

## Definitions of Terms and Explanations of Best Practices, Guidelines, Standards, and Norms that Pertain to Repositories

### Definitions

**Best Practice:** A management idea which asserts that there is a technique, method, process, or activity that is more effective at delivering a particular outcome than any other technique, method, process, or activity.

**Guidelines:** Any document that aims to streamline particular processes according to a set routine. Following guidelines / best practices is not mandatory.

**Standards or norms:** Design or format applicable because it is recognized by an official organization or because it is used by a majority of users. Following standards is mandatory.

- **Certification norm:** A norm geared around management which includes SOPs that are “feasible” (e.g. ISO9001:2000)
- **Accreditation norm:** A norm geared around competence which includes SOPs that are evidence-based and scientifically “validated” (e.g. ISO17025:2005)

One international norm (ISO) for biobanks does not exist. In the absence of an international norm, some countries may decide to develop national norms. Different guidelines / best practices have, however, been developed; these guidelines are necessary for the biobanking community because different issues are at stake (e.g. ethical guidelines for population biobanks, ethical guidelines for hospital-based biobanks, technical guidelines, IT guidelines, and cost-recovery guidelines). Such guidelines may serve as support to the more general-scope norm. Such guidelines can be national (e.g. NCI) or international (e.g. ISBER).

In practice, a biobank organization can become

- Compliant to national (e.g. NCI) and/or international (eg ISBER, OECD) guidelines. The biobank declares compliance, but no external audit is conducted. ISBER has recently developed a self-assessment tool for that purpose.

**and/or**

- Certified according to a national or international (ISO9001:2000) certification norm, by an external body.

**and/or**

- Accredited according to a national or international (ISO17025:2005) accreditation norm, by an external body.
- or**
- Collaborate with an accredited laboratory for quality control of the samples.

## **A. Best Practice / Guidelines:**

**A1. ISBER Best Practices for repositories: Collection, storage, retrieval and distribution of biological materials for research.** Cell Preservation Technology 6(1), 3-58, 2008 <http://www.isber.org/Pubs/BestPractices2008.pdf>

Best Practices for the use of biorepository managers and staff which covers both managerial and technical aspects and goes into practical details on several aspects such as infrastructure, equipment, security, and training. These best practices are applicable to biorepositories which manage either human or non-human origin material; with a focus on the establishment and day-to-day management of a biorepository.

A self-assessment tool will soon be available from ISBER. This self-assessment tool will permit auto-evaluation of compliance with ISBER's Best Practices and will deliver a risk-associated compliance score.

**A2. NCI Best Practices for Specimen Resources.** NCI, Bethesda, MD. Available from <http://biospecimens.cancer.gov/global/pdfs/NCI-Best-Practices-060507.pdf>

These Best Practices have been developed specifically for NCI-supported biorepositories which store biological samples of human origin. Management, quality and protection of data associated with the biological material are the document's main focus. A special section on intellectual property issues has been developed.

**A3. OECD Best Practice Guidelines for Biological Resource Centers – General Best Practice Guidelines for all BRCs.** OECD, Paris, France. Available from <http://www.oecd.org/dataoecd/7/13/38777417.pdf>

The Organization for Economic Cooperation and Development has developed guidelines for repositories of both human and microbial origin samples. The vision of the OECD Best Practices is certification of biorepositories to national and/or international standards/norms. The development of these guidelines has been influenced by the microorganism domain Biological Resource Centres, therefore one of the guideline's main areas of focus is on authentication of biological material.

## **B. Standards / Norms:**

### **International standards:**

**B1. International Standards Organization. ISO 9001:2000 – Quality Management Systems Requirements (Ed 3).**

ISO9001 is a generic management standard that can be applied to any business enterprise, and therefore to any repository. It refers to the organization's structure for managing its processes (activities) that transform inputs of resources into a product (biological sample or derivative) or service (biostorage) which meet the

repository's objectives, such as satisfying the customer's quality requirements or complying with regulations.

ISO9001 certifies that a repository has official written procedures and training documentation in the area of customer service (biostorage), product (biological sample or derivative), processing, analysis, packaging, shipping and accounting. This credential is very customer service oriented. Every complaint is documented, and corrective and preventative measures must be put into place.

As long as a repository is consistent in its documented actions, it can remain ISO9001-certified.

## **B2. EN ISO/IEC 17025 General Requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005 E)**

ISO 17025 was written to incorporate all the ISO9001 requirements that are relevant to the scope of testing services as well as specifying the technical requirements for technical competence of a laboratory. It is applicable to all organizations performing tests. These include, for example, first-, second- and third-party laboratories, and laboratories where testing forms part of inspection and product certification. ISO17025 can be applied to any repository or any laboratory performing tests on the biological samples.

ISO17025 certifies that quality-oriented tests are performed correctly. These tests establish that the product (biological sample or derivative) is a quality product. All aspects of the Quality Control activities are examined by this standard. The qualification, education, and training of all associates are examined against their job responsibilities. Every quality critical specification and even the qualifications of vendors and collaborators are checked.

To be ISO17025 certified, a repository must not only be consistent, but must also be proficient in testing the quality of their products (biological samples or derivatives).

## **B3. ISO Guide 34, General Requirements for the competence of reference material producers, second edition 2000.**

This is an accreditation that deals with Certified Reference Materials manufacturers. All methods that the manufacturer uses to certify their standards must be validated and proven to be accurate. It requires that an uncertainty, which includes all of the sources of error involved in certifying the standards, be reported on the Certificate of Analysis. ISO Guide 34 provides the highest level of Quality Assurance, confidently stating that the manufacturer's standards are produced correctly and competently.

To our knowledge, the only repository accredited to ISO Guide 34 today, is the ATCC.

**National standards:**

**B4. French national norm NF S96-900** “Management System of a Biological Resource Center and Quality of Biological Resources of Human or Microbial Origin”  
Based on ISO9001:2000 and ISO 15189, contains not only “system” requirements, but also some specific “technical” paragraphs on biorepositories.