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Biotechnology — Biobanking — General requirements for the validation and verification of processing methods for biological material in biobanks

*Biotechnologie — Biobanques — Exigences générales pour la
validation et la vérification des méthodes de traitement du matériel
biologique dans les biobanques*



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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.

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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.

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Introduction

Biobanks, producing viable and non-viable biological materials (human, animal, plant, microbial) for research purposes, within biotechnology, use processing methods. Many biobanks include processing laboratories where processing methods are performed and biological materials are produced as an output. Examples of widely used processing methods, applied by biobank laboratories, include DNA, RNA and protein extractions from blood, tissue, seeds, bacteria, or other biological material, or primary cell cultures. An example for the validation of a processing method is provided in Reference [27]. Biobank laboratories are not always equipped to perform testing methods, which are required for annotation or qualification of the biological material output.

This document sets out specific requirements for validation of processing methods. It is intended to help biobank laboratories who perform processing of biological materials, whether they perform themselves testing activities on the biological materials they have produced, or not. It enables validation of processing methods, complements the quality management system of any biobank laboratory performing processing of biological materials and gives more credibility to such an organization. It is understood that while the term “method” used in ISO/IEC 17025 corresponds to “testing method” or “calibration method”, a fundamental distinction exists between “processing methods” where the output is a biological material and “testing methods” where the output is a test result (see [Annex A](#)). It is understood that validation of processing methods performed by accredited testing laboratories, who test the biological material output themselves, is already included in their accreditation scope.

Validation of a processing method encompasses confirmation of the fitness for purpose of the output biological material, assessment of the homogeneity and stability of the biological material, and assessment of the reproducibility and robustness of the processing method. This validation requires testing in order to assess/measure the qualitative or quantitative properties of the biological material. This testing will lead to the assessment of the fitness for purpose, the reproducibility, and the robustness of the processing method. Examples of such properties are: viability, purity, pluripotency, molecular integrity, concentration, growth capacity, etc.