



ACCREDITATION CRITERIA FOR BIOBANKING

AC802

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PREFACE

The attached accreditation criteria have been issued to provide all interested parties with guidelines on implementing performance features of the applicable standards referenced herein. The criteria were developed and adopted following public hearings conducted by the International Accreditation Service, Inc. (IAS), Accreditation Committee and are effective on the date shown above. All accreditations issued or reissued on or after the effective date must comply with these criteria. If the criteria are an updated version from a previous edition, solid vertical lines (|) in the outer margin within the criteria indicate a technical change or addition from the previous edition. Deletion indicators (→) are provided in the outer margins where a paragraph or item has been deleted if the deletion resulted from a technical change. These criteria may be further revised as the need dictates.

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1. INTRODUCTION

- 1.1. **Scope:** These criteria set forth the requirements for obtaining and maintaining International Accreditation Service, Inc. (IAS), Biobank accreditation. These criteria supplement the IAS Rules of Procedure for Biobanking Accreditation.
- 1.2. **Normative and Reference Documents:** Publications listed below refer to current editions (unless otherwise stated).
 - 1.2.1. ISO 20387, Biotechnology – Biobanking – General requirements for biobanking
 - 1.2.2. ISO/TR 22758, Biotechnology – Biobanking – Implementation guide for ISO 20387
 - 1.2.3. ILAC P10, ILAC Policy on Metrological Traceability of Measurements Results

2. DEFINITIONS

- 2.1. Applicable definitions of ISO 20387
- 2.2. Applicable definitions of ISO/IEC 17000 series apply.

3. ELIGIBILITY

Accreditation services are available to Biobanking facilities that:

- 3.1. Perform biobanking, including biobanking of biological material from multicellular organisms (e.g. human, animal, fungus and plant) and microorganisms.
- 3.2. Following activities of biobanking are considered for accreditation: Acquisition, Collection, Distribution, Preparation/Processing, Preservation, Storage, and Testing/Examination.

Note 1: Exclusions as noted in Scope of ISO 20387:2018

4. REQUIRED BASIC INFORMATION

Biobanking facilities must demonstrate compliance with the following requirements:

- 4.1. ISO 20387:2018, Biotechnology – Biobanking – General requirements for biobanking
- 4.2. IAS Rules of Procedure for Biobanking Accreditation.
- 4.3. ILAC-P10, ILAC Policy on Metrological Traceability of Measurement Results.
- 4.4. Relevant IAS policy documents.
 - 4.4.1. IAS/ADM/044 IAS Policy on Relocation of Accredited Organizations
 - 4.4.2. IAS/ADM/092 IAS Policy on the use of IAS endorsement by Accredited Organizations in Restricted Zones.

5. ADDITIONAL INFORMATION (AS APPLICABLE)

Regulatory Requirements: Regulatory entities may place specific compliance requirements on biobanking facilities. If such a facility is required to comply with the regulatory requirements as may be applicable, they must agree to comply with additional requirements.

Biobanking facilities must comply with regulatory requirements of Authority Having Jurisdiction (AHJ) or other regulatory entities, including specific compliance requirements for qualification, licensing, etc., of personnel and operation of biobanking facilities.

6. LINKS TO ADDITIONAL REFERENCES

- 6.1 Asia Pacific Accreditation Cooperation – www.apac-accreditation.org
- 6.2 International Laboratory Accreditation Cooperation – www.ilac.org
- 6.3 International Organization for Standardization – www.iso.org
- 6.4 International Accreditation Service – www.iasonline.org