

April 21, 2025

TO: IAS REFERENCE MATERIAL PRODUCERS AND OTHER INTERESTED PARTIES.

SUBJECT: <u>Proposed Revisions to the Accreditation Criteria for Reference Material</u> <u>Producer, AC784-202506-R0 (LHDB/MS)</u>

Hearing Information:

IAS Accreditation Committee Wednesday, June 11, 2025 8:30 am (Pacific Time Zone) Webex Meeting – Refer to IAS website for details.

Dear Madam or Sir:

Proposed Revisions to the Accreditation Criteria for Reference Material Producer, (AC784) have been placed on the agenda for committee consideration at the above-noted meeting.

1. Under 'Normative and Reference Documents' and 'Required Basic Information' sections the following policy updates and new standards have been included:

Lines 37-38, 41-46, 77-78, and 81-86:

- ISO 33405:2024 -Reference materials Approaches for characterization and assessment of homogeneity and stability.
- ISO 33401:2024 Reference materials Contents of certificates, labels and accompanying documentation.
- ISO 33406: 2024 Approaches for the production of reference materials with qualitative properties.
- ISO 33407:2024 Guidance for the production of pure organic substance certified reference materials.

Lines 48-50:

• Update the title of reference in accordance with latest ILAC P9 and ILAC P10.

Lines 53-59 and 88-93:

- IAS/CL/014: IAS Policy on Calibration, Traceability and Measurement Uncertainty for Calibration Laboratories.
- IAS/TL/025: IAS Policy on Calibration, Traceability and Measurement Uncertainty for Testing Laboratories.

- IAS/ADM/109: IAS Policy on Establishing Metrological Traceability of Measurement for Accreditation of Proficiency Testing Providers and Reference Material Producers.
- IAS Transition Policy established for the transition of RMPs to the relevant ISO 334 series of standards.

Line 131:

• Addition of ISO/TC 334 Reference Materials weblink

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 **May 30, 2025**. 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. Comments must be emailed to <u>iasinfo@iasonline.org</u>.

Parties interested in proposed revised criteria may deliver written communications and submissions regarding such proposed criteria to IAS within approximately 30 days of posting of the public notice on the IAS website. The committee shall be informed of all pertinent written communications received by IAS. Any relevant communication and changes to a criteria arising from the written communication/submission shall be posted to the IAS website prior to the meeting.

Participants at the accreditation committee meetings shall have the opportunity to speak on the proposed criteria to provide information to the committee. Committee meetings are generally held by electronic means. Participants are responsible to ensure access to appropriate computer equipment, software, and internet connectivity to ensure effective participation during 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. You may also reach us by e-mail at <u>iasinfo@iasonline.org</u>.

Yours very truly,

International Accreditation Service

IAS Management

Enclosures: Proposed Revised AC784

cc: Accreditation Committee



PROPOSED REVISIONS TO THE ACCREDITATION CRITERIA FOR REFERENCE 1 2 MATERIAL PRODUCER 3 4 AC784 5 6 7 Proposed June 11, 2025 8 9 (Effective xxxx) 10 11 12 PREFACE 13 14 The attached accreditation criteria have been proposed to provide all interested parties with an opportunity to comment. These criteria may be further revised as needed. The 15 criteria are developed and adopted following public hearings conducted by the 16 International Accreditation Service, Inc. (IAS), Accreditation Committee and are 17 18 effective on the first of the month following approval by the Accreditation Committee, but no earlier than 30 days following the approval. 19

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21		PROPOSED REVISIONS TO THE ACCREDITATION CRITERIA FOR REFERENCE MATERIAL
22		PRODUCER
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24	1.	INTRODUCTION
25		1.1. Scope: These criteria set forth the requirements for obtaining and maintaining International
26		Accreditation Service, Inc. (IAS), Reference Material Producer (RMP) accreditation. These
27		criteria supplement the IAS Rules of Procedure for Reference Material Producer Accreditation.
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29		1.2. Normative and Reference Documents: Publications listed below refer to current editions
30		(unless otherwise stated).
31		1.2.1. ISO/IEC Standard 17034: 2016, General requirements for the competence of reference
32		material
33		1.2.2. ISO/IEC Standard 17025:2017, General requirements for the competence of testing and
34		calibration laboratories.
35		1.2.3. ISO Guide 35: 2017, Reference materials - Guidance for characterization and
36		assessment of homogeneity and stability
37		1.2.4. ISO 33405:2024, Reference Materials. Approaches for Characterization and
38		Assessment of Homogeneity and Stability
39		<u>1.2.5.</u> ISO Guide 31: 2015, Reference materials — Contents of certificates, labels and
40		accompanying documentation
41		1.2.6. ISO 33401:2024, Reference materials – Contents of Certificates, Labels and
42		Accompanying Documentation
43		1.2.7. ISO 33406:2024, Approaches for the Production of Reference Materials with Qualitative
44		Properties
45		1.2.4.1.2.8. ISO 33407:2024, Guidance for the Production of Pure Organic Substance
46		Certified Reference Materials
47		1.2.5.1.2.9. ISO Guide 30: 2015, Reference materials - Selected terms and definitions
48		1.2.6.1.2.10. ILAC-P9, ILAC Policy for Participation in Proficiency Testing and/or
49		Interlaboratory comparisons other than Proficiency Testing Activities.
50		1.2.7.1.2.11. ILAC P10:01/2013, ILAC Policy on Metrological Traceability of Measurement
51		Results
52		<u>1.2.12.</u> ISO/IEC Standard 17000, Conformity assessment – Vocabulary and general principles
53		1.2.13.IAS/CL/014, IAS Policy on Calibration, Traceability and Measurement Uncertainty for
54		Calibration Laboratories
55		1.2.14.IAS/TL/025, IAS Policy on Calibration, Traceability and Measurement Uncertainty for
56		Testing Laboratories

57		1.2.15.IAS/ADM/109, IAS Policy on Establishing Metrological Traceability of Measurement for
58		Accreditation of Proficiency Testing Providers and Reference Material Producers
59		1.2.8.1.2.16. IAS Transition Policy on new ISO 334 series standards
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61	2.	DEFINITIONS
62		Applicable definitions of ISO/IEC Standard 17000 series apply.
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64	3.	ELIGIBILITY
65		Accreditation services are available to organizations and/or laboratories that:
66		3.1. Have effectively implemented the management system as per ISO 17034:2016,
67		3.2. Assign property values and the associated uncertainties (where applicable) of reference
68		materials to establish metrological traceability of reference materials (RM) and certified reference
69		materials (CRM), and
70		3.3. Determine the shelf life of reference materials on the basis of stability studies conducted.
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72	4.	REQUIRED BASIC INFORMATION
73		RMP must demonstrate compliance with the following requirements:
74		4.1. ISO/IEC Standard 17034: 2016, General requirements for the competence of reference material
75		4.2. ISO Guide 35: 2017, Reference materials — Guidance for characterization and assessment of
76		homogeneity and stability
77		4.2.4.3. ISO 33405:2024, Reference Materials. Approaches for Characterization and Assessment
78		of Homogeneity and Stability
79		4.4. ISO Guide 31: 2015, Reference materials — Contents of certificates, labels and accompanying
80		documentation
81		4.5. ISO 33401:2024, Reference materials – Contents of Certificates, Labels and Accompanying
82		Documentation
83		4.6. ISO 33406:2024, Approaches for the Production of Reference Materials with Qualitative
84		Properties
85		4.3.4.7. ISO 33407:2024, Guidance for the Production of Pure Organic Substance Certified
86		Reference Materials
87		4.8. ISO Guide 30: 2015, Reference materials - Selected terms and definitions
88		4.9. IAS/CL/014, IAS Policy on Calibration, Traceability and Measurement Uncertainty for Calibration
89		Laboratories
90		4.10. IAS/TL/025, IAS Policy on Calibration, Traceability and Measurement Uncertainty for
91		Testing Laboratories
92		4.4.4.11. IAS/ADM/109, IAS Policy on Establishing Metrological Traceability of Measurement for
93		Accreditation of Proficiency Testing Providers and Reference Material Producers
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- 4.5.4.12. IAS Rules of Procedure for Reference Materials Producer.
- 95 5. ADDITIONAL INFORMATION (AS APPLICABLE) 96 97 5.1. Internal characterization: Where applicable, organizations performing internal characterization 98 (testing) and/or calibration are required to be in compliance with the requirements of ISO/IEC 99 Standard 17025, IAS Accreditation Criteria AC89 (Testing) and AC204 (Calibration), as 100 applicable. 101 Additionally, the following information must be provided or made available to IAS: 102 5.1.1. List of equipment that is calibrated internally for the production of reference material. 103 5.1.2. Specific procedures used for internal calibrations of equipment. 104 5.1.3. Training and gualification records of personnel gualified to perform the internal 105 calibration and/or characterization. 106 5.1.4. The internal measurement activity shall be audited as part of the organization's internal 107 audit. 108 5.1.5. The laboratory shall participate in proficiency testing, where available, for its testing 109 activity. The laboratory may also choose other options as indicated in Clause 7.7.1 of 110 ISO/IEC Standard 17025. 111 112 5.2. Subcontracting: A competent subcontractor used by the RMP is not limited to an accredited 113 IAS CAB or CAB accredited by a signatory to ILAC Mutual Recognition Arrangement. 114 115 5.3. Regulatory Requirements 116 5.3.1. Regulatory entities may place specific compliance requirements on RMP organizations. 117 If an RMP is required to comply with the applicable regulatory requirements, they must 118 agree to comply with additional requirements. 119 5.3.2. RMP must comply with regulatory requirements of Authority Having Jurisdiction (AHJ) 120 or other regulatory entities, including specific compliance requirements for qualification, 121 licensing, etc., of personnel and operation of RMP. 122 123 6. LINKS TO ADDITIONAL REFERENCES 124 6.1 Asia Pacific Accreditation Cooperation - www.apac-accreditation.org 125 6.2 Asia Pacific Legal Metrology Forum - www.aplmf.org 126 6.3 International Laboratory Accreditation Cooperation – www.ilac.org 127 6.4 International Organization for Standardization - www.iso.org 128 6.5 International Electrotechnical Commission - www.iec.ch 129 6.6 International Organization of Legal Metrology - www.oiml.org 130 6.7 International Accreditation Service – www.iasonline.org

131 6.76.8 ISO/TC334 Reference Materials – https://committee.iso.org/home/tc334

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134 <u>These criteria were previously issued September 2019.</u>