirements apply specifically to biobanks:

a) The biobank must be contacted to confirm the activities it performs (e.g., collection/procurement and/or acquisition, testing, labeling, logging, cataloging, analysis, preparation, preservation, storage, data management, disposal, packaging and securing, distribution, and transportation). Documents provided during this stage must also be evaluated for their relevance to the requested scope.

b) If the biobank conducts calibration activities internally, the relevant calibration areas, measurement ranges, and methods must be specified during the application.

Note: Internal calibration activities carried out by the biobank are not included within the scope of accreditation; they are only intended to ensure metrological traceability within the organization itself and not to extend traceability to external parties. The evaluation of these calibrations is performed by including a calibration expert in the assessment team.

c) The scope of the accreditation application will be reviewed by NAC to determine its eligibility. This review also includes:

i. Whether the requested scope constitutes actual biobanking activities (e.g., it excludes laboratories that handle biological materials for food/feed production or diagnostic/therapeutic analysis).
ii. Whether national or international accreditation schemes exist for the requested scope.
iii. Whether there are sufficient expertise and infrastructure within the NAC assessment team and decision-making bodies to evaluate the applicant's technical competence.

The application will be reviewed and recorded by NAC. If necessary, expert opinions may be requested for specific technical areas.

In determining the scope of the biobank, the above-mentioned criteria shall be considered together with the requirements set out in Section 4.1 of this guidance document and the scope definition requirements detailed in GL.063-NAC.BIO.

Biobanks applying for accreditation must have established a quality management system in accordance with ISO 20387:2018 and must have operated this system for at least three (3) months**.**

For an on-site assessment to take place, the biobank's management system must do internal assessments and management.

Applications must be submitted online via: **https://system.nac-us.org/**

The accreditation application is submitted via the NAC Corporate Services Portal (NAC System) by the person designated as the "Authorized Representative" of the biobank. The application is finalized upon completing the required information in the system and electronically signing the **"**FR.178-NAC.BIO Application Form**"** and the **"**FR.001-NAC Accreditation Agreement**"** by a person authorized to legally represent the organization.

When filling out the online application forms, biobanks must provide information on branch offices and other relevant locations, including (if applicable): virtual sites, temporary or mobile facilities, remote personnel, additional operational addresses, liaison offices, etc.

Once the application is accepted, the biobank must upload the documentation required by the ISO 20387:2018 standard to the relevant section in the NAC System.

The accreditation cycle for biobanks is **24 months** from the date of the initial accreditation. The first surveillance assessment is conducted 12 months after the initial accreditation date, and the renewal assessment process shall be initiated no later than 4 months before the expiry date of the 24-month accreditation period.

Additionally, sufficient operational work must have been conducted under the applied scope, and records of such work must be submitted to NAC. For each major activity, the biobank must declare the competence and responsibilities of the relevant personnel during the application process within the NAC System. This information must be kept up to date by the biobank.

NAC personnel and assessment team members are obligated to protect the confidentiality of all information obtained before, during, and after the accreditation assessment and are strictly prohibited from sharing any such information with third parties.

According to procedures of NAC, any changes that may affect accredited services—such as equipment replacement, relocation, or storage infrastructure or temperature-controlled environments —must be reported to NAC within the period stated in the contract. Based on the nature of the change, NAC may decide to take no action, partially or fully suspend the accreditation scope, or initiate a new assessment.

4. IMPLEMENTATION OF ISO 20387:2018 STANDARD

Biobanks that seek accreditation or are already accredited under ISO 20387:2018 by NAC are required to comply with the conditions outlined in this section.

4.1 Determination of Biobank Scope

The biobank must clearly describe the methods (procedures) used for the activities it performs in accordance with ISO 20387:2018 in its relevant documentation. The accreditation assessment is planned based on the declarations made by the biobank. During the application process, the biobank must select its scope from the predefined scope catalogue in the NAC System, or if not listed, define the scope explicitly. Prior to submission, the biobank may

consult the relevant Accreditation Program Manager for clarification or support in defining the scope.

To be recognized as a biobank and be eligible for accreditation under ISO 20387:2018, an entity must perform at least the following three essential biobanking activities:

- Acquisition (collection or procurement) of biological materials and/or associated data,
- Storage of the materials and data under defined conditions,
- Distribution of these materials and/or data to researchers or users.

These three activities are essential for ensuring the functional integrity of biobanking operations. Entities performing only one or two of these functions shall not be considered as biobanks under this standard.

If the biobank uses in-house developed methods or modified versions of validated techniques for handling specific biological materials, acceptable justification must be submitted to NAC.

4.2 General Requirements: Impartiality and Confidentiality

The biobank shall define its mission clearly, covering both current and foreseeable future objectives, establish its management structure and responsibilities, and make such information publicly available.

The biobank must conduct its operations in a manner that ensures impartiality and confidentiality. While fulfilling requirements for impartiality and confidentiality, the biobank must also declare its compliance with applicable national, regional, and international ethical principles for biological materials and associated data.

The biobank shall determine and maintain retention periods for all records, ensuring that confidentiality is preserved, traceability is maintained, and all applicable legal, regulatory, and scientific requirements are met.

The biobank shall continuously identify and assess risks that could compromise impartiality. Although ISO 20387:2018 does not prescribe a specific methodology, the risk assessment should consider the declared impartiality level (first, second, or third party), legal obligations, requirements in other mandatory documents, and potential threats to impartial conduct.

The biobank shall establish its management system in a way that addresses potential risks to impartiality and includes mitigation strategies. The risk assessment must identify scenarios that could pose threats to impartiality, outline control mechanisms to prevent these risks, and define procedures to follow in the event that such threats materialize. The biobank must demonstrate how these threats will be eliminated or reduced to an acceptable level.

At a minimum, the risk assessment for impartiality should consider risks arising from ownership, governance, administration, personnel, shared materials and data, financial interests, contracts, marketing (including branding), and stakeholder relationships (e.g., those assisting with user recruitment).

The biobank is responsible for managing all data obtained or created throughout its activities, particularly those related to donors/providers and recipients/users, in accordance with applicable legal obligations. Staff must ensure the confidentiality and protection of this information. In cases where national laws or regulations conflict with the standard's requirements, legal obligations shall prevail.

If the biobank is required by law to disclose confidential information, the donor/provider or recipient/user should be informed—unless prohibited by law. In situations where authorities access such information without the knowledge of the donor/provider, this condition must be clearly stated in the informed consent forms.

Informed consent documents must be prepared in a way that ensures the protection of personal privacy and the security of biological materials and associated data, safeguarding the rights of both the biobank and the donor/provider.

Upon request by the donor/provider, research results should be made available to them. When possible, any benefits arising from research using the biobank's resources—such as shared knowledge, licensing, technology, or material transfers—should be broadly shared.

4.3 Structural Requirements

Biobanks may be independent legal entities or organizational units within another legal entity that bear legal responsibility for biobanking operations. Under this standard, public institutions operating biobanks are considered public legal entities. To verify the legal status of such public biobanks, it is sufficient to review their founding documents, regulations, governmental decrees, or relevant laws.

Associations, foundations, and chambers of commerce may establish registered biobanks. For such biobanks, presentation of commercial registration documents shall be sufficient to prove their legal status. These biobanks must maintain professional liability insurance policies covering the scope for which they are accredited or seeking accreditation. The biobank shall be responsible for all activities carried out in its facilities or within designated areas.

Biobanks must be established and operated in accordance with applicable legal regulations and ethical principles. The biobank must have internal oversight mechanisms to ensure compliance of its management, operations, access to biological materials and/or associated data, sharing practices, and ongoing activities with legal and ethical requirements.

Protocols and procedures related to the biobank's establishment, governance, operation, access, use, and research activities shall be overseen by an independent governance body (e.g., advisory board or access/use committee). This body is responsible for advising the biobank on whether sample and data sharing requests align with the informed consent terms defined in the biobank's governance documents.

If there is a request to use biological materials or data in a way not specified in the original consent, the committee must ensure that relevant ethical review processes are followed in accordance with applicable laws and regulations.

Organizations must define administrative functions responsible for biobanking activities, along with clear delegations of authority and responsibilities, through an organizational chart. This chart must include both executive management and biobank management.

Regardless of how the organization is structured, the function that holds final authority for securing required resources (such as personnel, equipment, consumables, etc.) and bears overall responsibility for biobanking operations shall be considered the Biobank Management**.**

The biobank shall establish an independent Governance Body to safeguard the integrity and impartiality of its operations, ensuring compliance with legal requirements, ethical principles, and the ISO 20387:2018 standard.

The biobank shall establish an independent Governance Body to operate in compliance with legal obligations, ethical principles, and the ISO 20387:2018 standard, with the purpose of ensuring the integrity and impartiality of its activities.

This body shall have the authority to approve and oversee decisions governing biobanking processes, and it must consist of members capable of acting independently of any conflicts of interest. Members should be selected from individuals with expertise in ethics, science, law, and public responsibility. The Governance Body shall convene at defined intervals to review and evaluate relevant processes.

The Governance Body shall periodically review the activities of the biobank's management, ensure the prevention of unethical practices, examine declarations of impartiality, and monitor whether the biobank’s mission is being fulfilled in a manner that serves the public interest.

The roles, responsibilities, and operational procedures of the Governance Body shall be fully documented.

The biobank shall establish, implement, and maintain a documented financial sustainability plan to ensure the continuity of biobanking operations and the long-term preservation of biological materials and associated data.

This plan shall identify funding sources, operational cost estimates, and financial risk mitigation strategies to maintain the availability, security, and integrity of biobanked resources.

The financial plan shall be periodically reviewed and updated to reflect changes in operational scope, external risks, and strategic objectives. The review shall be documented and considered during management reviews.

4.4 Personnel

Personnel employed by biobanks must possess appropriate qualifications, competence, training, and experience necessary to carry out their professional responsibilities. Management must define the duties and responsibilities of all personnel, including minimum

competence requirements, and establish mechanisms to ensure that these responsibilities are well understood.

The biobank should identify the training needs of its personnel to fulfill their duties, authorities, and responsibilities. This training may include, but is not limited to, topics such as confidentiality, ethics, information technology, legal aspects, management, as well as procedures for collecting, preserving, and storing biological materials and/or associated data.

The biobank must employ all personnel (internal and external) in accordance with the requirements of its management system. A written employment contract must be signed between the biobank and its personnel. For personnel working abroad, contracts must also comply with the legal requirements of the respective country.

Confidentiality, impartiality, and conflict of interest agreements must be established in writing, signed by both the biobank responsible person and the staff member. These agreements must be executed directly with the personnel, documented, and made available to the assessment team upon request.

Records relating to personnel's social security status can only be requested in accordance with national legislation. ISO 20387:2018 does not explicitly require the submission of such documentation. Therefore, for accreditation assessments, the relevant documentation should include job descriptions, training records, competency evidence, and signed declarations or commitment forms.

The competence of personnel involved in biobank processes—whether internal staff or externally sourced—must be evaluated according to criteria established by the biobank. No distinction should be made between internal and external personnel during competence evaluations and performance observations.

4.5 Externally Provided Processes, Products and Services

Biobanks must define the specifications of externally provided biobanking processes/activities (e.g., calibration, maintenance, proficiency testing, training), as well as consumables, reference materials, certified reference materials, and equipment. External providers must be informed of these requirements, and the biobank must verify the conformity of such services/products/processes to defined criteria before their first use**.**

If any nonconformity with the specified requirements is detected during verification, appropriate corrective actions must be defined, and the provider must be informed.

The biobank shall identify which of its activities or processes are carried out in compliance with ISO 20387:2018. This identification must include the type of biological material and associated data subjected to biobanking and specify which of the following activities are performed by the biobank: collection/procurement and/or acquisition, testing, labeling, logging, cataloging, analysis, preparation, preservation, storage, data management, disposal, packaging and securing, distribution, and transportation.

Activities or processes that the biobank is permanently unable to perform and relies entirely on external providers for shall not be included in the scope of accreditation.

If the externally provided services have a critical impact on the integrity, preservation, or secure accessibility of biological materials and/or associated data, the biobank must assess the impact of these services in accordance with ISO 20387:2018 Clause 6.4.1.6**.** For such critical outsourced activities, the methods used by the external provider must be verified and/or validated in compliance with ISO 20387:2018 Clause 7.9**.**

The biobank shall identify the risks associated with outsourced activities and perform internal assessments of these services at defined intervals. Assessment records must be retained by the biobank, and conformity of the services must be evaluated. The biobank shall also obtain documented evidence that the external provider has planned and implemented a risk-based internal audit programme for the outsourced activities, and that such audits are performed at defined intervals (see ISO 19011). Additionally, the biobank must maintain evidence of the provider's qualifications, such as accreditation certificates, competence records, and assessment reports.

In the case of temporary outsourcing due to reasons such as workload or capacity limitations, the biobank must inform NAC and relevant stakeholders (e.g., providers, users, collaborators) in writing.

Criteria for outsourced services must be documented, including methods for procurement and evaluation. A list of external providers must be maintained, and contracts must explicitly state that such services cannot be subcontracted without prior authorization.

Before first use, services/products/processes must be reviewed by responsible personnel to verify conformity with the defined criteria, and these verifications must be documented (e.g., assessment of calibration certificate validity or compliance of purchased equipment with technical specifications).

Except in force majeure circumstances, biobanks must procure outsourced services preferably from bodies accredited by NAC or accreditation bodies that are signatories to mutual recognition agreements with NAC.

Note: Direct assessment of external providers by NAC or with NAC as an observer is not a requirement under ISO 20387:2018. Such practices are internal NAC policy matters and should be clearly distinguished from ISO requirements in this guidance. The responsibility to demonstrate the suitability of outsourced services lies with the biobank, and this must be ensured through documented procedures.

4.6 Equipment

The biobank shall establish, document, and implement procedures for the use, transportation, maintenance, scheduled servicing, and calibration of all equipment used to perform its activities. Operating instructions for all relevant equipment shall be documented and made readily accessible to all personnel.

In compliance with ISO 20387:2018, the biobank shall possess all necessary equipment and software to deliver its services. Under normal conditions, only equipment owned, long-term leased, or under controlled access should be used. If the use of externally sourced equipment is necessary, the biobank must demonstrate the suitability of such equipment for accredited activities and, when required, conduct validation and/or verification of its performance.

The biobank shall maintain a complete inventory of all equipment used, including category, performance specifications, maintenance history, verification, and, where applicable, validation data for each unit. Equipment (including backups) must also be classified as critical or non-critical, based on their potential impact on the quality of biological materials and/or associated data—this classification should follow a risk-based approach.

Detailed records for equipment categorized as critical must be maintained by the biobank. These records should include but are not limited to equipment and software identification, manufacturer and model/type information, unique serial numbers or equivalent identifiers, conformance records to specifications, location plans, manufacturer instructions, calibration/performance/acceptance criteria, next calibration dates, maintenance plans and logs, and information on failures or modifications. Critical equipment and associated software shall be protected against unauthorized external access, and necessary safeguards shall be defined by the organization.

All faulty or questionable equipment shall be removed from service until it is either repaired or confirmed to produce valid results through calibration, testing, or other verification methods. Such equipment must be clearly marked or isolated to prevent use.

If any equipment fault or deviation from specified conditions is identified, the biobank must assess the potential impact of such deviation on other activities or past results generated using the equipment. This assessment shall be performed in accordance with ISO 20387:2018 Clause 7.11 – Nonconforming Outputs**.**

The biobank shall ensure and maintain metrological traceability for all measurements where traceability is required.

4.7 Process Requirements

The biobank shall define and validate all processes relevant to the life cycle of biological materials and/or associated data. For each relevant process (e.g., sampling, acquisition, identification, preservation, long-term storage, quality control, transportation, disposal, etc.), the biobank must define a process flow diagram and document the detailed steps of each phase.

Documentation requirements for process records are described in Annex A of ISO 20387:2018, while Annex B provides examples of minimum documentation sets applicable to specific processes. The biobank shall use both Annexes as reference when designing and documenting its processes.

4.7.1 Collection of Biological Materials and/or Associated Data

If the biobank performs sample collection activities, it shall define and document all aspects of the collection process. This documentation must include the date, location, and method of collection. All methods must comply with applicable ethical principles.

Internationally recognized and up-to-date collection methods should be preferred. The biobank must inform the donor about the intended procedures and the biobanking steps related to the biological materials and/or associated data to be stored.

The biobank must ensure that informed consent is obtained from the donor, and the original or a copy of the consent form must be retained by the biobank. Compliance with regional, national, and international ethical principles shall be ensured—starting from the consent process.

The data recorded from the time of sample collection should preferably follow the ISO 8601 date/time format.

If the biobank does not carry out the sample collection itself, it must verify that the procedures used for collection are appropriate for its intended use. All relevant information about the collection process must be obtained and retained.

4.7.2 Reception and Distribution of Biological Materials and Associated Data

Requirements related to the reception and distribution of biological materials and/or associated data shall be defined and documented. The biobank shall establish and document access principles that define eligibility and conditions for access to samples and associated data. Acceptance of samples shall include verification against predefined criteria (e.g., biosafety, confidentiality, intellectual property, informed consent). Where necessary, authentication of samples shall be performed. Acceptance and rejection decisions shall be documented and records retained. Where applicable, relevant information (such as material acceptance criteria) should be made available to interested parties (e.g., via publication on a website).

Ethical principles applicable during the receipt of biological materials and/or associated data from individuals or institutions (e.g., confidentiality of data) shall be identified and compliance with the intended use must be verified.

Policies governing the distribution of biological materials shall be defined and aligned with relevant national and international legal frameworks. These requirements include:

- Ensuring the privacy and confidentiality of donor/provider information.
- Consistency of use in research with the informed consent (when applicable).
- Fulfillment of any contractual obligations regarding the use of biological materials.

When biological materials or associated data are shared with other users or biobanks, the biobank shall assess and document the applicable legal principles (e.g., Material and/or Data Transfer Agreements).

4.7.3 Transport of Biological Materials and Associated Data

The biobank shall define all necessary elements to ensure the integrity of biological materials and/or associated data during transportation.

Biobanks shall establish procedures, agreements, and documents required for the dispatch, transport (by air, land, or sea), and receipt of biological materials and/or associated data. Transfers may occur between institutions or within different units of the same institution.

Prior to transport, a Material/Data Transfer Agreement must be established between the biobank and the sending/receiving party, defining the terms and conditions of the transfer.

During transportation, the biobank shall maintain complete chain-of-custody records from dispatch through receipt, including documentation of any deviations, corrective actions taken, and confirmation of sample integrity upon arrival. All parameters that may impact the quality of biological materials and/or associated data (e.g., temperature, humidity, light exposure, maximum transport time) shall be defined and monitored. In case of deviation from specified conditions, appropriate contingency procedures must be documented and implemented.

4.7.4 Traceability of Biological Materials and Associated Data

The biobank shall ensure traceability of biological materials and/or associated data throughout their entire lifecycle, from acquisition to disposal. Relationships and dependencies among all processes must be defined and documented.

A system must be established that allows for comprehensive documentation and traceability across the collection, processing, and sharing of samples—aligned with the biobank's information management systems. This system should support access to key data including informed consent, sample characteristics, procurement method, processing details, test plans, storage conditions, reuse status, and quality control information.

Data recorded throughout the biobanking process should preferably conform to the ISO 8601 standard for date and time formatting.

The biobank must implement a system that allows authorized personnel to query sample-related information. The software infrastructure must ensure that all sample records are secure, tamper-proof, and integrity protected.

Data loss prevention and recovery plans must be in place and tested periodically for effectiveness. The biobank shall implement information security measures such as user authorization controls, access limitations, and audit trails to monitor changes.

Electronic traceability systems must be validated, and software updates shall be documented as necessary.

All technical and administrative measures taken to ensure data security and traceability must be documented by the biobank. These measures must be planned in accordance with ISO 20387:2018 Clause 7.3, to ensure accuracy, accessibility, and sustainability of the system.

Personnel involved in biobanking activities must have access to traceability information and be authorized to update records when necessary.

4.7.5 Preparation and Preservation of Biological Materials

The biobank should prefer the use of internationally recognized and validated standard methods for the preparation and preservation of biological materials.

4.7.6 Storage of Biological Materials

The biobank shall establish, document, and implement a process for the storage and monitoring of biological materials. This shall include, but not be limited to, distinct labeling of samples, establishment of appropriate storage conditions, ensuring traceability of stored materials, and defining an emergency action plan in case of deviations from the required storage conditions.

The biobank shall also ensure that all stored biological materials and/or associated data remain within the scope of the agreements (e.g., informed consent forms) signed with donors/providers, including conditions, purpose, and duration of storage. It must be acknowledged that the donor/provider has the right to withdraw consent for storage and use at any time.

In case of emergencies (e.g., fire, earthquake, flood, power outage), the biobank shall apply risk-based thinking to ensure the integrity of biological materials and/or associated data is preserved. The biobank must define and maintain environmental conditions aligned with the latest biosafety standards based on the nature of the biological material.

This includes implementing contamination control and physical isolation measures between areas to ensure sample protection and safety.

4.7.7 Quality Control (QC)

The biobank shall establish, implement, and maintain a documented quality control (QC) program covering all processes and data, in order to demonstrate the suitability, reliability, and comparability of biobanking activities.

The biobank shall define and perform a minimum set of QC checks for each critical process (e.g. collection, transport, storage, preparation/preservation, testing), ensuring that deviations are detected, recorded, and subject to corrective action. QC data shall be monitored for trends and reviewed at defined intervals.

The biobank shall verify the accuracy and consistency of data generated and reported. QC information relevant to users (e.g. sample integrity checks, environmental monitoring results, stability testing outcomes) shall be made available in reports.

Where applicable, the biobank shall use external quality assessment tools (e.g. EQA schemes, PT/ILC participation) or alternative approaches to demonstrate comparability of results. Records of participation and outcomes shall be retained and evaluated for continuous improvement.

4.7.8 Method Validation and Verification

The biobank shall validate non-standard methods, laboratory-developed methods, and modified standard methods to demonstrate that they are fit for their intended purpose. Validation activities shall be documented, including the procedure followed, acceptance criteria, and results obtained.

For standard methods, the biobank shall verify that it can properly perform these methods within its own environment before use. Verification shall be documented with records of the procedure and outcomes.

The biobank shall maintain a written statement of the "fit for purpose" status of each validated or verified method within its scope.

Whenever methods are modified, or there are significant changes in conditions that may affect the validity of results, the biobank shall perform revalidation or reverification as appropriate.

Records of validation and verification, including reports, acceptance decisions, and related documentation, shall be retained as part of the quality management system.

4.8 Reporting

The reporting system of the biobank shall comply with the requirements of the ISO 20387:2018 standard. Additionally, when using the accreditation mark, the provisions of the document **GL.007-NAC Guideline on the Use of the NAC Accreditation Mark** must be followed.

4.9 Complaints

The biobank shall establish, document, and implement a complaint-handling procedure. The procedure shall include:
– receipt, validation, and registration of complaints.
– impartial investigation and decision-making.
– communication of outcomes to the complainant without undue delay.
– retention of complaint records.
The biobank shall ensure that the handling of complaints does not compromise impartiality.

4.10 Proficiency Testing and Interlaboratory Comparisons

If the biobank performs testing activities, it shall comply with the requirements outlined in PR.019-NAC Procedure for Proficiency Testing and Interlaboratory Comparison Programs

4.11 Risks and Opportunities

The biobank shall identify, assess, and record risks and opportunities related to its biobanking activities, including risks and opportunities associated with operational continuity, particularly with respect to biological materials and/or associated data.

This assessment must consider:

- Loss of samples
- Loss of Data
- Breach of data security
- Ethical risks
- Improper storage conditions
- Unauthorized access
- Infrastructure failures
- Natural disasters
- Emergency Situations
- Financial Failures

For each identified risk, appropriate control measures**,** monitoring plans, and emergency response strategies shall be defined. The effectiveness of these measures must be periodically reviewed and improved when necessary.

Since ISO 20387:2018 does not prescribe a specific method for risk and opportunity assessment, the biobank is expected to apply a systematic approach, considering its objectives, the complexity of its management system, applicable regulations, and other mandatory documents.

When conducting risk assessments, the biobank should consider criteria such as:

- The criticality of biobanking processes
- Personnel competence levels
- System and infrastructure capabilities
- The role of outsourced services
- Security of data and samples

The biobank shall evaluate risks and opportunities in line with its accredited scope, and there are no restrictions on applying common risk monitoring/prevention methods across different biobank activities.

Risk assessments shall be regularly reviewed and updated based on changing internal and external conditions. These evaluations should also be addressed during management review meetings.

The biobank shall also establish and maintain a documented contingency and legacy plan. This plan shall address both short-term emergencies (e.g., natural disasters, infrastructure failures) and long-term scenarios such as the discontinuation or termination of biobank operations. It shall define procedures for the secure transfer or disposal of biological materials and associated data, stakeholder notification, selection of appropriate recipient institutions, and requirements for record retention or data archiving. The legacy plan shall be periodically reviewed, tested where feasible, and updated to ensure effectiveness.

4.12 Quality Management System

The biobank shall implement a quality management system in accordance with either Option A or Option B described in ISO 20387:2018, selecting the one most suitable to its structure. Both options aim to ensure the biobank's management system consistently fulfills the standard's requirements.

- Option A refers to the direct implementation of all management system requirements specified in Clause 8 of ISO 20387:2018. The biobank defines, implements, and maintains its management system in full compliance with the standard.
- Option B allows for the use of a quality management system that is fully aligned with ISO 9001, structured to also meet the requirements of ISO 20387:2018. However, holding ISO 9001 certification does not imply full compliance with ISO 20387:2018. In this case, the assessment team must verify that all ISO 20387:2018 requirements are fully addressed.

From an accreditation standpoint, there is no difference between Option A and B. In both cases, the evaluation team assesses conformity with all ISO 20387:2018 requirements.

Biobanks must organize their management systems to fulfill ISO 20387:2018 requirements and accreditation criteria. All documentation shall be clear and traceable to demonstrate the system's integrity.

Although optional, biobanks are encouraged to prepare a Quality Manual describing the structure, processes, and controls of the management system, as it facilitates traceability and auditability.

Internal audits must be conducted at intervals not exceeding 12 months by competent personnel independent of the audited activity and must cover the entire system, including biobanking operations. Management reviews must also be planned and conducted on a 12-month basis.

5. RISK-BASED ASSESSMENT PLANNING AND SAMPLE SELECTION APPROACH

To ensure a more structured and effective surveillance assessment process, the assigned accreditation officer shall develop an assessment program for each biobank, considering the organization's services and personnel.

In accordance with NAC's assessment program preparation procedures, an accreditation cycle plan shall be prepared for each biobank. This plan shall cover the entire accreditation scope and management system and be designed to ensure on-site assessments are conducted at the relevant locations.

A risk-based assessment approach shall be applied in the preparation of the accreditation cycle program. When planning assessments, the following risk factors—among others—shall be taken into consideration:

- Nonconformities detected in previous assessments and areas requiring follow-up
- Changes in personnel
- Changes in accreditation scope
- Changes in equipment
- Outsourced products and services
- Unsatisfactory Proficiency Testing (PT) / Interlaboratory Comparison (ILC) results
- Revisions to standards within the accreditation scope
- Feedback and complaints
- Legal, regulatory, and standard updates
- Corrective actions taken by the biobank in response to nonconformities
- Revisions in IAAC, APAC, and ILAC procedures
- The intensity of biobanking activities and the number of biobank reports

During the initial accreditation assessment, all locations and the entire scope of the biobank shall be evaluated.

Biobanking services and all relevant service locations shall be assessed at least once within a 24-month accreditation cycle, following the principles of risk-based assessment planning.

6. REVISION TABLE

Date	Section	Amendment
25.08.2025	All	Initial issue.