



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

July 15, 2019

TO: IAS-APPLICANT PROFICIENCY TESTING PROVIDERS AND OTHER INTERESTED PARTIES

SUBJECT: Proposed Accreditation Criteria for Proficiency Testing Providers, Subject AC785-0919-0919-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 Proficiency Testing Providers (PTP), AC785, has been placed on the agenda for committee consideration at the above-noted meeting.

The proficiency testing provider program will benefit laboratories by increasing the confidence that by using accredited PTP's, the proficiency programs they participate in are operated competently in accordance with specified technical and management system requirements. These requirements are based on agreed and accepted international standards used for the planning, statistical analysis and implementation of proficiency testing programs.

Participation in proficiency testing programs is a mandatory requirement for laboratories and is used as part of the laboratory accreditation assessment to establish the laboratories' capability to perform tests or calibrations competently and accurately.

This new program operates on the technical requirements contained within:

- ISO/IEC 17043:2010, Conformity assessment - General requirements for proficiency testing.

- ISO 13528:2015, Statistical methods for use in proficiency testing by interlaboratory comparison

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.

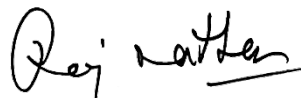
Any written material submitted for committee consideration will be available for public distribution as set forth in Section 4.0 of the Rules of Procedure for Accreditation Committee Meetings (copy enclosed).

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.

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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 PROFICIENCY TESTING
PROVIDERS**

AC785

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.

20 **PROPOSED ACCREDITATION CRITERIA FOR PROFICIENCY TESTING PROVIDERS**

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22 **1. INTRODUCTION**

23 1.1. **Scope:** These criteria set forth the requirements for obtaining and maintaining International
24 Accreditation Service, Inc. (IAS), Proficiency Testing Provider (PTP) accreditation. These
25 criteria supplement the IAS Rules of Procedure for Proficiency Testing Provider Accreditation.

26
27 1.2. **Normative and Reference Documents:** Publications listed below refer to current editions
28 (unless otherwise stated).

29 1.2.1. ISO/IEC 17043:2010, Conformity assessment - General requirements for proficiency
30 testing.

31 1.2.2. ISO 13528:2015, Statistical methods for use in proficiency testing by interlaboratory
32 comparison.

33 1.2.3. ISO Guide 35:2017, Reference materials — Guidance for characterization and
34 assessment of homogeneity and stability.

35 1.2.4. IUPAC Harmonized Protocol: 2006.

36 1.1.1. ILAC-P9, ILAC Policy for Participation in Proficiency Testing Activities.

37 1.1.2. ILAC P10:01/2013, ILAC Policy on Traceability of Measurement Results.

38 1.1.3. ISO/IEC 17000, Conformity assessment – Vocabulary and general principles.

39
40 **2. DEFINITIONS**

41 Applicable definitions of ISO/IEC Standard 17000 series apply.

42
43 **3. ELIGIBILITY**

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

45 3.1. Have effectively implemented the management system according to ISO/IEC 17043:2010

46 3.2. Are competent to conduct inter-laboratory comparisons in accordance with ISO/IEC
47 17043:2010

48 3.3. Have access to expertise with the specific Proficiency Testing (PT) item being offered (i.e.,
49 conversant with the behavior of the product or item used in the PT Scheme)

50 3.4. Are competent in the measurement of the properties being determined:

51 The PT Provider must have a testing/calibration laboratory

52 **Note:** Where a subcontractor is used, the subcontractor must have a testing/calibration
53 laboratory.

54 **Note:** If the testing/calibration of the PT items are conducted for the purpose of ensuring the
55 homogeneity and/or stability of the PT items used as well as for the purpose of assigning the

56 property value for measurand/characteristic then the facilities must comply with ISO/IEC 17025
57 and/or ISO 15189 laboratory requirements.

58 4. REQUIRED BASIC INFORMATION

59 PTP must demonstrate compliance with the following requirements:

- 60 4.1. ISO/IEC 17043:2010, Conformity assessment - General requirements for proficiency testing,
- 61 4.2. ISO 13528:2015, Statistical methods for use in proficiency testing by interlaboratory
62 comparison,
- 63 4.3. IAS Rules of Procedure for Reference Materials Producer.

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65 5. ADDITIONAL INFORMATION (AS APPLICABLE)

66 5.1. **Homogeneity/stability check:** The PT items used for conducting the PT Schemes must be
67 sufficiently homogeneous and stable. Organizations performing characterization of the PT
68 samples are required to be in compliance with the requirements of ISO/IEC Standard 17025 (or
69 ISO 15189 for medical laboratories) and where applicable, comply with IAS Accreditation
70 Criteria AC89 (Testing) or AC204 (Calibration).

71

72 5.2. **Internal calibration:** The following information must be provided or made available to IAS prior
73 to an assessment:

- 74 5.2.1. List of equipment that is calibrated internally for the production of the PT sample.
- 75 5.2.2. Specific procedures used for internal calibration of equipment.
- 76 5.2.3. Training and qualification records of personnel performing the internal calibration
77 and/or characterization of samples.
- 78 5.2.4. Internal audit, including internal measurement activity.

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80 5.3. **Subcontracting:** A competent subcontractor used by the PTP is not limited to an accredited
81 IAS CAB or CAB accredited by a signatory to ILAC Mutual Recognition Arrangement. The
82 subcontractor must be competent and meet the requirements of the latest version of ISO/IEC
83 17025.

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85 6. LINKS TO ADDITIONAL REFERENCES

86 6.1 Asia Pacific Accreditation Cooperation – www.apac-accreditation.org

87 6.2 Asia Pacific Legal Metrology Forum - www.aplmf.org

88 6.3 International Laboratory Accreditation Cooperation – www.ilac.org

89 6.4 International Organization for Standardization – www.iso.org

90 6.5 International Electrotechnical Commission – www.iec.ch

91 6.6 International Organization of Legal Metrology – www.oiml.org

92 6.7 International Accreditation Service – www.iasonline.org