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INTERNATIONAL ACCREDITATION SERVICE®

May 6, 2024

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

SUBJECT: Proposed Revisions to the Accreditation Criteria for Medical Laboratories, AC780-2024-06-26 (LHDB/MS)

Hearing Information:
IAS Accreditation Committee
Wednesday, June 26, 2024
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 Medical Laboratories, (AC780) has been placed on the agenda for committee consideration at the above-noted meeting.

Proposed changes include:

1. Line 70 – The majority of Medical Laboratories located in Asian and Middle Eastern regions are associated with Sample Collection Centers to ensure continuous samples for medical laboratories. Therefore, due reference is to be given in the accreditation documents to recognize the sample collection centers covered under the accreditation of the main medical laboratory and prevent the misuse of accreditation by sample collection centers.

On the above background, it is proposed to include sample collection centers in the clarification note given under line 70.

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 June 3, 2024. 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,

International Accreditation Service

IAS Management

Enclosures: Proposed Revised AC780

cc: Accreditation Committee

INTERNATIONAL ACCREDITATION SERVICE®

PROPOSED REVISIONS TO THE ACCREDITATION CRITERIA FOR MEDICAL LABORATORIES

AC780

June 26, 2024
Effective TBD

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 MEDICAL LABORATORIES

1. INTRODUCTION

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

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

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

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

1.2.3 IAS Rules of Procedure for Medical Laboratory Accreditation.

1.2.4 ILAC-G26, Guidance for the Implementation of a Medical Accreditation Scheme.

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

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

1.2.7 ISO/IEC Guide 99, International vocabulary of metrology – Basic and general concepts and associated terms (VIM).

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

*Not applicable when ISO 15189:2022 is used.

2 DEFINITIONS

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

3 ELIGIBILITY

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

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

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

- 3.3.1 Clinical Biochemistry
  Toxicology
- 3.3.2 Clinical Microbiology
- 3.3.3 Clinical Pathology
- 3.3.4 Genetics
  Cytogenetics
- 3.3.5 Haematology
- 3.3.6 Histopathology
  - 3.3.6.1 Cytopathology (Cytology)
  - 3.3.6.2 Hospital Autopsy
- 3.3.7 Immunology
- 3.3.8 Medical Imaging
- 3.3.9 Molecular Pathology
- 3.3.10 Nuclear Medicine
- 3.3.11 Point-of-care Testing (POCT)
- 3.3.12 Pharmacology

Note: In general, for diagnostic medical laboratories, scopes may include aspects regarding the discipline of practice, sample type, ~~and~~ techniques employed, and approved sample collection centers. ILAC G18: *Guideline for describing Scopes of Accreditation* is taken into consideration when formulating the scope of accreditation for medical laboratories.

4 REQUIRED BASIC INFORMATION

Medical Laboratories must demonstrate compliance with the following requirements:

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

4.2 IAS Rules of Procedure for Medical Laboratory Accreditation.

5 ADDITIONAL INFORMATION (AS APPLICABLE)

Specific national and/or international regulatory requirements.

6 LINKS TO ADDITIONAL REFERENCES

6.1 International Laboratory Accreditation Cooperation – www.ilac.org

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

6.3 IAS – www.iasonline.org

These criteria were previously issued April 2017, January 2019, December 2021, February 2022, and October 2023.