INTERNATIONAL ACCREDITATION SERVICE®

August 5, 2023

TO: **IAS – TESTING LABORATORIES AND OTHER INTERESTED PARTIES.**

SUBJECT: Proposed Revisions to the Accreditation Criteria for Testing Laboratories, AC89-202310-R0 (DK)

Hearing Information:
IAS Accreditation Committee
Wednesday, October 4, 2023
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 Testing Laboratories, (AC89) has been placed on the agenda for committee consideration at the above-noted meeting.

Proposed changes include:

1. Lines 32-47: Added all relevant documents required for the test lab to meet ILAC and IAS requirements.
2. Lines 48-56: Added a new section for “Other Documents”. This section includes documents that are required for specific labs or as needed.
3. Line 62: Added the sampling organizations as eligible entities for accreditation under this program. IAS already has accredited sampling organization that are not involved in testing (providing only sampling services).
4. Line 65: Added subclause 3.3: Added this sentence to explain the addition in line 38 and be clear that sampling organizations can be accredited under the AC89.
5. Line 68: added the wording “sampling organization” to comply with previous additions.
6. Line 69: Added the phrase “as applicable” since some of the documents referenced may not be applicable to all CABs seeking accreditation under this Program.
7. Lines 73-81: Since a full list of Normal Documents and Other Documents are listed in Section 1.2 and 1.3, there is no need to repeat this list in Section 4. Therefore, Sections 4.3, 4.4 and 4.5 have either been revised or removed.

8. Lines 95-97: Added the paragraph "*This clause applies also to any subprogram under the Testing Laboratory Accreditation Program where a Regulator has provided with any additional requirements or guidance required to meet accreditation/recognition status*" to include any regulatory documents/requirements that are required for the accreditation of CABs under this program.
9. Lines 105-106: Added the link to US FDA ASCA Program webpage.
10. Lines 107-108: Added the link to US FDA LAAF Program webpage.
11. Line 109: Added the link to California State ELAP Program webpage.
12. Lines 110-111: Added the link to Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP) webpage.
13. Lines 112-113: Added the link to the Department of Environmental Consolidated Audit Program (DoE CAP) webpage.
14. Line 114: Added the link to the NELAC Institute (TNI) webpage.
15. Lines 116-117: Deleted the reference to an Article on ISO/IEC 17025:2017 as this was used mainly through the transition period (between the 2005 and 2017 version) to the new version of ISO/IEC 17025 and has been 6 years since the latest version was launched.

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 September 4, 2023. 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 iasinfo@iasonline.org.

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.

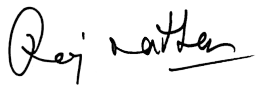
Participants at the accreditation committee meetings shall have the opportunity to speak on the proposed criteria to provide information to the committee. Committee meetings are generally held by electronic means. Participants are responsible to ensure access to appropriate computer equipment, software, 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 iasinfo@iasonline.org.

Yours very truly,



Raj Nathan
President

Enclosures: Proposed Revised AC89

cc: Accreditation Committee

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PROPOSED REVISIONS TO THE ACCREDITATION CRITERIA FOR TESTING LABORATORIES

AC89

Proposed October 4, 2023

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 REVISIONS TO THE ACCREDITATION CRITERIA FOR TESTING LABORATORIES

1. INTRODUCTION

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

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

1.2.1. ISO/IEC Standard 17025, General requirements for the competence of testing and calibration laboratories.

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

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

1.2.4. ILAC-P10, ILAC Policy on Metrological Traceability of Measurement Results.

1.2.5. IAS Rules of Procedure for Testing Laboratory Accreditation,

1.2.6. IAS/TL-CL/013 IAS Calibration and Testing Laboratory Accreditation Programs Definitions

1.2.7. IAS/TL/025 IAS Policy on Calibration, Traceability and Measurement Uncertainty for Testing Laboratories

1.2.8. IAS/TL-CL/026 Policy on Off-Site Testing/Calibration

1.2.9. IAS/TL-CL/031 IAS Policy On Proficiency Testing for Laboratories

1.2.10. IAS/ADM/044 IAS Policy On Relocation of Accredited Organizations

1.2.11. ILAC P8: Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies,

1.2.12. LAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration.

1.2.13. ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity

1.2.14. ILAC G17:01/2021 ILAC Guidelines for Measurement Uncertainty in Testing

1.2.15. ILAC G18:12/2021 Guideline for describing Scopes of Accreditation

1.2.16. ILAC G24:2022 Guidelines for the determination of recalibration intervals of measuring equipment

1.3. **Other Documents as Needed:**

1.3.1. ILAC G7:04/2021 Accreditation Requirements and Operating Criteria for Horseracing Laboratories

1.3.2. ILAC G19:06/2022 Modules in a Forensic Science Process

1.3.3. ILAC R7:05/2015 Rules for the Use of the ILAC MRA Mark

1.3.4. IAS/TL-AA-PCA/058 IAS Guideline for Defining Scopes of Accreditation Related to PS 1-19 (Structural Plywood), PS 2-18 (Performance Standard for Wood Structural Panels) and

Applicable European Union (EU) Directives/Regulations

~~1.2.4.~~1.3.5. IAS/ADM/084 Policy on the Use of the ILAC/IAF/IAS Combined Marks

2. DEFINITIONS

Applicable definitions of ISO/IEC Standard 17000 series apply.

3. ELIGIBILITY

Accreditation services are available to testing laboratories / sampling organizations ~~laboratories~~ that:

3.1. Perform tests of its legal entities' own products (internal).

3.2. Perform tests of products of external organizations (external).

~~3.2.~~3.3. Perform sampling activities for subsequent testing.

4. REQUIRED BASIC INFORMATION

Testing laboratories/ sampling organizations must demonstrate compliance with the following requirements (as applicable):

4.1. ISO/IEC Standard 17025, General requirements for the competence of testing and calibration laboratories.

4.2. IAS Rules of Procedure for Testing Laboratory Accreditation.

~~4.3. ILAC P-9, ILAC Policy for Participation in Proficiency Testing Activities.~~

~~4.4. ILAC-P10, ILAC Policy on Metrological Traceability of Measurement Results.~~

4.3. Refer to Section 1.2 and 1.3 for relevant documents as required.

~~4.5. Relevant IAS policy documents.~~

~~4.5.1. IAS/CL/025 IAS Policy on Calibration, Traceability and Measurement Uncertainty for Testing Laboratories~~

~~4.5.2. IAS/TL-CL/026 Policy on Off-Site Testing/Calibration~~

~~4.5.3. IAS/TL-CL/031 IAS Policy on Proficiency Testing for Laboratories~~

~~4.5.4. IAS/ADM/044 IAS Policy on Relocation of Accredited Organizations~~

5. ADDITIONAL INFORMATION (AS APPLICABLE)

5.1. **Proficiency Testing Activity**: Proficiency testing activity shall be completed in accordance with ILAC-P9 and IAS/TL-CL/031, IAS Policy on Proficiency Testing for Laboratories.

5.2. **Regulatory Requirements**: Regulatory entities may place specific compliance requirements on laboratories. If a laboratory is required to comply with the regulatory requirements as may be applicable, they must agree to comply with additional requirements.

Testing laboratories 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 testing laboratory.

This clause applies also to any subprogram under the Testing Laboratory Accreditation Program where a Regulator has provided with any additional requirements or guidance required to meet accreditation/recognition status.

6. LINKS TO ADDITIONAL REFERENCES

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

6.2 International Laboratory Accreditation Cooperation – www.ilac.org

6.3 International Organization for Standardization – www.iso.org

6.4 International Electrotechnical Commission – www.iec.ch

6.5 International Accreditation Service – www.iasonline.org

6.6 US FDA ASCA Program - www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

6.7 US FDA LAAF Program - https://datadashboard.fda.gov/ora/fd/laaf.htm https://nelac-institute.org/

6.8 California State ELAP Program - www.waterboards.ca.gov/drinking_water/certlic/labs/

6.9 Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP) - www.denix.osd.mil/edqw/accreditation/home/index.html

6.10 The Department of Environmental Consolidated Audit Program (DoE CAP) - www.energy.gov/ehss/analytical-services-program

6.11 The NELAC Institute (TNI) - https://nelac-institute.org/

~~6.5~~

~~6.66.12 Article on ISO/IEC 17025:2017 – https://www.iasonline.org/wp-content/uploads/2018/01/The-New-ISO-IEC-17025-2017.pdf~~

These criteria were previously issued September 2002, June 2003, May 2004, May 2005, August 2006, April 2008, May 2010, September 2013, February 2015, February 2016, April 2017, September 2018, Editorially revised January 2019, ~~and~~ October 2020 and December 2021.