GUIDELINE FOR THE ACCREDITATION OF BIOBANKS AND GUIDANCE FOR THE ASSESSMENT AND APPLICATION OF ACCREDITATION CRITERIA

ESYD BB

Issue: 01
Revision: 00
Issue Date: 25-05-2026
Issued by: Quality Manager of ESYD
Approved by: Chairman of ESYD

Quality Manager of ESYD **Chairman of ESYD**

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1. Introduction

This document is a policy document and provides further clarification of the accreditation criteria applied within the scheme.

2. Criteria and Related Guidelines for the Accreditation of Biobanks

Criteria:
ESYD Criteria: ISO 20387, Accreditation Regulations, ESYD GA1, ESYD GA2, ESYD PDI, ILAC P9, ILAC P10, ESYD G-FLEX, EA 2/15

3. Accreditation of Biobanks

Biobanking, as defined in Clause 3.6 of ISO 20387, is the process of acquiring and storing, together with some or all activities associated with the collection, preparation, preservation, testing/examination, quality control, and distribution of defined biological material, as well as related data. The scope of accreditation includes information on the activities of the accredited biobank, namely the biobanking of biological material, for which ESYD has confirmed the competence of the biobank in relation to the applicable accreditation requirements.

Therefore, each biobanking accreditation scope shall include, as a minimum, the acquisition, storage, and one or more of the following activities: collection, preparation, preservation, testing/examination, analysis, and distribution of defined biological material, as well as associated data. Any other specified activity within an accreditation scope shall be traceable to one of the biobanking activity categories referred to in the definition.

The scope of accreditation shall also define the biological material and its source (e.g. human, animal, plant, microbial, or fungal biological material), the storage conditions under which it is maintained (e.g. cryogenic storage at −80 °C to −190 °C), and the standards, normative documents, and/or regulatory requirements containing the specifications against which the conformity assessment activity is performed, as applicable.

Biological material may further be classified into subcategories (e.g. saliva, plasma, serum, tissues, DNA extracts).

Particular importance is given to the clear description of the biobanking methods applied, including whether these are standard methods, third-party validated methods, in-house methods appropriately validated by the biobank, methods adopted from comparable fields with suitable validation, or other equivalent approaches.

4. Accreditation Process

The general ESYD accreditation procedure (ESYD PA) is applied and further specified in document ESYD PAL, Accreditation Procedures for Laboratories.

The biobank assessment process consists of:

- review of the biobank documentation,
- on-site assessment,
- witnessing of the biobank activities for which accreditation is applied.

Samples of activities related to the biobanking of biological material, within the requested scope of accreditation, are selected for on-site assessment during the accreditation process, considering the risk of incorrect assessment of the biobank's competence and of drawing inadequate conclusions regarding confidence in its capability.

The determination of the assessment duration is based on a risk-based approach, considering the following factors:

- type and specific nature of the biological material,
- scope of processes performed by the biobank (requested scope of accreditation),
- extent and type of externally provided services/processes,
- number of locations where biobanking-related activities are carried out,
- personnel involved in the biobanking process.

In the case of an application for accreditation covering multiple locations, the on-site assessment is conducted at the headquarters of the biobank and at other sites where activities directly related to the biobanking of biological material are performed. The outcomes of this process include:

- policy formulation and approval, process and/or procedure development,
- implementation of biobanking procedures,
- selection and verification of external services/processes and suppliers,
- approval of reports/declarations.

4.1 Sampling of Activities During Initial Assessment

The sample of biobank activities assessed by ESYD shall be selected to be representative of the processes (activities) directly related to biobanking within the scope of the requested accreditation. The on-site assessment is conducted using the following assessment techniques, depending on the type of sample being verified: interviews and discussions, review of documents and records providing evidence of the biobank's competence, vertical assessments of biobanking processes for biological material, and witnessing activities.

The sample of activities observed during the on-site assessment covers a representative range of processes performed by the biobank as part of the activities submitted for accreditation, taking into account the diversity of the biobanking subject matter, including the types of

biological materials as well as the different biobanking processes (pre-analytical processes, quality control, related testing/examinations, etc.).

When selecting activities for witnessing, all biobanking processes performed directly by the biobank are considered, as well as the demonstration of activities carried out by technical personnel authorized to perform specific tasks.

The selection of the sample shall ensure the observation of as many personnel members as possible involved in technical activities related to the biobanking of biological material.

For biobanking processes for which witnessing cannot be performed during the scheduled on-site assessment (e.g. biological material collection procedures, biological material preparation procedures, etc.), the biobank's competence to perform the activities is assessed based on documented evidence of performed activities and the outcomes of interviews conducted, always applying a risk-based approach. This approach shall be justified by the Lead Assessor, demonstrating that it does not affect the assessment team's ability to evaluate the requested technical competence.

In cases where the biobank uses external services/suppliers that have a significant (critical) impact on the biological material subjected to biobanking and/or on the outcomes of the process (e.g. procurement, preservation, storage, or identification of biological material), ESYD verifies, during the on-site assessment, the biobank's activities related to the evaluation, selection, monitoring, and re-evaluation of external providers for compliance with the requirements established by the biobank.

4.2 Sampling of Activities During Surveillance and Reassessment

The assessment programmes for individual surveillance and reassessment activities take into account information relating to: the operation and complexity of the biobank's management system, the scope of previous assessments and the assessment techniques used, including the technical biobanking activities witnessed, previous assessment experience (including the outcomes of previous assessments within the cycle—nonconformities and concerns, as well as the biobank's response to assessment findings), biobank-related activities (complaints and other relevant information concerning the biobank), and significant changes affecting compliance with accreditation requirements (e.g. personnel changes, technical changes, etc.). During surveillance and reassessment activities, samples of the biobank's technical activities and samples of the management system operation are selected, taking into account the minimization of the risk of error in assessing competence and in drawing conclusions regarding confidence in the biobank's capability.

The rules for sampling selection during surveillance and reassessment assessments are the same as those applied in the accreditation process. The assessed sample shall be representative of the agreed assessment scope and shall cover all or part of the activities under evaluation. When selecting samples, assessors are guided by the principle of verifying the maximum extent of the biobank's competence, taking into account, in subsequent samples, changes in assessed personnel and the type of activities performed by biobank personnel that were verified/witnessed in previous assessments.

In addition, samples in all surveillance and reassessment activities shall provide the basis for a comprehensive evaluation of the biobank across the full scope of the implemented management system and its technical competence for the biobanking of biological materials covered by the accreditation scope.

ESYD selects for assessment activities, including witnessing, those related to biobanking, taking into account the diversity of the processes performed by the biobank and/or the types of items subjected to biobanking. Within a given accreditation cycle, ESYD shall witness at least the implementation of biological material acquisition and preparation (including testing/analysis, where applicable), and biological material preservation and storage.

5. Requirements for Flexible Scope

Degrees of flexibility may relate to specific aspects of biobanking activities where the same acquisition and storage techniques are applied. Where the biobank requests a greater level of flexibility than that inherently defined within the scope, the requirements set out in the ESYD policy for granting flexibility, ESYD G-FLEX, shall apply.

6. Requirements for PT/EQA

In addition to the requirements arising from the implementation of external quality assessment (EQA)/Proficiency Testing for tests/examinations that the biobank may perform under compliance with ISO 15189 or ISO/IEC 17025 – where the ESYD policy documented in ESYD PDI applies – the biobank is also required to participate, if available, in PT schemes related to **biobanking**. The determination of the frequency of participation in such PT schemes, as well as the manner in which the results affect the accreditation recommendation, is in accordance with the provisions of ESYD PDI.

7. Requirements for Measurement Traceability

Where the establishment of measurement traceability is required—either through equipment calibration, the use of certified reference materials, or alternative approaches—the requirements of ESYD GA2 shall apply.

8. Requirements for Multi-Site Accreditation

The requirements specified in the ESYD general document Multi-Site Accreditation Procedure - ESYD DDEPT shall apply.

9. Specification of Standard Requirements

9.1 Clause 5 of ISO 20387

The biobank is expected to clearly identify the legal entity being accredited, as well as the top management of the organization responsible for its operation, and any board or panel of experts acting in an advisory or supporting role in its functioning. The biobank shall establish a framework defining its civil liability arising from biobanking operations and related activities.

9.2 Clause 6.1.3 of ISO 20387

The biobank shall have a documented strategy for the continuous financial sustainability of its activities, which is periodically reviewed. This requirement ensures that the biobank has the necessary resources for the long-term operation and proper biobanking of specimens.

Compliance with this requirement may be demonstrated by the biobank through, for example:

- a business strategic plan or sustainability plan,
- agreements with funding bodies,
- relationship with a parent organization.

Continuous financial sustainability shall be assessed through a strategic plan that takes into account future expansions or modifications (see 6.3.6).

9.3 Clause 6.1.2.5 of ISO 20387

The biobank, or the legal entity of which it forms part, shall ensure that health and safety requirements are established, documented, implemented, and maintained. The required level of safety training shall be determined through a comprehensive risk assessment of the biological and chemical materials, processes, and equipment used. A professional risk assessment (for biological/chemical hazards) is required to identify the appropriate training for personnel.

A professional risk assessment is expected for all staff working in the biobank. Measures to reduce workplace hazards for biobank personnel must be implemented and maintained, and these measures shall inform the staff training program.

9.4 Clause 6.3.7 of ISO 20387

The biobank shall have a contingency plan to ensure the maintenance of the required environmental conditions in its facilities/defined areas, according to the relevant risks.

The business continuity plan shall be documented and based on a risk assessment approach, covering scenarios such as floods, fires, equipment failures, and loss of personnel.

9.5 Clause 6.4.1.1 of ISO 20387

Examples of externally provided services include cryogenic facility maintenance services, equipment calibration services, and biological material testing services (e.g. purity testing, molecular integrity, cell count, composition, viability, gene expression).

An example of a product is liquid nitrogen.

For equipment calibration, see Clause 6.5; calibration traceability shall be ensured in accordance with ESYD GA2.

9.6 Clause 6.5 of ISO 20387

Equipment may include analogue or digital measuring devices, personal protective equipment, reference materials, physical and digital backup systems, incubators, ultra-low temperature freezers, lyophilizers, and tools used for long-term storage.

Access of the biobank (BBK) to equipment not owned by it, for example through loan or shared use with other groups, shall be documented and regulated in terms of responsibility for control and maintenance.

9.7 Clause 6.5.10 of ISO 20387

Where applicable, the biobank shall establish and maintain metrological traceability of measurement results through a documented unbroken chain of calibrations or comparisons, linking them to an appropriate reference.

Further guidance on equipment and traceability can be found in ESYD GA1 and ESYD GA2.

9.8 Clause 7.2.2.1 of ISO 20387

The minimum information related to sample collection is provided in Appendix A2. Examples are given in Appendix B2 of ISO 20387.

9.9 Clause 7.2.3.4 of ISO 20387

The transport of biological samples shall be carried out in accordance with national legislation.

9.10 Clause 7.3.1.1 of ISO 20387

Examples of interested parties include:

- and/or persons responsible for a specific collection of biological material,
- the custodian or a person authorized to make decisions on behalf of the biobank,
- public reference authorities,
- those involved in the governance of the biobank,
- researchers,
- depositors, donors/patients.

9.11 Clause 7.6.2 of ISO 20387

A risk-based approach may assist in defining critical activities, as well as appropriate parameters and process monitoring measures for preparation and/or storage processes. Documentation of these processes may be developed as described in Annex A (A.4).

9.12 Clause 7.9 of ISO 20387

It is expected that Biobanking Method validation/verification is carried out in accordance with ISO 21899:2020 but it is of absolute importance to emphasize here that if the biobank adopts an alternative validation/verification methodology, demonstrating at the same time the

suitability of the alternative approach, then this will accepted as conforming to the requirements of ISO 20387.

- The biobank shall clearly understand the distinction between the biobanking (processing) method and the testing method.
- The biobanking method shall be suitable for its intended use, and appropriate acceptance criteria shall be established.
- Validation shall be performed within the laboratory facilities or elsewhere under controlled conditions (see ISO 21899:2020, Clause 8.4.3).
- Where verification/validation activities are outsourced to subcontracted entities, either internal or external to the biobank organization, the requirements same as those set out in paragraphs 4 and 5 of ESYD G-DIESX shall apply.
- The biobank shall clearly define the critical factors/steps of the biobanking method that need to be optimized.
- The homogeneity study shall be based on the limiting factor of the biological material (e.g. a sensitive protein), and measurements shall include at least 2/vial.
- The stability study may be divided into long-term stability and transport stability studies.

9.13 Other Guidance

Additional guidance is provided in the document ISO/TR 22758:2020, Biotechnology — Biobanking — Implementation guide for ISO 20387.