

	<b>ENAS Technical Requirement for Participation in Proficiency Testing</b>		<b>ID. No. : ETR 02</b>
	<b>Revision No: 05</b>	<b>Revision Date: 20-03-2019</b>	<b>Page 1 of 8</b>

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## 1. Purpose/ Scope

- 1.1 This document sets out the requirements of ENAS regarding participation of conformity assessment body (CAB) seeking ENAS accreditation in inter-laboratory comparison (ILC) or proficiency testing (PT) programs.
- 1.2 These requirements are applicable to all testing and calibration laboratories (including medical laboratories) seeking accreditation from ENAS. This also holds for some types of accredited inspection bodies where testing activities affect and determine the inspection result and/or the activities are within the mandatory scopes of accreditation as per UAE law and regulation.

## 2. Definitions

- 2.1 **Proficiency testing (PT)** is the evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (ISO/IEC 17043).
- 2.2 **Inter-laboratory comparison (ILC)** is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories or inspection bodies (where applicable) in accordance with predetermined conditions (ISO/IEC 17043).
- 2.3 **Measurement Technique** is process of testing/calibrating/identifying the property, including any pre-treatment required to present the sample, as received by the laboratory, to the measuring device. (e.g. ICP-MS, Rockwell Hardness, PCR, Microscopy, Force Measurement).
- 2.4 **Property** is the quantity being measured (e.g. Arsenic, Fat, Creatinine, Length, Hardness, Force, Voltage).
- 2.5 **Product** is the item that the measurement technique is being applied (e.g. Soil, Vegetables, Serum, Polystyrene, Concrete, Switchgear).
- 2.6 **Sub-discipline** is an area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related (e.g. Determination of Arsenic in soil by ICP-MS).
- 2.7 **Level of Participation** is the number of sub-disciplines that an organization includes within its scope, and therefore the number of specific proficiency tests that should be considered for participation.
- 2.8 **Frequency of Participation** is how often a laboratory (or inspection body where applicable) needs to participate in PT for a given sub-discipline. Intervals may vary from sub-discipline to sub-discipline within a laboratory.

## 3. ENAS Requirements

### 3.1 General

- 3.1.1 CABs seeking to achieve or to maintain their status as accredited with ENAS shall demonstrate their competence as per relevant requirements. One of the elements by which accredited calibration laboratories, testing and medical laboratories, and inspection bodies where relevant, can demonstrate technical competence is by satisfactory participation in available and appropriate PT activities.

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3.1.2 Proficiency tests are an essential tool to demonstrate laboratory and inspection body (where relevant) competence and to assist in maintaining the quality of the laboratory or inspection body performance. This enables ENAS to review and evaluate the competence for the implementation of tests/calibration methods or inspections and the viability of the management system independently.

3.1.3 CAB is responsible for identifying and search for the suitable PT/ILC provider according to the requirement of this document; however, the CAB can refer to EPTIS, which is a worldwide PT database ([www.eptis.org](http://www.eptis.org)).

3.1.4 ENAS aims to involve the CABs, regularly in international proficiency tests selected by organisation similar but not limited to APAC or ARAC to compare the performance of their accredited CABs internationally.

3.1.5 ENAS approved providers of PT/ILC services shall be accredited as per ISO/IEC 17043 Standard or among the PT/ILC providers approved by ENAS which may be duly communicated via ENAS website ([www.enas.gov.ae](http://www.enas.gov.ae)) or directly to the interested CABs. Use of other PT/ILC services providers not meeting that requirement shall require previous approval by ENAS.

### 3.2 Requirements prior to gaining ENAS accreditation

3.2.1 For the attainment of their accreditation, laboratories and inspection bodies (CAB) are committed to evidence satisfactory participation in PT representative for the applied scope of accreditation as long as these are available and also technically and economically adequate. Results shall refer to sub-discipline(s), facilities, personnel and equipment as requested in the application for accreditation. Additionally, to be accepted by ENAS, PT results shall not be older than 4 years from the application date of the CAB.

**N.B:** *For calibration, CABs must participate in PT schemes who are suitable for the CMC in the requested scope (e.g. PT for Mass calibration class  $M_1$  is not acceptable for lab applying for Mass calibration class  $E_2$ ).*

3.2.2 Furthermore, for the attainment of their accreditation, CABs shall prepare a suitable PT participation plan as defined in clause 3.3 next.

3.2.3 These requirements shall be applicable to extension of scopes of accreditation too.

### 3.3 PT Participation Plan: Level and Frequency of Participation

3.3.1 ENAS requires annual activity on PT that is appropriate to the scope of accreditation and consistent with a defined and approved PT participation plan.

3.3.2 The PT participation plan shall be formulated by the laboratory or inspection body (where relevant) considering ENAS PT participation requirements defined in this document, any PT requirements set by regulators, common PT practices and benchmark in relevant industry or professional sectors, Regional Cooperation bodies, or other interested parties.

3.3.3 The PT participation plan shall define the level and frequency of PT participation of the CAB and shall be consistent with the scope of accreditation.

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3.3.4 Preparation of the PT participation plan shall start by the CAB identifying the sub-disciplines that apply for the test/calibrations for which they seek accreditation. The number of sub-disciplines identified define the level of PT participation required.

ENAS acknowledges that participation in a specific PT for every measurement technique used by the CAB and for every property measured in every product, is unlikely to be feasible, both logistically and economically. Therefore, ENAS expects that the CAB shall identify groups of sets of measurement techniques, properties and products (see figure 1 in Annex) on which the outcome of a PT for one of these sets can be directly correlated to the others sets of measurement techniques, properties and products contained within the group. These groups of sets of measurement techniques, properties and products are termed a sub-discipline.

A sub-discipline, as defined above, may contain more than one measurement technique, property or product as long as equivalence and comparability can be demonstrated. When determining a sub-discipline, the CAB shall consider that it should generally not contain different technical competences. Different technical competences can usually be identified by the need for different qualifications, training, and use of different equipment, knowledge or experience.

In order to assure that the PT participation plan covers the whole scope of accreditation, definition of the sets of measurement techniques, properties and products shall be done so that it can be directly correlated with the scope under accreditation.

When determining a sub-discipline, it may be helpful to consider a stepwise approach working up from measurement technique through properties to products. This is because it is more likely that there will be several products and/or properties associated with one measurement technique within a given sub-discipline than vice versa:

- With reference to the measurement technique: It is possible but not common to include different measurement techniques in the same sub-discipline.
- With reference to the property to be measured, determined or identified: It may be possible to include more than one property (parameter) in the same sub-discipline.
- With reference to products to be tested: It may be possible to include different products in the same sub-discipline provided that the matrices, objects or materials included, are of equivalent nature.

Note: Section 5 of the document EA-4/18 INF:2010 provides some case studies to illustrate how a CAB might review their scope of work and derive a number of sub-disciplines.

3.3.5 After identifying the sub-disciplines / level of PT participation suitable to cover all the scope of accreditation, the PT participation plan shall be completed by defining the frequency of participation.

ENAS requires annual successful participation in PT/ILC projects to sub-disciplines identified in the PT participation plan. Additionally, the CAB shall develop their PT participation plan so that it is completed at least once in one accreditation cycle (3-year period between full reassessments) which means that evidence of successful PT activity to all sub-disciplines suitable to cover the whole scope of accreditation within one accreditation cycle shall be provided.

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3.3.6 The CAB shall review the PT participation plan for its suitability on an annual basis, usually during formal management review, in response to changes in staffing, methodology, instrumentation, etc. Evidence of this activity shall be available upon ENAS request.

### 3.4 Assessment of PT participation and performance

3.4.1 ENAS may consider suitable PT participation plan, successful participation in PT/ILC projects and proper evaluation and analysis of results by CAB, as enough evidence of the technical competence of the CAB under assessment.

3.4.2 PT participation plan, evidence of PT/ILC participation as planned, PT/ILC results, analysis and conclusions shall be provided by the CAB to ENAS when requested and to the assessment team for evaluation, together with ACF 11-33 form about PT/ILC participation follow-up, and the rest of ENAS relevant forms.

3.4.3 The PT participation plan prepared by the CAB shall provide evidence to ENAS assessment team with regards to:

- Consistency of the sub-disciplines identified by the CAB. When a CAB determines that more than one measurement technique, property or product is classified under the same sub-discipline, the assessment team shall evaluate whether the CAB can justify and demonstrate equivalence. This can be usually done by e.g., method validation data, or use of the same standard method.
- Suitability of the PT participation plan in relation to the scope of accreditation.
- Frequency of participation is defined as per the relevant requirements in this document.

Failing at meeting these requirements may affect the scope of accreditation of the CAB.

3.4.4 For the case where some areas of testing and calibration are not available or a suitable PT does not exist or is not practical, ENAS and the laboratory (or where relevant, the inspection body) shall come up with a suitable alternative by which the performance can be assessed and monitored in order to confirm the quality of results. The discussion between the assessment team and the CAB on the development of the alternative plan should involve the ENAS Program Manager and agreement should be reached prior submitting Assessment deliverables to ENAS. When necessary, technical support from ENAS Technical Officer and/or TAC members may be requested. In the above-mentioned context, the following alternatives may be considered:

- Inter-laboratory comparisons to evaluate the performance characteristics of a method.
- Inter-laboratory comparisons to characterise a reference material.
- Inter-laboratory comparisons involving two (bilateral) or more laboratories to compare results on their own initiative. The organizer shall have a comprehensive documented procedure how to carry out the comparison and perform statistical analysis, based on ISO/IEC 17043, ISO 13528 and ISO 5725 standards.
- Inter-laboratory comparisons to support statements of the equivalence of measurement of NMIs.

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- Other QA/QC measures as per the relevant requirements in ISO/IEC 17025 Standard, or ISO 15189 Standard for medical laboratories.

3.4.5 PT/ILC results shall provide ENAS assessment team with evidence regarding:

- Frequency of participation is according to the defined PT participation plan of the CAB.
- Facilities where the PT/ILC measurements were conducted to verify they correspond to the facilities object of accreditation.
- Equipment used to carry out PT/ILC measurements is on the list of equipment provided by the CAB in the frame of the accreditation process.
- Personnel involved in the PT/ILC measurements match the information provided by the CAB regarding personnel resources involved in activities within the scope of accreditation. It shall be verified that PT/ILC measurements are done not only by senior staff not directly involved in the day-to-day measurement performance of the CAB.
- Consistency between CAB's measurement uncertainty to the PT/ILC measurements and the corresponding CMC of the CAB (when applicable).
- Measurement uncertainty of the CAB to PT/ILC measurements is consistent with the corresponding PT reference value (uncertainty and biased).
- Compatibility of CAB's PT/ILC results with the reference values as per the criteria defined in the PT program.

Failing at meeting these requirements may affect the scope of accreditation of the CAB.

3.4.6 CAB shall carry out suitable analysis and evaluation for each PT/ILC participation and results withdrawing its own conclusions of its own performance. To draw its conclusions, the CAB shall take into consideration the following information:

- Sub-discipline;
- PT/ILC provider / coordinator;
- Identity/profile of the participants;
- PT/ILC schedule;
- origin and character of testing samples / travel standard;
- test/measurement methods used and, where possible, the assignment of the results to particular methods;
- organisation of the PT/ILC (e.g., the statistical model, the number of replicates, the parameters to be measured, the manner of execution, the measurement conditions);
- criteria used by the organising body to evaluate the participants' performance.

A CAB shall withdraw its conclusions considering the fact that PT/ILC can be used as an education and risk management tool. Therefore, PT/ILC results shall be analysed applying a comprehensive approach aiming the conclusions to cover not only method validation, but also other requirements such as

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laboratory facilities and conditions, maintenance and/or improvement of personnel competence, evidence and/or improvement of CMCs, suitability of equipment.

3.4.7 A CAB must record its own conclusions on results of each PT/ILC activity it has participated. If a CAB comes to the conclusion that its performance was inadequate it must follow this up by carrying out root-cause analysis and taking appropriate corrective action, which must be recorded, aiming to improve its performance within a timescale. This information shall be available to the ENAS assessors. If a laboratory did not participate in proficiency testing, it must record its reasons for failing to do so.

3.4.8 The assessment team shall evaluate the analysis of PT/ILC results and conclusions prepared by the CAB. If a CAB does not participate or participation is only partially successful in PT/ILC, which are available and adequate for its scope of accreditation, it may affect accreditation of the laboratory. Incorrect or insufficient PT/ILC results need to be processed as nonconforming testing (or inspection) by ENAS assessors.

In principle, insufficient participation in a single proficiency test shall not have immediate consequences for the accreditation. The assessment team shall evaluate CAB's justification for failing to do so and suitable corrective action shall be agreed within a timeframe. Repeat failure in PT/ILC participation commitment by the CAB may affect its scope of accreditation.

In the case where the participation in proficiency tests is unsuccessful, the assessment team shall evaluate suitability of root-cause analysis by the CAB and corrective actions defined to improve its performance. Further proficiency tests or additional assessments may be imposed by ENAS upon evaluation by assessment team.

Repeat unsuccessful PT/ILC participation shall be analysed by the assessment team taking into consideration aspects such as resources involved (lab facilities, equipment, technical staff), PT/ILC results analysis and evaluation as well as CAB's conclusions and corrective actions. A reduction of the accreditation scope may be enforced.

#### 4. References

ISO/IEC 17043 - Conformity assessment -- General requirements for Proficiency Testing.

ISO/IEC 17011 - Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies.

ISO/IEC 17020 - Conformity assessment — Requirements for the operation of various types of bodies performing inspection.

ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories.

ISO 15189 - Medical laboratories – Requirements for quality and competence.

ILAC P9:06 - ILAC Policy for Participation in Proficiency Testing Activities.

## ANNEX

Figure 1 – PT Participation Plan. Guidance to identify Sub-disciplines / Level of PT Participation.

