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Biotechnology — Biobanking — Implementation guide for ISO 20387

Biotechnologie — Biobanking — Guide de mise en oeuvre de l'ISO 20387

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is intended to be a supplement to, rather than a substitute for, ISO 20387; as such, it is not a stand-alone document. It can be helpful for the reader to first review ISO 20387, and refer to this technical report in parallel or thereafter.

The following is noted in regards to the contents of this document:

— A technical report, by definition, contains no requirements. For this reason, the language is intentionally non-prescriptive to avoid the introduction of new requirements.

— This document does not address those clauses and subclauses of ISO 20387 which are considered to be self-explanatory (e.g. ISO 20387:2018, Clauses 1, 2, and 3, and Annexes A, B, and C, etc.).

— Clauses 4, 5, 6 and 7 of this document address some general concepts that underlie the requirements of ISO 20387.

— Clause 8 of this document addresses a selection of the specific requirements in ISO 20387, as noted above.

— Examples are provided throughout the text of this document, and are used to illustrate a non-exhaustive list of possibilities.

— Acronyms are used to simplify the text:

1) BMaD: ISO 20387 defines *biological material* (ISO 20387:2018, 3.7) and *associated data* (ISO 20387:2018, 3.3). For the purpose of this document the terms are combined as "biological materials and/or associated data" (BMaD). There are places where references are made to either biological material or associated data. The term is spelled out in these cases.

2) FIP: *Fit for purpose* or *fitness for intended purpose* (ISO 20387:2018, 3.24) is also defined by ISO 20387. For the purpose of this document this term is denoted by FIP.

The term biobank has been previously defined in a number of ways and no single definition has yet been universally accepted by the scientific community.

ISO 20387 defines a *biobank* (ISO 20387:2018, 3.5) as *a legal entity or part of a legal entity that performs biobanking*, and the term *biobanking* (ISO 20387:2018, 3.6) as *the process of acquisitioning and storing, together with some or all of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data*. For the purposes of this document, the term *biobank* includes the personnel performing biobanking activities on behalf of the biobank, as well as the entity itself.

Biobanks can vary widely in:

— domains that are managed, e.g., human, animal, fungus, microbial, and/or plant, etc. or a multiple of these;

— types of biological material and data in the biobank, e.g. nucleic acids, tissue, etc.;

— activities being performed;

— types of organizations that are involved; and

— structure, governance, oversight, and operation.

At the time of acquisition, biobanks can perform acquisition, processing and storage of BMaD for not-yet-identified future use(s). In these cases, the biobank can acquire the BMaD according to standard operating procedures (SOPs) appropriate for the projected end-use(s). Alternatively, biobanks can acquire BMaD in response to a request from a user. The user can specify criteria for the BMaD and/or SOPs developed or applied for that specific use.

Biobanks can acquire BMaD for investigators studying new methods of collecting, storing, or processing biological materials and the effects of these new methods on various analytes. In these cases, the biobank can tailor the procedures to specifically meet the investigator's needs rather than following widely-accepted SOPs for handling of the BMaD.

Biobanks vary in the types of activities they perform. They can either perform the full range of activities included in the definition of biobanking in ISO 20387, i.e. collecting/acquisitioning, preparing, preserving, testing, storage, analysing and distributing BMaD or a subset of these activities for example collecting/acquisitioning and distributing.

Biobanks can involve different types of organizations. They can be independent legal entities or reside within governmental entities, academic institutions, hospitals, non-profit or commercial organizations.

Biobanks can include multiple sites of operation and can sometimes involve parties at multiple institutions or organizations. In addition, they can involve sites of operations within different regions or sometimes even different countries.

It is up to the biobank to identify the scope of biobank activities for which it wants to implement ISO 20387.

Biotechnology — Biobanking — Implementation guide for ISO 20387

1 Scope

This document provides guidance to biobanks on how to implement the quality management, management, and technical requirements of ISO 20387. It expands on aspects of ISO 20387 and provides examples for illustration purposes. The aim of this document is to assist biobanks to address competency of personnel and appropriate quality of biological material and data collections. This document is equally applicable to newly established and existing biobanks.

This document is applicable to all organizations performing biobanking, including biobanking of biological material from multicellular organisms (e.g., human, animal, fungus and plant) and microorganisms for research and development.

This document does not apply to biological material intended for feed/food production, laboratories undertaking analysis for food/feed production and/or therapeutic use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 20387:2018, *Biotechnology — Biobanking — General requirements for biobanking*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Background information for the development of ISO 20387

4.1 General

ISO 20387 was developed to benefit biobanks of all sizes, types, resources and levels of maturity and/or complexity as covered by the scope.

The motivation for the development of ISO 20387 was to enable robustness and reliability of research undertaken with these BMaD, supporting quality and reproducibility in research and development. This in turn can contribute to increased and broader utilization of biological materials and associated data. It is intended that conformity to ISO 20387 can help demonstrate a commitment to professionalism within biobanking, promoting trust for key stakeholders, such as the public, donors, patients, users, or funders. Benefits such as increased efficiency of biobank operations and interoperability among biobanks, and improved marketability can result from a commitment to ISO 20387. These benefits can also facilitate sustainability at a time of increasing complexity of research requirements.

4.2 Intended audience for ISO 20387 and this document

Because ISO 20387 covers a wide variety of biobanks, the intended audience is broad. This document serves as a tool to assist with implementation of ISO 20387 for the spectrum of biobanks and their activities, such as:

a) multicellular organism (e.g., human, animal, plant) and microorganism biobanks (for implementation and self-assessment);

b) biobanks with a wide range of processes such as collecting/procuring and/or acquiring and receiving, tagging, accessioning/logging, cataloguing/classifying, examining, preparing, preserving, storing, managing data, destroying, packaging as well as safeguarding, distributing and transporting (ISO 20387:2018, 4.1.1);

c) biobanks with a focus on some of the above processes such as acquisition and storage;

d) biobanks at different stages of implementation, such as newly established and existing biobanks;

e) biobanks located in countries of diverse economical scales, such as high, middle or low-income countries;

f) biobanks, assessors and others interested in biobanking conformity assessment schemes, such as first party (self-declaration), second party (contract/agreement), and third party (certification/accreditation) approaches;

g) biobanks that wish to incorporate innovative approaches such as biological material-related data repositories (virtual biobanking).

Biological material from multicellular organisms and microorganisms share many common requirements in the implementation of ISO 20387, but each of these fields has its own needs. Domain specificity can influence biobanking and subsequently the quality management due to the different nature of biological material, special regulations, ethical guidelines, procedural needs or scientific and user-based requirements. More specific biobanking-related standards are currently under development in ISO/TC 276 *Biotechnology*.

4.3 Implementation of ISO 20387

Implementing ISO 20387 and the guidance as set out in this document can provide confidence in the quality of the samples and subsequent data analysis. However, implementing the standard will require resources. A gap analysis of a biobank's current practice against these standard requirements can be beneficial, and can lead to a plan for implementation of requirements. This can be done in a phased approach and can take some time, particularly for smaller organizations where resources can be constrained.

Each biobank can identify and implement corresponding requirements according to its defined and documented individual activities (ISO 20387:2018, 5.7). ISO 20387, as a conformity assessment enabling standard, can be described as having three types of requirements – general, QMS, and competence:

a) General requirements are found in all standards by definition. By demonstrating that a product or service meets specific requirements in a standard, a potential user has a basis for assessing a product's fitness for an intended purpose.

b) A Quality Management System (QMS) addresses quality policies and objectives in its processes, thus enabling the demonstration of efficient use of resources, improved risk management, and increased robustness of practices, plans, and records, all of which serves to further increase user confidence.

c) Technical competence adds the assessment of personnel to the evaluation, and provides means of demonstrating that an entity has the ability to apply knowledge and skill to successfully achieve an intended result, such as meeting the requirements in a standard. Technical competence provides opportunity to the biobank to demonstrate that not only is it able to meet requirements, but its

personnel has the ability to consistently support the quality environment to promote further user confidence.

The combined implementation of all three elements above can result in increased robustness and confidence in biobanking operations and the resultant biobanking output. It is recognized that the implementation of all these elements can be both complex and expensive, and the pursuit of all three of these elements may or may not have sufficient business justification from the point of view of the biobank. It can be prudent to build up the implementation of ISO 20387 in steps. Therefore, as a step towards implementation of some parts or all of the standard, a biobank can choose to address certain requirements earlier than others, e.g.:

— Emerging biobanks have the opportunity to initially implement only certain sections of ISO 20387 and can then later implement other sections.

— Specialized biobanks can decide to implement only the portions of ISO 20387 (ISO 20387:2018, 5.7) that are relevant to their activities.

— Biobanks that have already implemented a robust QMS can choose to complement their efforts with requirements of ISO 20387.

Biobanks can choose to differentiate themselves from competitors by pursuing the demonstration of technical competence (e.g., through third party conformity assessment, or accreditation).

Note that the technical competence element cannot be implemented in isolation from the other two elements, as the assessment of competence can only be done if there are other requirements to assess.

5 Fitness for the intended purpose (FIP) (ISO 20387:2018, 3.24) in biobanking

5.1 General

The driving force for the development of ISO 20387 was the necessity for BMaD of appropriate quality for an intended purpose, to enable robust and reliable research and development. While the concept of *fitness for an intended purpose* (FIP) can be new to some, it underpins many of the requirements in ISO 20387. Quality is often considered a key target for the individual outputs from biobanks. Fitness for the intended purpose is broader in that it incorporates quality management and quality control, specifically targeting an intended purpose or end-use. This can extend to legal or ethical requirements, resource availability, biological characteristics of the BMaD, and other factors.

As the biobank evolves its understanding of potential FIP, it can also evolve the way it treats the BMaD, thus adding value in the context of an intended purpose. The user, when known, can also provide input.

The term 'fit for purpose', or 'fitness for the intended purpose', is defined in ISO 20387:2018 (3.24).

5.2 Fitness for the intended purpose and biological material and/or associated data (BMaD) life cycle

Considerations related to FIP can come into play during the design and various stages of biobanking. Figure 1 traces the progression of BMaD and the potential for continual revisions of the definition of FIP. During all stages of the life cycle, processing and analysis are important as they contribute to the FIP criteria. During all steps, relevant documentation will be maintained.

While Figure 1 is drawn as a linear progression, steps can be repeated, skipped, or ordered differently than shown. This customization of BMaD and its intended end-use can be further supported by continual refinement related to FIP by both the biobank and the user (or the projected range of intended end-use where a user has not yet been identified).

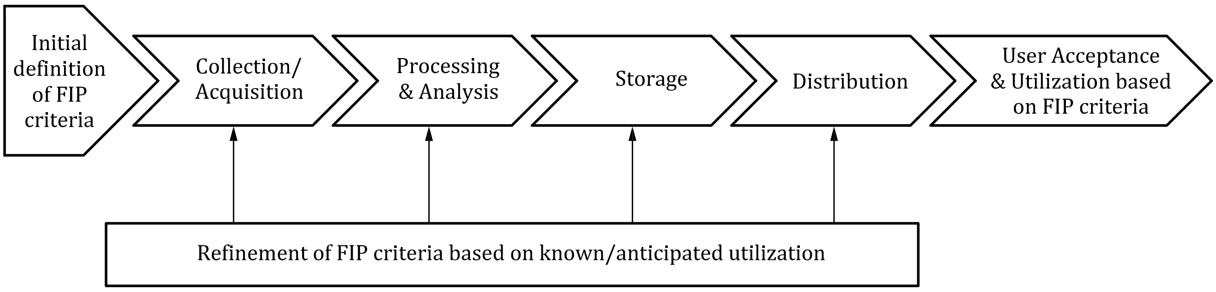

Figure 1 — The progression of BMaD and associated FIP criteria over its life cycle

Biological materials and associated data are subject to research, development and/or many other forms of utilization over time. The range of these potential uses is dependent on the known and documented condition of the biological materials and associated data. BMaD users and biobanks can play complementary roles during this life cycle.

Biobanks usually cover only parts of the BMaD life cycle and contribute mutually with the users of BMaD to their sustainable research and utilization. Each biobank has an individual share on the life cycle.

While BMaD is under the control of the biobank, there is the opportunity to support and add value by a range of means, such as tightly controlling the environment, enriching data and analysis, maintaining a chain of custody, and minimizing degradation through the use of appropriate long-term preservation and storage. The addition of value through these activities can extend the useful life of BMaD and broaden the range of potential end-uses, i.e., expand BMaD fitness for the intended purpose. Whether the specific end-use and/or user is known or unknown, a biobank can still establish and refine FIP criteria and/or activities over time, focusing on BMaDs and the range of potential end-uses.

From a user's perspective, BMaD life cycle can take a wide range of paths, but often begins with identification or sourcing of materials based on a research purpose or intended application and leading to BMaD utilization — the criteria that are set for the BMaD relate to fitness for the intended purpose. The user can design its research plan to tie requirements to intended end-use, and later assess both whether established requirements have been met, and whether these established requirements render the BMaD as fit for purpose for the intended end-use.

Early and/or iterative communications between the biobank and end-user can often result in BMaD that are optimally fit for an intended end-use.

Examples of possible pre-arranged requirements to ensure fitness for the intended purpose are documented in ISO 20387:2018, Annexes A and B, and can include choice of BMaD (including selection of specific data variables), testing methods, storage conditions, handling, and choice of consumables, etc.

5.3 Factors affecting fitness for the intended purpose

Given the wide variety of biobanks, their nature and purpose, and the biological materials and associated data therein, the factors affecting FIP will be context-specific. Requirements (or anticipated requirements) to ensure FIP can be affected by study design, analytical techniques, ethical/legal, and other factors.

EXAMPLE 1 If the purpose of the biobank is to provide biological material from which DNA can be extracted for molecular analysis, then handling the biological material according to International Standards (ISO 20166-3, CEN/TS 16826-3 (soon ISO 20184-3), ISO 20186-3, CEN/TS 17305 or best practices for molecular techniques can help to ensure fitness for purpose (unless the end-use involves evaluation of exploratory approaches for DNA extraction).

Considerations for the determination of FIP for a particular use might include pre-analytical variables, the characterization of the biological material, the level of understanding of the specimen's and its data's provenance, and/or other factors as appropriate.

