

Guidance on Scopes of Accreditation for Biobanks

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1. SCOPE

This document is intended for accreditation bodies seeking to define the scope of accreditation (see definition listed below) for biobanks accredited to ISO 20387. These biobanks provide biological material and associated data of appropriate quality for research and development. The aim is to provide guidance to promote clarity and consistency in the publicly available information on accredited biobanks.

1. DEFINITIONS

**Scope of accreditation**

Specific conformity assessment activities for which accreditation is sought or has been granted.

SOURCE: ISO/IEC 17011:2017, 3.6

1. REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the editions cited applies. For undated references, the latest edition of the reference document applies.

1. ISO/IEC 17011, *Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies*
2. ISO 20387, *Biotechnology – Biobanking – General requirements for biobanking*
3. BACKGROUND

The initial version of ISO 20387 was published by the ISO Technical Committee ISO/TC 276 *Biotechnology* in August 2018. Subsequently, the ILAC General Assembly at its 22nd meeting in Singapore in October 2018. ILAC endorsed resolution ILAC GA 22.19, stating that the standard applicable to biobanks for the purposes of accreditation would be ISO 20387 as a standalone standard.

This resolution provided interested conformity assessment bodies, accreditation bodies, and regional cooperation groups with clear direction on the path forward towards an eventual MRA for activities falling under this new accreditation scheme.

APAC surveyed its members and concluded that there was sufficient interest in this area of accreditation, and thus formed a working group to investigate expanding the APAC MRA to include biobanking as per ISO 20387.

The working group’s recommendation to the MRA Council was ultimately to expand the APAC MRA, while noting there was a significant amount of work to be accomplished in order to complete the extension process; most notably, the development of guidance on how to properly express the scope of accreditation for a biobank, since biobanking is not specifically addressed by ISO/IEC 17011.

The APAC MRA Council provided its recommendation to expand the APAC MRA to the APAC General Assembly, and on October 21, 2020, the extension was approved through APAC GA Ballot 2020-02.

1. PRINCIPLES
   1. General

While ISO/IEC 17011 is silent on the inclusion of biobanks in its contents, accreditation bodies should apply the following principles when preparing the scope of accreditation of a biobank that provides biological material and associated data.

* 1. Accuracy

The description of the scope of accreditation should be accurate without causing any misunderstanding or ambiguity.

* 1. Sufficiency

The information should be sufficient to identify range of activities conducted by the biobank within the scope of accreditation.

* 1. Clarity

The description of the scope of accreditation for the biobank should be clear, concise and understandable.

* 1. Consistency

The consistency between accreditation bodies on how accreditation bodies define the scope of the Biobank should be promoted.

1. GUIDANCE
   1. Information to Include in the Scope of Accreditation for a Biobank

The scope of accreditation for a biobank accredited to ISO 20387 should include the following information::

1. the type and/or characteristics of biological material and associated data;
2. the biobanking activities performed in relation to the biological material and associated data by the biobank;
3. storage conditions; and
4. the techniques or principles used, which may include reference to the standard and/or method, to perform the specific activities.

NOTE Appendix 1 provides an example of the elements.

* 1. Types of Biological Material and Associated Data

6.2.1 The type of biological material and associated data may refer to materials from multicellular organisms (e.g. human, animal, fungus, and plant) and/or microorganisms.

6.2.2 The type of biological material should be accurate and specific enough to employ appropriate methods and/or standards to ensure fitness for the intended purpose. In addition, the biological material and associated data should define the source (e.g. human tissue, animal blood, fungus, microbial cell lines, etc.)

* 1. Biobanking Activities

Not all activities will necessarily be performed by the Biobank. The biobanking activities (see 6.1 b)) which should be defined in the scope of accreditation include a minimum of three activities for defined biological material as well as associated data, each of which can be categorized within a biobanking activity per the ISO 20387 definition:  acquisitioning (required), storing (required), and one or more among the following:

1. collection;
2. preparation;
3. preservation;
4. testing;
5. analysing; and
6. distributing.
   1. Storage Conditions

The storage conditions should describe the environment for which the biological materials are kept short or long term.

* 1. Reference to the Techniques, Principles and/or Standards

The techniques or principles used to perform the biobank activities should be clearly articulated and understood by users of the biobank services. Where standard methods are included, these should reference the year of publication where relevant (e.g. a superseded method may be in use to meet the need of users of the biobank services).

* 1. Flexible Scopes

The level of detail included in the scope of accreditation will depend on the degree of flexibility that is offered by the AB. ABs are encouraged to allow a degree of flexibility for scopes to not restrict access to biological materials and associated data.

1. Amendment Table

This table provides a summary of the changes to the document with this issue.

|  |  |  |
| --- | --- | --- |
| **Date** | **Section(s)** | **Amendment(s)** |
| 2022-08-23 | 6.3 | Delete “Note.”  Change scope reference to a minimum of three activities and revise the content accordingly. |
| 2022-08-23 | Appendix 1 | Separate animal and human samples. |
| 2021-06-10 | All | APAC TEC1-001 approved by the APAC Executive Committee. |

Appendix 1 Example Scope of Accreditation for a biobank

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Category: | Subcategory: | Activities: | Internal/External Methods: | Storage Conditions: |
| e.g.  Human | e.g.  Biofluids, cells, Biological Molecule, tissue, blood, extracts, blood spot, hair, nails, bacteria, viruses | e.g.  Acquisition (required)  Storage (required)  Any one or more from the following:   * Collection * Preparation * Processing * Examination * Authentication * Preservation * Distribution | e.g.  reference to ISO standards,  National standards,  Industrial standards,  Association standards,  Biobank SOPs,  etc. | e.g.  -80 Freezer, Slides, Cryofreezer, etc. |
| Animal | e.g.  Biofluids, cells, Biological Molecule, tissue, blood, extracts, bacteria, viruses |
| Plant Material | e.g.  Whole plant material, organic solvent extracts, aqueous extracts |
| Fungal | e.g.  Whole material, mycelium, spores |