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IQAS-031

Supplementary Criteria for Medical Testing Laboratories

AMENDMENT SHEET

Sr. No.	Page No.	Clause No.	Date of Amendment	Reasons of amendment	Amendment details	Remark	Approved by
1.	4	5.2	02.09.2024	Outcome of APAC evaluation	Typographical error corrected	-	R.S. Rana
2.	5	9	02.12.2025	Requirement of Regulatory Compliance	Addition of Regulatory Compliance	-	R.S. Rana
3.	4	3.1	02.12.2025	Latest version of standard incorporated	2022 version of ISO 15189 referenced	-	R.S. Rana

1.Objective

This procedure outlines requirement criteria for applicant medical testing laboratories towards quality compliance.

2.Scope: This document covers the requirement criteria for medical testing laboratories.

3.Normative and Other Reference

3.1 ISO/IEC 15189:2012 and 2022, Medical laboratories — Requirements for quality and competence.

3.2SO/IEC 17000:2020 Conformity Assessment – Vocabulary and General Principles.

3.3ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities

3.4 ILAC P10:07/2020 ILAC Policy on the Traceability of Measurement Results

3.5 ILAC B9:02/2017 ILAC Guidelines for Medical Laboratory Accreditation

4.Definitions

Applicable definitions of ISO/IEC Standard 17000 series and any other relevant standard are applied.

5.Proficiency Testing Activity

The minimum amount of appropriate proficiency testing required per laboratory is given below:

5.1One PT/ILC activity from each applied field prior to gaining accreditation.

5.2One PT/ILC activity relating to each group of laboratory's scope of accreditation at least every four years.

6. Traceability of Measurement Results

All measuring devices including subsidiary measuring devices which can impact the results should have the Traceability of Measurement to SI units, directly from National Physical Laboratory (NPL) New Delhi/ any other National Metrological Laboratory or from a laboratory from India or abroad accredited by a laboratory accreditation body which is signatory to MRA with APAC/ILAC.

7.Method used:

Medical Testing based on the international standard, National Standard, local standard, method published in the journal/ book etc. are acceptable.

The laboratory developed method can be used and the method shall be validated as per ISO 15189.

The method adopted by International Metrological Institute/ National Metrological Institute or any other international organization working in the field of medical testing is also acceptable.

8.Uncertainty in Measurement

Medical Testing laboratories shall estimate uncertainties of measurement as per:

ILAC-B9:02/2017 ILAC Guidelines for Medical Laboratory Accreditation.

9. Regulatory Compliance Requirement

The CAB shall adhere to all applicable local state rules and regulations in accordance with prescribed norms.