



مركز الإمارات العالمي للاعتماد

Emirates International Accreditation Centre

المتطلبات العامة للاعتماد

Accreditation Scheme for Proficiency Testing Provider (PTP)

EIAC-RQ-PTP-001

Signatories	
Approved:	Director, Laboratories Accreditation Department

Revision history			
Issue no.	Rev. No.	Details	Date
1	0	First Issue for use under EIAC Name	18-06-2020
1	1	In response to the internal audit findings 2023, revised to update the references.	08-03-2024
1	2	Revised due to the incorporation of the new identity of the Dubai Government	23-07-2024



Contents

1	Scope and Objectives:.....	3
2	Terms and Definitions	3
3	Accreditation Requirements.....	3
4	References	6

This document and all its contents are property of Emirates International Accreditation Centre (EIAC). The content is protected by copyrights laws. Any printed copy of it shall be treated as 'Uncontrolled'. Always refer to the controlled online version

1 Scope and Objectives:

This document defines accreditation requirements for proficiency test providers. This document is to be used by the PTP to prepare for EIAC accreditation together with the management and technical requirements stated in the standard ISO/IEC 17043 and the relevant EIAC General Accreditation Requirements (EIAC-RQ-GEN-001).

2 Terms and Definitions

For the purpose of this document, the terms and definitions given in ISO /IEC 17043: 2010 and ISO/IEC Guide 99 apply.

3 Accreditation Requirements

3.1 Technical Requirements:

3.1.1 Statistical Design (ISO/IEC 17043 – 4.4.4)

3.1.1.1 The statistics related to proficiency tests shall use either the methods identified in ISO 13528 or by use any approved statistically valid approaches. In such cases the other methods shall be fully described to participants.

3.1.2 Assigned Values (ISO/IEC 17043 – 4.4.5)

3.1.2.1 When the PTP determines the assigned value solely based on the values assigned to reference materials (RM) , or based on the value provided by a single laboratory only or when the PTP laboratory or its subcontractor(s) is responsible for providing measurements based on which the PTP will determine the assigned value.

PTP shall ensure that all testing results obtained from those subcontractor laboratories are metrologically traceable whenever applicable through:

- a) using equipment that is calibrated by ISO/IEC 17025 accredited calibration lab;
- b) using Certified Reference Materials (CRMs) from a competent ISO/IEC 17034 reference material producer.

3.1.3 Data Analysis (ISO/IEC 17043 – 4.7)

3.1.3.1 The Commercially available software for data processing are considered to be validated, whereas e. g. based on test sets of data the functionality according to the intended purposes has to be verified. As well, self-programmed software for the data processing the functionality has to be proved on the basis of sufficient number of test sets of data according to the intended purposes.

3.1.4 Subcontracting Services (ISO/IEC 17043 – 5.5)

3.2.1.1 The PTP may use subcontractors or operates an internal laboratory for activities permitted by ISO/IEC 17043 standard.

3.2.1.2 If the PTP or its specified subcontractor is not accredited to ISO/IEC 17025 or ISO 15189 by EIAC and/or an ILAC MRA signatory for the testing, calibration, and measurement activities it undertakes in the operation of proficiency testing

This document and all its contents are property of Emirates International Accreditation Centre (EIAC). The content is protected by copyrights laws. Any printed copy of it shall be treated as 'Uncontrolled'. Always refer to the controlled online version

schemes, the PTP shall have the needed competence to evaluate the performance of the subcontractor to ensure its compliance with the ISO/IEC 17025 and ISO 15189 standard. EIAC may determine that sampling through an on-site assessment of the subcontractor(s) is necessary to directly assess competence.

3.2 Technical Requirements:

- 3.2.1.3 If a PTP subcontracts services pertaining to determination of assigned value, conducting homogeneity and stability studies etc. to a laboratory, the PTP shall ensure that such services are subcontracted to competent laboratories conforming to relevant requirements of ISO/IEC 17043:2010 and any relevant standard.
- 3.2.1.4 If the PTP operates an internal laboratory but is not accredited to ISO/IEC 17025 or ISO 15189, EIAC's assessment of the PTP shall include an assessment of the PTP activities against the relevant parts of ISO/IEC 17025 or ISO 15189, as determined by EIAC.
- 3.2.1.5 When the PTP uses one or more subcontractor(s) to perform the testing, calibration, measurement, and/or examination activities and the subcontractor does not hold ISO/IEC 17025 or ISO 15189 accreditation by EIAC or another accreditation body that is a signatory of the ILAC MRA for these activities, EIAC will assess how the PTP determines the competence of the subcontractor(s). The PTP shall determine compliance in accordance with the relevant parts of ISO/IEC 17025 or ISO 15189. EIAC may determine that sampling through an on-site assessment of the subcontractor(s) is necessary to directly assess competence.

3.3 Other Requirements

- 3.3.1. The PTP shall state the following info in the requested scope of accreditation:
- Type of proficiency testing item;
 - The measurand(s) or characteristic(s) that are to be identified, measured or tested;
 - Techniques for determination of the assigned value and its uncertainty. The PTP shall use one of the following common techniques stated in the ISO/IEC 17043, Annex B, clause B.2.1:
 - a) known values – with results determined by specific proficiency test item formulation (e.g. manufacture or dilution);
 - b) certified reference values – as determined by definitive test or measurement methods (for quantitative tests);
 - c) reference values – as determined by analysis, measurement or comparison of the proficiency
 - d) test item alongside a reference material or standard, traceable to a national or international standard;
 - e) consensus values from expert participants – experts (which may, in some situations, be reference laboratories) should have demonstrable competence in the determination of the measurand(s) under test, using validated methods known to be highly accurate and comparable to methods in general use;
 - f) consensus values from participants – using statistical methods described in ISO 13528 and the IUPAC International Harmonized Protocol, and with consideration of the effects of outliers.

This document and all its contents are property of Emirates International Accreditation Centre (EIAC). The content is protected by copyrights laws. Any printed copy of it shall be treated as 'Uncontrolled'. Always refer to the controlled online version



3.4 Participation in Proficiency Testing

- 3.4.1 When the PTP or its subcontractor(s) perform testing, calibration, or measurement that significantly affects the validity and uncertainty of the assigned value of a measurand or characteristic in a particular PT scheme, the PTP or its subcontractor(s) shall participate in appropriate proficiency testing/inter-laboratory comparison (PT/ILC) activities representing the parameters, ranges, measurements, test technologies, methods and uncertainty of measurement described on the scope of accreditation.
- 3.4.2. The PTP or its subcontractor(s) shall maintain a documented plan that ensures participation for the period of accreditation cycle covering all the testing/calibration items within the scope of accreditation, and shall maintain records of their participation.
- 3.4.3. The PTP or its subcontractor(s) shall investigate any results found outside of predefined performance criteria, such as unsatisfactory results and corrective action shall be performed.
- 3.4.4 The PTP or its subcontractor(s) shall ensure that PT activities are not performed by the same person if other qualified personnel in the system perform accredited work.
- 3.4.5 Before accreditation can be granted, the PTP and relevant subcontractor(s) used in scheduled PT schemes by the PTP for that calendar year shall have performed satisfactorily at least one approved PT/ILC activity within the year prior to application for each test/calibration item within scope of accreditation.
- 3.4.6 PTPs or its subcontracted laboratories shall select PT/ILC providers that can demonstrate that their programs meet the requirements of the current version of ISO/IEC 17043. Acceptable PT/ILC providers are those accredited to ISO/IEC 17043 by EIAC or another accreditation body that is a signatory of the ILAC MRA for proficiency testing and when accredited PT/ILC providers are not available, the PTPs or its relevant subcontracted laboratories shall use programs that operate in accordance with ISO/IEC 17043.

4 References

- 4.1 Law No. 27/2015 establishment of Emirates International Accreditation Centre
- 4.2 Local order number 2/2010 on conditions required for licensing laboratories operating in the emirate of Dubai.
- 4.3 ISO/IEC 17011: Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies
- 4.4 ISO/ IEC 17025 General requirement for the competence of testing and calibration laboratories.
- 4.5 ISO/ IEC 15189 Medical laboratories – Requirements for quality and competence.
- 4.6 ISO/ IEC 17043 Conformity assessment – General requirements for proficiency testing
- 4.7 ISO/ IEC 13528 Statistical methods for use in proficiency testing by interlaboratory comparison
- 4.8 ILAC P10 ILAC Policy on Metrological Traceability of Measurement Results
- 4.9 ILAC P14 ILAC Policy for Measurement Uncertainty in Calibration
- 4.10 EIAC Publications EIAC-RQ-GEN-001 EIAC General Accreditation Requirements
- 4.11 EIAC Publications EIAC-RQ-GEN-002 Conditions for the use of EIAC Accreditation Symbol and ILAC MRA / IAF MLA Marks