



**International Accreditation Service, Inc.**  
3060 Saturn Street, Suite 100  
Brea, CA 92821 USA  
t: 562.364.8201  
t: 866.427.4422  
www.iasonline.org

August 10, 2022

**TO: IAS ACCREDITED ORGANIZATIONS AND OTHER INTERESTED PARTIES.**

**SUBJECT: Proposed Accreditation Criteria for Accreditations of Biobanking, AC802-202210 (DK/MS)**

**Hearing Information:**

IAS Accreditation Committee  
Thursday, October 6, 2022  
8:00 am (Pacific Standard Time)  
WebEx Meeting – Refer to IAS website for details.

Dear Madam or Sir:

IAS is proposing a new Accreditation Criteria for Accreditation of Biobanking, AC802. This criteria is primarily based on ISO 20387 *General requirements for biobanking* published in 2018. The International Laboratory Accreditation Cooperation (ILAC) has recently extended its portfolio to include accreditation of Biobanking facilities. IAS is proposing this criteria to meet the needs of accreditation of Biobanking facilities.

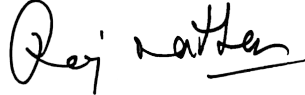
You are cordially invited to submit written comments, or to attend the WebEx committee hearing and present verbal comments. Written comments will be forwarded to the committee, **prior to the hearing**, if received by September 6, 2022. For your convenience, a comment form is provided. The link can be found on the Accreditation Committee meeting page on the IAS website, [www.iasonline.org](http://www.iasonline.org). Comments may be postal mailed to the address above or emailed to [iasinfo@iasonline.org](mailto:iasinfo@iasonline.org).

Any written material submitted for committee consideration will be available for public distribution as set forth in the Rules of Procedure for Accreditation Committee Meetings found on the IAS website. Since this is a web meeting, comments for public distribution will be placed on the IAS website prior to the meeting.

Your cooperation is requested in forwarding to IAS, as noted above, all material directed to the committee. Prior to the hearing, parties interested in the deliberations of the committee should refrain from communicating, whether in writing or verbally, with committee members regarding agenda items. The committee reserves the right to refuse communications that do not comply with this request.

If you have any questions, please contact IAS at 562-364-8201 ext. 3309. You may also reach us by e-mail at [iasinfo@iasonline.org](mailto:iasinfo@iasonline.org).

Yours very truly,

A handwritten signature in black ink that reads "Raj Nathan". The signature is written in a cursive style with a horizontal line underneath the name.

Raj Nathan  
President

Enclosures: Proposed AC802

cc: Accreditation Committee



1                                   **PROPOSED ACCREDITATION CRITERIA FOR BIOBANKING**

2  
3                                   **AC802**

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5  
6                                   **Proposed October 6, 2022**

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10                                  **PREFACE**

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12    The attached accreditation criteria have been proposed to provide all interested parties with an  
13    opportunity to comment. These criteria may be further revised as needed. The criteria are  
14    developed and adopted following public hearings conducted by the International Accreditation  
15    Service, Inc. (IAS), Accreditation Committee and are effective on the first of the month following  
16    approval by the Accreditation Committee, but no earlier than 30 days following the approval.

17                   **PROPOSED REVISION TO THE ACCREDITATION CRITERIA FOR BIOBANKING**

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19   **1. INTRODUCTION**

20       1.1. **Scope:** These criteria set forth the requirements for obtaining and maintaining International  
21           Accreditation Service, Inc. (IAS), Biobank accreditation. These criteria supplement the IAS Rules  
22           of Procedure for Biobanking Accreditation.

23       1.2. **Normative and Reference Documents:** Publications listed below refer to current editions  
24           (unless otherwise stated).

25           1.2.1. ISO 20387 – Biotechnology – Biobanking – General requirements for biobanking.

26           1.2.2. ISO/TR 22758 – Biotechnology – Biobanking – Implementation guide for ISO 20387.

27           1.2.3. ILAC P10 – ILAC Policy on Metrological Traceability of Measurements Results

28   **2. DEFINITIONS**

29       2.1. Applicable definitions of ISO 20387

30       2.2. Applicable definitions of ISO/IEC 17000 series apply.

31   **3. ELIGIBILITY**

32   Accreditation services are available to Biobanking facilities that:

33       3.1. Perform biobanking, including biobanking of biological material from multicellular organisms (e.g.  
34           human, animal, fungus and plant) and microorganisms.

35       3.2. Following activities of biobanking are considered for accreditation: Acquisition, Collection,  
36           Distribution, Preparation/Processing, Preservation, Storage, and Testing/Examination.

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

38   **4. REQUIRED BASIC INFORMATION**

39   Biobanking facilities must demonstrate compliance with the following requirements:

40       4.1. ISO 20387:2018 – Biotechnology – Biobanking – General requirements for biobanking

41       4.2. IAS Rules of Procedure for Biobanking Accreditation.

42       4.3. ILAC-P10, ILAC Policy on Metrological Traceability of Measurement Results.

43       4.4. Relevant IAS policy documents.

44           4.4.1. IAS/ADM/044 IAS Policy on Relocation of Accredited Organizations

45           4.4.2. IAS/ADM/092 IAS Policy on the use of IAS endorsement by Accredited Organizations in  
46           Restricted Zones.

47   **5. ADDITIONAL INFORMATION (AS APPLICABLE)**

48 5.1. **Regulatory Requirements:** Regulatory entities may place specific compliance requirements on  
49 biobanking facilities. If such a facility is required to comply with the regulatory requirements as  
50 may be applicable, they must agree to comply with additional requirements.

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

## 55 6. LINKS TO ADDITIONAL REFERENCES

56 6.1 Asia Pacific Accreditation Cooperation – [www.apac-accreditation.org](http://www.apac-accreditation.org)

57 6.2 International Laboratory Accreditation Cooperation – [www.ilac.org](http://www.ilac.org)

58 6.3 International Organization for Standardization – [www.iso.org](http://www.iso.org)

59 6.4 International Accreditation Service – [www.iasonline.org](http://www.iasonline.org)