1. PURPOSE

This guideline establishes the general rules that biobanks applying for NAC accreditation under ISO 20387:2018 must follow when defining their accreditation scope.

2. RELATED DOCUMENTS

- ISO 20387:2018 Biotechnology – Biobanking – General requirements
- ISO/TR 22758:2020 Biotechnology – Biobanking – Implementation Guidance
- GL.062-NAC.BIO Guideline on the Accreditation of Biobanks
- FR.178-NAC.BIO Application Form for Biobanks

3. GENERAL RULES

Scopes shall be prepared considering the standard's terminology and this guideline's structure.

Each activity listed in the accreditation scope must clearly define:

Column	Description
Biological Sample / Product / Data	The type of **biological material, derivative, or associated dataset** handled by the biobank.
Subcategory	The specific subclass of the biobank (e.g., Human, Animal, Microbial, Virtual).
Activities	Key biobank operations (collection, reception, storage, analysis, distribution, etc.).
Storage Conditions	Controlled parameters (temperature, atmosphere, containment level).
Methods / References	Procedures, standards, or validated protocols used in the activity.

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.

4. BIOBANK TYPES AND SCOPE CATEGORIES

This section provides the classification of biobank types and related scope categories applicable for accreditation under ISO 20387:2018.

The classification aims to assist both biobank applicants and assessors in defining, reviewing, and interpreting the biobank's declared scope of activities, materials, and operational environments.

Each biobank type described below is characterized by the origin of biological material, intended use, and core processes conducted within its operations.

Subcategories and scope examples are given to support consistent and comparable scope definitions across different biobank domains.

Code/Type	Description	Typical Samples/Products/ Data	Example Subcategories	Typical Activities
B1 – Human Biobank	Stores and manages biological materials of human origin and associated data for research, diagnostic, or public-health use.	Blood, serum, plasma, tissues, DNA/RNA, cells, associated clinical data	Population-based biobank, disease-specific biobank, hospital biobank, clinical-trial repository	Collection, Reception, Processing, Storage, Distribution, Data management
B2 – Animal Biobank	Preserves biological materials of animal origin for veterinary, environmental, or research purposes.	Tissues, blood, cell lines, DNA, microbiota	Livestock biobank, wildlife sample bank	Collection, Storage, Preservation, Quality control, Distribution
B3 – Microbial / Plant Biobank	Maintains microorganisms, cell lines, and plant materials for conservation, research, or reference purposes.	Microbial cultures, spores, plant seeds, tissues, DNA extracts	Reference strain collection, seed bank, cell culture collection	Isolation / Collection, Preservation, Revival testing, Quality control, Distribution
B4 – Virtual Biobank / Data Repository	Manages metadata, datasets, and digital records without physical storage.	Digital records, datasets, metadata, consent forms	Data integration platform, metadata repository	Data curation, Information management, Access control, Risk management
(Optional) B5 – Hybrid Biobank	Integrates both physical sample management and digital data operations.	Physical samples and associated datasets	Networked biobank consortium, multi-site repository	Collection, Storage, Data management, Distribution, Quality control

5. SCOPE CONTENT RULES

- Use consistent SI units for temperature, humidity, or concentration.
- "Biological Sample/Product/Data" descriptions shall specify the source and material class (e.g., human blood, human tissue, animal serum, microbial cell line, fungal spores), and shall avoid using only generic category terms.
- "Activities" must correspond to defined ISO 20387 processes (7.3 to 7.13).
- "Storage conditions" must identify the controlled environmental parameters.
- "Methods" shall reference internal SOP codes, validation records, or international standards.
- Any non-routine or collaborative processes must be clearly marked (e.g., "*On-site activity").

6. EXAMPLES OF BIOBANK SCOPE STATEMENTS

Biological Sample/Product/ Data	Subcategory	Activities	Storage Conditions	Methods
Serum samples	Human Biobank	Collection from clinical visits, processing by centrifugation, long-term storage, distribution to researchers	−80 °C freezer, backup power supply with alarm system	SOP-HB-001
Animal DNA extracts	Animal Biobank	Extraction, quantification, storage, traceability	−20 °C freezer	SOP-AB-002
Fungal cultures	Microbial Biobank	Preservation under liquid nitrogen, viability testing	−150 °C LN_2 tank	ISO 11133
Metadata records	Virtual Biobank	Database management, confidential data protection, access audit logs	Server room + cloud backup	SOP-VB-004

7. NOTES FOR ASSESSORS AND CABs

- Scopes must demonstrate traceability, data integrity, and ethical compliance.
- Storage conditions should reflect real biobank infrastructure (e.g., LN_2, −80 °C, −20 °C).
- Methods should be validated or verified as fit for purpose (ISO 20387 Clause 7.9).

- For hybrid or virtual biobanks, information security controls (ISO 20387 Clause 7.10) must be verified.

8. REVISION TABLE

Date	Section	Amendment
25.08.2025	All	Initial issue.