

July 27, 2018

TO: IAS-ACCREDITED TESTING LABORATORIES AND OTHER INTERESTED PARTIES

SUBJECT: Proposed Revisions to the Accreditation Criteria for Testing Laboratories, Subject AC89-0918-0918-R1 (PR/GA)]

Hearing Information:

IAS Accreditation Committee Thursday, September 27, 2018 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 Testing Laboratories, AC89, has been placed on the agenda for committee consideration at the above-noted meeting. The changes are being requested to incorporate the new ISO/IEC Standard 17025:2017.

The changes proposed are summarized below:

- 1. Section 1.2.1: Add version 2005 to the standard.
- 2. Section 1.2.2: Add new version of the ISO/IEC Standard 17025 to the Normative and Reference Documents.
- 3. Section 4.1: Add version 2005 to the standard.
- 4. Section 4.2: Add new version of the ISO/IEC Standard 17025 to the Required Basic Information.
- Section 5.4: Add information on IAS transition policy to ISO/IEC Standard 17025: 2017.
- 6. Section 6.6: Add link to IAS transition policy to ISO/IEC Standard 17025: 2017.

7. Section 6.7: Add link to article on ISO/IEC 17025:2017.

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 **September 6, 2018.** 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 <u>iasinfo@iasonline.org</u>.

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 **<u>Brea</u>** 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 Dr. George Anastasopoulos, director, conformity assessment, at 562-364-8201, extension 3705, or the undersigned at 562-364-8201. You may also reach us by e-mail at <u>iasinfo@iasonline.org</u>.

Yours very truly,

Rej nather

Raj Nathan President

RN/nl

Enclosures

cc: Accreditation Committee



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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.

A majority of the voting Accreditation Committee members shall constitute a quorum. A majority vote of members
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:

A Baccalaureate degree from an accredited institution or a minimum of ten years equivalent experience as determined by
IAS;

- Current employment within the conformity assessment, regulatory field, academia, industry, or IAS accredited CAB; and
- Demonstrated expertise in one or more accreditation programs offered by IAS.

29 4.0 MEETING RECORDS

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

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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

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

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

68 7.1.2 Existing Criteria

7.1.2.1 Changes to existing accreditation criteria may be submitted by interested parties to IAS, and/or shall be
changed by the IAS staff. Existing accreditation criteria may be revised by the committee either (i) at a public meeting pursuant
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:

75

Туре	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.

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

7.1.3.3 The electronically balloted criteria shall be brought back to the next regularly scheduled accreditation
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 IAS94 website.

95 7.2 Approval

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

97 8.0 ACCREDITATION COMMITTEE MEMBERS

98 8.1 The IAS Accreditation Committee members are appointed or reappointed annually by the IAS Board of Directors in99 consultation with the IAS President.

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



1	PROPOSED REVISIONS TO THE ACCREDITATION CRITERIA FOR TESTING
2	LABORATORIES
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4	AC89
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7	Proposed September 2018
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10	PREFACE
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14	The attached accreditation criteria have been proposed to provide all interested parties
15	with an opportunity to comment. These criteria may be further revised as needed. The
16	criteria are developed and adopted following public hearings conducted by the
17	International Accreditation Service, Inc. (IAS), Accreditation Committee and are
18	effective on the first of the month following approval by the Accreditation Committee, but
19	no earlier than 30 days following the approval.
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PROPOSED REVISIONS TO THE ACCREDITATION CRITERIA FOR TESTING LABORATORIES

22		
23	1.	INTRODUCTION
24		1.1. Scope: These criteria set forth the requirements for obtaining and maintaining International
25		Accreditation Service, Inc. (IAS), Testing Laboratory accreditation. These criteria supplement the
26		IAS Rules of Procedure for Laboratory Accreditation.
27		
28		1.2. Normative and Reference Documents: Publications listed below refer to current editions
29		(unless otherwise stated).
30		1.2.1. ISO/IEC Standard 17025:2005, General requirements for the competence of testing
31		and calibration laboratories.
32		1.2.1.1.2.2. ISO/IEC Standard 17025:2017, General requirements for the competence of
33		testing and calibration laboratories.
34		1.2.2.1.2.3. ILAC-P9, ILAC Policy for Participation in Proficiency Testing Activities.
35		1.2.3.1.2.4. ISO/IEC Standard 17000, Conformity assessment – Vocabulary and general
36		principles
37		
38	2.	DEFINITIONS
39		Applicable definitions of ISO/IEC Standard 17000 series apply.
40		
41	3.	ELIGIBILITY
42		Accreditation services are available to testing laboratories that:
43		3.1. Perform tests of its legal entities' own products (internal).
44		3.2. Perform tests of products of external organizations (external).
45		
46	4.	REQUIRED BASIC INFORMATION
47		Testing laboratories must demonstrate compliance with the following requirements:
48		4.1. ISO/IEC Standard 17025:2005, General requirements for the competence of testing and
49		calibration laboratories.
50		4.1.4.2. ISO/IEC Standard 17025:2017, General requirements for the competence of testing and
51		calibration laboratories.
52		4.2.4.3. IAS Rules of Procedure for Laboratory Accreditation.
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54	5.	ADDITIONAL INFORMATION (AS APPLICABLE)
55		5.1. Internal/In-house Calibrations: Laboratories performing internal/in-house calibrations are
56		required to be in compliance with the requirements of clause 5.6 of ISO/IEC Standard 17025.
57		Additionally, the following information must be provided or made available to IAS:

58		5.1.1.	List of equipment that is calibrated internally.
59		5.1.2.	List of equipment used as the reference standard(s) for internal calibration.
60		5.1.3.	Specific procedures used for internal calibrations of equipment.
61		5.1.4.	Training and qualification records of personnel qualified to perform the internal
62			calibration.
63		5.1.5.	The internal calibration activity shall be audited as part of the laboratory's internal audit.
64		5.1.6.	The laboratory shall participate in proficiency testing, where available, for its calibration
65			activity. The laboratory may also choose other options as indicated in Clause 5.9 of
66 (7			ISO/IEC Standard 17025.
67 68			
68 60			ency Testing Activity: Proficiency testing activity shall be completed in accordance with
69 70		Clause 4	4.2 of ILAC-P9.
70 71		50 Benular	
71 72		-	tory Requirements: Regulatory entities may place specific compliance requirements on
72 72			bries. If a laboratory is required to comply with the regulatory requirements as may be
73 74		applicat	ble, they must agree to comply with additional requirements.
74 75		Testing	laboratories must comply with regulatory requirements of Authority Having Jurisdiction
76		(AHJ) o	r other regulatory entities, including specific compliance requirements for qualification,
77		licensing	g, etc., of personnel and operation of testing laboratory.
78			
79		<u>5.4 IAS Tr</u>	ansition Policy for International Standard ISO/IEC 17025:2017: The laboratory
80		manag	gement may select the 2005 version or the 2017 version for assessments conducted prior
81		to Nov	ember 30, 2018. All applicant and existing accredited organizations will not be permitted
82		<u>to be a</u>	assessed to the 2005 version of the international standard after December 1, 2018.
83		Labora	atories that have not demonstrated full compliance with ISO/IEC 17025:2017 international
84		<u>standa</u>	rd by December 1, 2020, are subject to suspension and their accreditation certificate will
85		<u>be rem</u>	noved from the IAS website until further compliance is demonstrated. For further details,
86		please	refer to the transition policy posted on the IAS website,
87			
88	6.	LINKS TO A	DDITIONAL REFERENCES
89		6.1 Asia Pac	ific Laboratory Accreditation Cooperation – www.aplac.org
90		6.2 Internation	onal Laboratory Accreditation Cooperation – <u>www.ilac.org</u>
91		6.3 Internation	onal Organization for Standardization – <u>www.iso.org</u>
92		6.4 Internation	onal Electrotechnical Commission – <u>www.iec.ch</u>
93		6.5 Internation	onal Accreditation Service – <u>www.iasonline.org</u>

94	6.6 IAS Transition Policy – https://www.iasonline.org/wp-content/uploads/2018/01/17025-Transition-
95	Policy-Jan-2018.pdf
96	6.56.7 Article on ISO/IEC 17025:2017 – https://www.iasonline.org/wp-
97	content/uploads/2018/01/The-New-ISO-IEC-17025-2017.pdf
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99	These criteria were previously issued September 2002, June 2003, May 2004, May 2005, August 2006, April 2008, May 2010,
100	September 2013, February 2015 <u>, and February 2016 and April 2017</u>
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