



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

October 14, 2021

TO: IAS – MEDICAL LABORATORIES AND OTHER INTERESTED PARTIES.

SUBJECT: Proposed Revisions to the Accreditation Criteria for Medical Laboratories AC780-202112-R0 (DK)

Hearing Information:

IAS Accreditation Committee
Tuesday, December 14th, 2021
8:30 AM (California - PST)
WebEx Meeting – Refer to IAS website for details.

Dear Madam or Sir:

Proposed Revisions to the Accreditation Criteria for Medical Laboratories (AC780) has been placed on the agenda for committee consideration at the above-noted meeting.

Proposed changes include:

1. Clause 6.2: Change the name of the regional group from APLAC to APAC and change their website address.

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 November 14, 2021. 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.

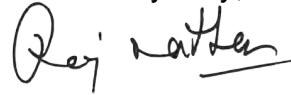
Participants at the accreditation committee meetings shall have the opportunity to speak on the proposed criteria to provide information to the committee. Committee meetings are generally held by electronic means. Participants are responsible to ensure access to

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,

A handwritten signature in black ink that reads "Raj Nathan". The signature is written in a cursive style with a horizontal line underneath the name.

Raj Nathan
President

Enclosures: Proposed Revised AC780

cc: Accreditation Committee

18 **PROPOSED REVISIONS TO THE ACCREDITATION CRITERIA FOR MEDICAL LABORATORIES**

19
20 **1. INTRODUCTION**

21 1.1 **Scope:** These criteria set forth the requirements for obtaining and maintaining International
22 Accreditation Service, Inc. (IAS), Medical Laboratory accreditation. Medical Laboratories seeking
23 accreditation shall comply with the requirements specified in ISO 15189, *Medical Laboratories –*
24 *Requirements for quality and competence*; and supplemented by this IAS Accreditation Criteria,
25 IAS Rules of Procedure for Medical Laboratories, and International Laboratory Accreditation
26 Cooperation (ILAC) guidance documents on application of ISO 15189.

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

30 1.2.1 ISO 15189, Medical laboratories -- Requirements for quality and competence.

31 1.2.2 ISO 22870 Point-of-care Testing (POCT) – Requirements for quality and competence.

32 1.2.3 IAS Rules of Procedure for Medical Laboratory Accreditation.

33 1.2.4 ILAC-G26, Guidance for the Implementation of a Medical Laboratory Accreditation
34 System.

35 1.2.5 ILAC-P9, ILAC Policy for Participation in Proficiency Testing Activities.

36 1.2.6 ISO/IEC Guide 2, Standardization and related activities – General Vocabulary.

37 1.2.7 ISO/IEC Guide 99, International Vocabulary of Metrology – Basic and general concepts
38 and associated terms.

39 1.2.8 ISO/IEC 17000, Conformity assessment – Vocabulary and general principles.

40
41 **2 DEFINITIONS**

42 Applicable definitions of ISO Standard 15189 and ISO/IEC 17000 series apply.

43
44 **3 ELIGIBILITY**

45 3.1 All applicants seeking accreditation must demonstrate their competence and establish
46 conformance with the requirements of ISO 15189.

47
48 3.2 Medical laboratories must always demonstrate competence to perform specific tests or type of
49 tests on samples in the scope for which they wish to become accredited.

50
51 3.3 IAS accreditation services are available to medical laboratories that meet the requirements of
52 ISO 15189 and who operate in the following disciplines:

53 3.3.1 Clinical Biochemistry

54 Toxicology

- 55 3.3.2 Clinical Microbiology
- 56 3.3.3 Clinical Pathology
- 57 3.3.4 Genetics
- 58 Cytogenetics
- 59 3.3.5 Haematology
- 60 3.3.6 Histopathology
- 61 3.3.6.1 Cytopathology (Cytology)
- 62 3.3.6.2 Hospital Autopsy
- 63 3.3.7 Immunology
- 64 3.3.8 Medical Imaging
- 65 3.3.9 Molecular Pathology
- 66 3.3.10 Nuclear Medicine
- 67 3.3.11 Point-of-care Testing (POCT)
- 68 3.3.12 Pharmacology

69

70 **Note:** In general, for diagnostic medical laboratories, scopes may include aspects regarding the
71 discipline of practice, sample type and techniques employed. ILAC G18: *Guideline for the*
72 *Formulation of Scopes of Accreditation for Laboratories* is taken into consideration when formulating
73 the scope of accreditation for medical laboratories.

74

75 **4 REQUIRED BASIC INFORMATION**

76 Medical Laboratories must demonstrate compliance with the following requirements:

77 4.1 ISO Standard 15189, Medical laboratories -- Requirements for quality and competence.

78 4.2 IAS Rules of Procedure for Medical Laboratory Accreditation.

79

80 **5 ADDITIONAL INFORMATION (AS APPLICABLE)**

81 Specific national and/or international regulatory requirements.

82

83 **6 LINKS TO ADDITIONAL REFERENCES**

84 **6.1** International Laboratory Accreditation Cooperation – www.ilac.org

85 **6.2** Asia Pacific ~~Laboratory~~ Accreditation Cooperation – www.aplac.org www.apac-accreditation.org

86 **6.3** IAS – www.iasonline.org

87

88 *These criteria were previously issued April 2017 and January 2019.*