



International Accreditation Service, Inc.
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July 15, 2019

TO: IAS-APPLICANT REFERENCE MATERIAL PRODUCERS AND OTHER INTERESTED PARTIES

SUBJECT: Proposed Accreditation Criteria for Reference Material Producers, Subject AC784-0919-0919-R1 (MS)

Hearing Information:

IAS Accreditation Committee
Monday, September 16, 2019
8:00 a.m.

Fullerton Marriott at California State University

2701 Nutwood Avenue
Fullerton, CA 92831
(714) 738-7800

Dear Madam or Sir:

The proposed IAS Accreditation Criteria for Reference Material Producers (RMP), AC784, has been placed on the agenda for committee consideration at the above-noted meeting.

In general, the program provides users of reference materials, such as testing and calibration laboratories, with confidence that reference materials and certified reference materials produced in accordance with specified technical and management system requirements are of suitable quality. This ensures that method validation, calibration and measurement traceability can be established when using reference materials produced for its intended purpose within the associated measurement uncertainty range.

RMP accreditation provides assurance in the production, labeling, and assignment of property values to materials, including stability and homogeneity. Many RMPs hold accreditation to both ISO/IEC 17025 and ISO 17034.

This new program operates on the technical requirements based on:

- ISO/IEC 17034:2016, General requirements for the competence of reference material producers
- ISO Guide 35:2017, Reference materials -- Guidance for characterization and assessment of homogeneity and stability

You are cordially invited to submit written comments, or to attend the committee hearing and present verbal comments. Written comments will be forwarded to the committee, **prior to the hearing**, if received by **August 28, 2019**. Please use the comment form link found on the Accreditation Committee meeting page on the IAS website, www.iasonline.org. Comments may be postal mailed to the address above or emailed to iasinfo@iasonline.org.

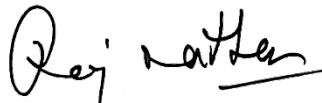
Any written material submitted for committee consideration will be available for public distribution as set forth in Section 4.0 of the Rules of Procedure for Accreditation Committee Meetings (copy enclosed).

Visual aids (including, but not limited to, charts, slides, videos, or presentation software) for viewing at meetings will be permitted only if the presenter provides to IAS, before the presentation, a copy of the visual aid(s) in a medium that can be retained by IAS with its record of the meeting, and that can also be provided to interested parties.

Your cooperation is requested in forwarding to the **Brea** office, 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 Mohan Sabaratnam, accreditation officer, at 562-364-8201, extension 3337, or the undersigned at 562-364-8201. You may also reach us by e-mail at iasinfo@iasonline.org.

Yours very truly,



Raj Nathan
President

RN/nl

Enclosures

cc: Accreditation Committee



RULES OF PROCEDURE FOR ACCREDITATION COMMITTEE MEETINGS

1 1.0 PURPOSE

2 The purpose of the Accreditation Committee and its meetings is to safeguard IAS' impartiality to monitor the work of and
3 to approve accreditation criteria for International Accreditation Service, Inc. (IAS).

4 The committee meetings, which are open public hearings, provide an opportunity for effective involvement by all
5 interested parties.

6 2.0 MEETINGS

7 **2.1** The Accreditation Committee shall schedule meetings that are open to the public in discharging its duties under
8 Section 1, subject to Section 5.0 of these rules.

9 **2.2** To properly discharge its responsibilities with respect to monitoring of IAS accreditation activities, the committee shall
10 have a standing item on its meeting agenda for a presentation by staff on the status of its accredited programs and information
11 on any pending appeals.

12 **2.3** All scheduled meetings shall be publicly announced.

13 **2.4** A majority of the voting Accreditation Committee members shall constitute a quorum. A majority vote of members
14 present is required on any action.

15 **2.5** If a specific interest group is not represented, votes by the committee on subjects related to that interest group will be
16 held in abeyance. IAS staff shall make pertinent information available to absentee committee members, and ballot the
17 members at a later stage. Records of such ballots shall be made available upon request.

18 **2.6** In the absence of the nonvoting Chair-Moderator, Accreditation Committee members present shall elect an alternate
19 Chairman from the committee for that meeting. The alternate Chairman shall be counted as a voting committee member for
20 purposes of maintaining a committee quorum and to cast a tie-breaking vote of the committee.

21 **2.7** Minutes of the meetings shall be kept.

22 3.0 MEMBER COMPETENCE CRITERIA

23 Members of the Accreditation Committee shall be familiar with conformity assessment and the implementation of
24 regulatory requirements within their industry sector. They shall possess:

- 25 • A Baccalaureate degree from an accredited institution or a minimum of ten years equivalent experience as determined by
26 IAS;
- 27 • Current employment within the conformity assessment, regulatory field, academia, industry, or IAS accredited CAB; and
- 28 • Demonstrated expertise in one or more accreditation programs offered by IAS.

29 **4.0 MEETING RECORDS**

30 Official meeting records shall be kept by IAS; no other audio, video, electronic or stenographic recordings of the meetings
31 will be permitted. Visual aids (including, but not limited to, charts, slides, videos, or presentation software) viewed at meetings
32 shall be permitted only if the presenter provides IAS before presentation with a copy of the visual aid in a medium which can
33 be retained by IAS with its record of the meeting and which can also be provided to interested parties requesting a copy. A
34 copy of the IAS minutes of the meeting and such visual aids, if any, will be available to interested parties upon written request
35 made to IAS together with a payment as required by IAS to cover costs of preparation and duplication of the copy. These
36 materials will be available shortly after the conclusion of the meeting but will no longer be available after 60 days have elapsed
37 from the conclusion of the meeting.

38 **5.0 WRITTEN COMMUNICATIONS AND SUBMISSIONS**

39 Parties interested in the deliberations of the committee should refrain from communicating, whether in writing or verbally,
40 with committee members regarding agenda items. All written communications and submissions regarding agenda items
41 should be delivered to IAS. All such written communications and submissions shall be considered nonconfidential and
42 available for discussion in open session of an Accreditation Committee meeting, and shall be delivered *at least twenty days*
43 before the scheduled Accreditation Committee meeting if they are to be forwarded to the Committee. Correspondence
44 received by IAS will not be released to any party, except to the Accreditation Committee, prior to the meeting without
45 permission of the author. The committee reserves the right to refuse recognition of communications which do not comply with
46 the provisions of this section. All such communications and submissions will be available from IAS upon written request and
47 payment of costs associated with duplication. The materials will be available shortly after the conclusion of the meeting but will
48 no longer be available after 60 days have elapsed from the conclusion of the meeting.

49 **6.0 CLOSED SESSIONS**

50 Meetings shall be open except that the chairman may call for a closed session to seek advice of counsel.

51 **7.0 ACCREDITATION CRITERIA**

52 Criteria are established by the committee to provide a basis for International Accreditation Service, Inc., accreditations.
53 Consideration of accreditation criteria must be in conjunction with a current and valid application for an IAS accreditation listing
54 or as otherwise determined by the Accreditation Committee.

55 **7.1 Procedure**

56 **7.1.1 New Criteria**

57 **7.1.1.1** Proposed accreditation criteria may be submitted by interested parties to IAS, and/or shall be developed by the
58 IAS staff and discussed in open session with the Accreditation Committee during a scheduled meeting

59 **7.1.1.2** Proposed accreditation criteria shall be available to interested parties approximately 60 days before discussion
60 at the committee meeting, unless determined by IAS management that extraordinary consideration and electronic balloting are
61 needed.

62 **7.1.1.3** The committee shall be informed of all pertinent written communications received by IAS. Parties interested in
63 proposed new criteria may deliver communications and submissions regarding such proposed criteria to IAS within 40 days of
64 the posting of the public notice on the IAS website. Such communications and submissions will otherwise be subject to the
65 provisions of Section 4.0 of these rules.

66 **7.1.1.4** Attendees at Accreditation Committee meetings shall have the opportunity to speak on accreditation criteria
67 listed on the meeting agenda, to provide information to committee members.

68 **7.1.2 Existing Criteria**

69 **7.1.2.1** Changes to existing accreditation criteria may be submitted by interested parties to IAS, and/or shall be
70 changed by the IAS staff. Existing accreditation criteria may be revised by the committee either (i) at a public meeting pursuant
71 to the procedures set forth herein, or (ii) by electronic ballot, provided public notice is provided as stipulated I Section 7.1.1.2.

72 **7.1.2.2** The committee shall be informed of all pertinent written communications received by IAS. Parties interested in
73 the proposed revisions to accreditation criteria may deliver communications and submissions regarding such proposed
74 revisions to IAS within the following timelines:

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Type	Dates
Public Meeting	40 Days after posting of proposed criteria
Electronic Balloting Process	30 Days after posting of proposed criteria

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77 Such communications and submissions will otherwise be subject to the provisions of Section 4.0 of these rules.

78 **7.1.3 ELECTRONIC BALLOTING**

79 **7.1.3.1** IAS management shall provide written rationale and seek permission and documented approval from the IAS
80 Accreditation Committee chair to propose new criteria or to revise existing criteria for extraordinary consideration and
81 electronic balloting by the committee.

82 **7.1.3.2** Proposed accreditation criteria shall be available to interested parties approximately 30 days before
83 consideration by the committee. All pertinent written communications received by IAS relating to the proposed criteria shall be
84 received no later than 30 days after the posting of the criteria. Ballots, along with comments received and staff
85 recommendations, will be submitted to the committee for consideration. The committee shall return their ballots with their
86 recommendations within 10 days from the date ballots are sent. The results of the balloting will be compiled and forwarded to
87 the chair of the committee for validation and decision.

88 **7.1.3.3** The electronically balloted criteria shall be brought back to the next regularly scheduled accreditation
89 committee hearing as per Section 7.1.2 of these rules,

90 **7.1.4 Effective Date of Published Criteria**

91 **7.1.4.1** The effective date of approved accreditation criteria or approved revisions to existing accreditation criteria shall
92 be no earlier than 30 days following the public meeting.

93 **7.1.4.2** Approved criteria using electronic balloting shall be effective the date of posting of the criteria on the IAS
94 website.

95 **7.2 Approval**

96 Approval of accreditation criteria shall be as specified in Section 2.4 of these rules.

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98 **8.0 ACCREDITATION COMMITTEE MEMBERS**

99 **8.1** The IAS Accreditation Committee members are appointed or reappointed annually by the IAS Board of Directors in
100 consultation with the IAS President.

101
102 **8.2** Committee members are selected from senior management positions within accredited organizations, users of
103 accreditation, industry groups and governmental or regulatory organizations. The individuals appointed to the committee shall
104 have knowledge of regulatory codes within their industry sector and international conformity assessment process and
105 practices. ■



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**PROPOSED ACCREDITATION CRITERIA FOR REFERENCE MATERIAL
PRODUCERS**

AC784

Proposed September 16, 2019

PREFACE

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 criteria are developed and adopted following public hearings conducted by the International Accreditation Service, Inc. (IAS), Accreditation Committee and are effective on the first of the month following approval by the Accreditation Committee, but no earlier than 30 days following the approval.

PROPOSED ACCREDITATION CRITERIA FOR REFERENCE MATERIAL PRODUCERS

1. 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 producers.

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 Guide 31:2015, Reference materials — Contents of certificates, labels and accompanying documentation.

1.2.5. ISO Guide 30:2015, Reference materials - Selected terms and definitions.

1.2.6. ILAC-P9, ILAC Policy for Participation in Proficiency Testing Activities.

1.2.7. ILAC P10:01/2013, ILAC Policy on Traceability of Measurement Results.

1.2.8. ISO/IEC Standard 17000, Conformity assessment – Vocabulary and general principles.

2. DEFINITIONS

Applicable definitions of ISO/IEC Standard 17000 series apply.

3. 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),

3.3. Determine the shelf life of reference materials based on stability studies conducted.

4. 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 producers,

- 57 4.2. ISO Guide 35:2017, Reference materials — Guidance for characterization and assessment of
58 homogeneity and stability,
59 4.3. ISO Guide 31:2015, Reference materials — Contents of certificates, labels and accompanying
60 documentation,
61 4.4. ISO Guide 30:2015, Reference materials - Selected terms and definitions,
62 4.5. IAS Rules of Procedure for Reference Materials Producers.
63

64 5. ADDITIONAL INFORMATION (AS APPLICABLE)

- 65 5.1. **Internal/In-house characterization:** Organizations performing internal/in-house
66 characterization (testing) and/or calibration are required to be in compliance with the
67 requirements of ISO/IEC Standard 17025, IAS Accreditation Criteria AC89 (Testing) and AC204
68 (Calibration), as applicable.

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

- 70 5.1.1. List of equipment that is calibrated internally used to produce reference material.
71 5.1.2. List of equipment using the reference standard(s) from internal production for
72 calibration.
73 5.1.3. Specific procedures used for internal calibration of equipment.
74 5.1.4. Training and qualification records of personnel qualified to perform the internal
75 calibration and/or characterization.
76 5.1.5. Evidence that internal measurement activity is audited as part of the organization's
77 internal audit.
78 5.1.6. Evidence of the laboratory's participation in proficiency testing, where available, for its
79 testing activity. The laboratory may also choose to provide evidence of other options as
80 indicated in Clause 7.7 of ISO/IEC Standard 17025.
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- 82 5.2. **Subcontracting:** A competent subcontractor used by the RMP is not limited to an accredited
83 IAS CAB or CAB accredited by a signatory to ILAC Mutual Recognition Arrangement.
84 Subcontractors shall have sufficient experience and technical competence for their assigned
85 tasks and that they comply with the relevant clauses of ISO/IEC 17034 and other relevant
86 standards.
87

88 5.3. **Regulatory Requirements**

- 89 5.3.1. Regulatory entities may place specific compliance requirements on RMP organizations.
90 In this case, the RMP shall demonstrate compliance to these requirements.
91 5.3.2. RMP must comply with regulatory requirements of Authority Having Jurisdiction (AHJ)
92 or other regulatory entities, including specific compliance requirements for qualification,
93 licensing, etc., of personnel and operation of RMP.

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95 **6. LINKS TO ADDITIONAL REFERENCES**

96 6.1 Asia Pacific Accreditation Cooperation – www.apac-accreditation.org

97 6.2 Asia Pacific Legal Metrology Forum - www.aplmf.org

98 6.3 International Laboratory Accreditation Cooperation – www.ilac.org

99 6.4 International Organization for Standardization – www.iso.org

100 6.5 International Electrotechnical Commission – www.iec.ch

101 6.6 International Organization of Legal Metrology – www.oiml.org

102 6.7 International Accreditation Service – www.iasonline.org

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