



ACCREDITATION CRITERIA FOR REFERENCE MATERIAL PRODUCER

AC784

June 11, 2025
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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, refer to table of revisions at the end of the criteria. These criteria may be further revised as the need dictates.

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ACCREDITATION CRITERIA FOR REFERENCE MATERIAL PRODUCER

1.0 INTRODUCTION

- 1.1. **Scope:** These criteria set forth the requirements for obtaining and maintaining International Accreditation Service, Inc. (IAS), Reference Material Producer (RMP) accreditation. These criteria supplement the IAS Rules of Procedure for Reference Material Producer Accreditation.
- 1.2. **Normative and Reference Documents:** Publications listed below refer to current editions (unless otherwise stated).
 - 1.2.1. ISO/IEC Standard 17034: 2016, General requirements for the competence of reference material.
 - 1.2.2. ISO/IEC Standard 17025:2017, General requirements for the competence of testing and calibration laboratories.
 - 1.2.3. ISO Guide 35: 2017, Reference materials — Guidance for characterization and assessment of homogeneity and stability.
 - 1.2.4. ISO 33405:2024, Reference Materials. Approaches for Characterization and Assessment of Homogeneity and Stability.
 - 1.2.5. ISO Guide 31: 2015, Reference materials — Contents of certificates, labels and accompanying documentation.
 - 1.2.6. ISO 33401:2024, Reference materials – Contents of Certificates, Labels and Accompanying Documentation.
 - 1.2.7. ISO 33406:2024, Approaches for the Production of Reference Materials with Qualitative Properties.
 - 1.2.8. ISO 33407:2024, Guidance for the Production of Pure Organic Substance Certified Reference Materials.
 - 1.2.9. ISO Guide 30: 2015, Reference materials - Selected terms and definitions.
 - 1.2.10. ILAC P9, ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing.
 - 1.2.11. ILAC P10, ILAC Policy on Metrological Traceability of Measurement Results.
 - 1.2.12. ISO/IEC Standard 17000, Conformity assessment – Vocabulary and general principles.
 - 1.2.13. IAS/CL/014, IAS Policy on Calibration, Traceability and Measurement Uncertainty for Calibration Laboratories.
 - 1.2.14. IAS/TL/025, IAS Policy on Calibration, Traceability and Measurement Uncertainty for Testing Laboratories.

- 1.2.15. IAS/ADM/109, IAS Policy on Establishing Metrological Traceability of Measurement for Accreditation of Proficiency Testing Providers and Reference Material Producers.
- 1.2.16. IAS Transition Policy on new ISO 334 series standards.

2.0 DEFINITIONS

Applicable definitions of ISO/IEC Standard 17000 series apply.

3.0 ELIGIBILITY

Accreditation services are available to organizations and/or laboratories that:

- 3.1. Have effectively implemented the management system as per ISO 17034:2016,
- 3.2. Assign property values and the associated uncertainties (where applicable) of reference materials to establish metrological traceability of reference materials (RM) and certified reference materials (CRM), and
- 3.3. Determine the shelf life of reference materials on the basis of stability studies conducted.

4.0 REQUIRED BASIC INFORMATION

RMP must demonstrate compliance with the following requirements:

- 4.1. ISO/IEC Standard 17034: 2016, General requirements for the competence of reference material,
- 4.2. ISO Guide 35: 2017, Reference materials – Guidance for characterization and assessment of homogeneity and stability,
- 4.3. ISO 33405:2024, Reference Materials. Approaches for Characterization and Assessment of Homogeneity and Stability,
- 4.4. ISO Guide 31: 2015, Reference materials – Contents of certificates, labels and accompanying documentation,
- 4.5. ISO 33401:2024, Reference materials – Contents of Certificates, Labels and Accompanying Documentation,
- 4.6. ISO 33406:2024, Approaches for the Production of Reference Materials with Qualitative Properties,
- 4.7. ISO 33407:2024, Guidance for the Production of Pure Organic Substance Certified Reference Materials,
- 4.8. ISO Guide 30: 2015, Reference materials – Selected terms and definitions,
- 4.9. IAS/CL/014, IAS Policy on Calibration, Traceability and Measurement Uncertainty for Calibration Laboratories,

- 4.10. IAS/TL/025, IAS Policy on Calibration, Traceability and Measurement Uncertainty for Testing Laboratories,
- 4.11. IAS/ADM/109, IAS Policy on Establishing Metrological Traceability of Measurement for Accreditation of Proficiency Testing Providers and Reference Material Producers,
- 4.12. IAS Rules of Procedure for Reference Materials Producer.

5.0 ADDITIONAL INFORMATION (AS APPLICABLE)

- 5.1. **Internal characterization:** Where applicable, organizations performing internal characterization (testing) and/or calibration are required to be in compliance with the requirements of ISO/IEC Standard 17025, IAS Accreditation Criteria AC89 (Testing) and AC204 (Calibration), as applicable.

Additionally, the following information must be provided or made available to IAS:

- 5.1.1. List of equipment that is calibrated internally for the production of reference material,
 - 5.1.2. Specific procedures used for internal calibrations of equipment,
 - 5.1.3. Training and qualification records of personnel qualified to perform the internal calibration and/or characterization,
 - 5.1.4. The internal measurement activity shall be audited as part of the organization's internal audit,
 - 5.1.5. The laboratory shall participate in proficiency testing, where available, for its testing activity. The laboratory may also choose other options as indicated in Clause 7.7.1 of ISO/IEC Standard 17025.
- 5.2. **Subcontracting:** A competent subcontractor used by the RMP is not limited to an accredited IAS CAB or CAB accredited by a signatory to ILAC Mutual Recognition Arrangement.
- 5.3. **Regulatory Requirements**
 - 5.3.1. Regulatory entities may place specific compliance requirements on RMP organizations. If an RMP is required to comply with the applicable regulatory requirements, they must agree to comply with additional requirements.
 - 5.3.2. RMP 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 RMP.

6.0 LINKS TO ADDITIONAL REFERENCES

- 6.1 Asia Pacific Accreditation Cooperation – www.apac-accreditation.org
- 6.2 [Asia Pacific Legal Metrology Forum - www.aplmf.org](http://www.aplmf.org)
- 6.3 International Laboratory Accreditation Cooperation – www.ilac.org

- 6.4 International Organization for Standardization – www.iso.org
- 6.5 International Electrotechnical Commission – www.iec.ch
- 6.6 International Organization of Legal Metrology – www.oiml.org
- 6.7 International Accreditation Service – www.iasonline.org
- 6.8 ISO/TC 334 Reference Materials – <https://committee.iso.org/home/tc334>

These criteria were previously issued September 2019.

Revision Date	Summary of Changes
June 11, 2025	<ul style="list-style-type: none">• Under Reference Documents and Required Basic Information, added: ISO 33405, 33401, 33406, and 33407.• Corrected titles of ILAC P9 and P10.• Under Reference Documents and Required Basic Information, added: IAS/CL/014, IAS/TL/025, IAS/ADM/109, and IAS Transition Policy• Under Links, added: ISO/TC 334.