ISO 20387: ACCREDITATION FOR BIOBANKING FACILITIES

ISO 20387 - GENERAL REQUIREMENTS FOR BIOBANKING

Biobanking is integral to many different scientific disciplines, and applications for biobanking are becoming more widespread.

Reliability of materials and their associated data is essential to underpin confidence in their many uses. Banked materials and associated data may be provided as single samples to a single user for a specific purpose or as larger number of samples for scientific studies e.g. research in diseases connected with a certain analyte in the blood.

Specific to biobanks is that **data associated with a sample may include measurement data** as well as other characteristics and demographic information associated with the origin of the material. Whether organizations utilizing banked samples have biobanks in-house or use banked resources from outside facilities, they must **be certain that samples are properly handled, consistent, traceable and appropriate for the intended use.**

While there are several standards that cover aspects of biobanking in some way, such as ISO 15189 **Medical laboratories - Requirements for quality and competence**, ISO/IEC 17025 **General requirements for the competence of testing and calibration laboratories** and ISO 17034 **General requirements for the competence of reference material producers**, many crucial aspects of maintaining a biobank had not been directly addressed until the publication of ISO 20387 - **General requirements for biobanking** in 2018. ISO 20387 was developed with the entire range of biobanking functions in mind, covering the banking of biological materials from multicelular organisms, e.g.:

- Human samples
- Animal samples
- Fungal samples
- Plant samples
- Microorganisms

The standard also includes requirements regarding the preparation and long-term preservation of samples and long-term sample traceability. The requirements address considerations for biobank-specific collection and transportation procedures and, as with other ISO standards, **ISO 20387 covers both the management system and technical aspects of operation providing a multi-faceted framework for organizational health.**

ACCREDITATION TO ISO 20387

Accreditation of a biobank to ISO 20387 involves **independent**, unbiased assessment of the biobanking facility to determine **competence, impartiality,** and **consistent operation.**

Specialist assessors with relevant experience in biobanking conduct an assessment of the biobank, its management system, processes, facilities, personnel, and other essential elements of its operation to determine if it meets the requirements listed in the standard.

Based on information provided by assessors, a separate decision-making process under the accreditation body determines whether to grant accreditation. **Once an organization achieves accreditation, they are periodically re-evaluated to ensure that they are maintaining the necessary competencies and continue to meet the relevant requirements.**

THE BENEFITS OF ACCREDITATION

Biobanking has a broad impact, and those utilizing banked materials **demand quality and consistency** in the **collection, transport, preservation, storage, quality assurance, reception, traceability and data management distribution of those materials.** Accreditation to ISO 20387 is an unambiguous indicator of an organization's capabilities, provided by an objective third party. This provides valuable insight for the organization that can help them improve or streamline their operations, **potentially saving time and money.**

Accreditation also increases confidence in the biobank's output and assures stakeholders that crucial requirements are being consistently met. Furthermore, **accreditation creates a framework for greater consistency and reliability** of biological materials to increase the value and reliability in their 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 biobanking practices.

ABOUT ILAC

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement – among Accreditation Bodies (ABs) in order that the data and test results issued by organizations, collectively known as Conformity Assessment Bodies (CABs), **accredited by ILAC Accreditation** Body members **are accepted globally.** Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realizing the free-trade goal of

"ACCREDITED ONCE, ACCEPTED EVERYWHERE".

In addition, **accreditation reduces risk** for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, **the results from accredited facilities are used extensively by regulators for the public benefit** in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

ABs that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent application of those standards.

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organizations throughout the world.

It is a representative organization that is involved with:

- The development of accreditation practices and procedures.
- The promotion of accreditation as a trade facilitation tool.
- Supporting the provision of local and national services.
- The assistance of developing accreditation systems.
- The recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers, reference material producers and biobanks around the world.

ILAC actively cooperates with other relevant international organizations in pursuing these aims.

ABs having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognized regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members.

Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at: **www.publicsectorassurance.org**

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