



QUALITY INFRASTRUCTURE FOR RENEWABLE ENERGY SOURCES & ENERGY EFFICIENCY  
IN LATIN AMERICA AND THE CARIBBEAN

## **Project**

**“Quality Infrastructure in Renewable Energy and Energy Efficiency in Latin America and the Caribbean”**

**PN. 2015.2162.4 (95309)**

## **REPORT**

**Activity „ QICA workshop on ISO/IEC 17043  
and ISO 13528 “**

Holiday Inn at the Panama Canal  
Panama City, Panama  
20-22 March, 2017

Realized by: (Daniel Tholen, USA)



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### 0 Executive Summary

The Workshop was conducted in Panama City as a Project of the Quality Infrastructure Council of the Americas (QICA). There were 32 participants representing Metrology Institutes and Accreditation Bodies in 19 different countries. The Workshop consisted of lectures, discussion, and a group exercise, concerning international standards for proficiency testing. Participants had a broad range of experience, including experts who have recently been assigned responsibility for PT, and experts who have been offering or overseeing PT schemes for many years. Discussion allowed investigation of points where the standards are not clear, or where different countries might implement the standards in different ways. The workshop could discuss differences between requirements in the standards, and requirements for accreditation including regulatory approval.

In a concluding discussion the participants could define further steps to develop PT in the Americas. Participants will send responses to the PTB Coordinator, on PT schemes being used, and needs for additional PT in the region.

### 1 Introduction

#### Background:

There is a general need for proficiency testing schemes in all fields of testing regarding health and industry. Some of the needs are being met, but many are not. There are PT schemes being conducted by SIM members, so there is expertise in conducting schemes; however there are few PT schemes that are commercially available.

The different countries in the SIM/IAAC region have differing requirements for accreditation and proficiency testing. There are differences also in how PT schemes are approved for use in accreditation. A third source of differences is in allowance for external validation, when PT is not available.

In order to build availability of PT schemes, there is a need for a common understanding of the relevant international standards, and their application in a multi-national economy. The Workshop was conducted to address the need for a common application of the ISO standards, and to build a foundation for cooperation in development of PT schemes.

#### Task (according to ToR):

The Task for the Contractor was to develop and conduct a 3-day Workshop on the requirements of ISO/IEC 17043 and ISO 13528. The participants are from SIM and IAAC member organizations, with varying levels of experience in a wide variety of fields of measurement. The Contractor will then report on the outcome of the Workshop.

#### Preparation:

The Contractor prepared presentation slides, discussion material, exercises, and spreadsheets for examples in ISO 13528. This was more material than could be covered in the Workshop, but it could be useful background material.



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### Methodology:

The primary format was lecture and discussion. Participants were encouraged to ask questions at any time. The expertise within the group was sufficient to have discussion on difficult points in the standards, and their implementation.

There was one breakout group exercise, with different groups (2-7 people) designing schemes for five different fields of measurement.

### Programme:

The Programme consists of slides, text files of exercises, and spreadsheets for ISO 13528 examples. This material has been provided to the Client in advance of the Workshop. It could be available as attachment to this report.

## **2 Realization and Results of the Activity**

The Workshop provided an effective forum for creating a common understanding of the standards for PT and how the requirements fit into local accreditation needs and national regulations. This would lead to better regional consistency in the application of the standards, which should help develop regional PT schemes.

### Specifically:

- a. The Workshop provided basic background information on the development of the ISO standards, and the intent of the specific requirements. This was especially useful for Workshop participants who are fairly new to PT, and used the Workshop as basic awareness training.
- b. For all participants there was better understanding of the nature of ISO Standards, which is limited by the available experts involved, ISO Directives and editorial style, and by difficulty in reaching consensus on all topics. The better understanding should lead to greater flexibility for the provider and for the accreditation bodies, but also a need for sufficient expertise in the topic.
- c. For Workshop participants that had long experience in providing or overseeing PT, there was a forum for discussion of issues that are not clear in the standards, or are related to issues of application by accreditation bodies or regulations.
- d. There were brief discussions of statistical calculations, for the small number of participants that do data analysis. Participants were provided with spreadsheets to allow replication of the examples in ISO 13528. The spreadsheets are understandable by persons familiar with statistical analysis, Excel, and ISO 13528.
- e. The last session of the Workshop provided an opportunity for discussion of follow-up activities for SIM, IAAC, and QICA. The first step is a survey of members on PT schemes that are approved for the various bodies, schemes being offered within their countries, and PT schemes needed or not feasible.

## **3 Evaluation – Not conducted**



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### 4 Conclusions and Recommendations

Conclusions are based on the Contractor's observations during the Workshop proceedings.

a. There is a good understanding of the standards among experts who have experience with operating PT schemes or establishing criteria for PT participation. However there are some differences in how the requirements are applied across the region.

Recommendation: Build on interpersonal contacts and agreements achieved at the Workshop. Perhaps clarify IAAC policies on PT participation, and MRA agreements.

b. There is a wide variety of needs in different countries (e.g., coffee, rum, radiologic contamination, concrete), but few laboratories per country. Regional cooperation could lead to better availability of schemes that are relevant to regional needs.

Recommendation: The QICA survey of members should identify opportunities for developing PT schemes that can be shared throughout the region.

c. Use of reference values and external criteria for performance criteria (e.g., experience, expert judgment, or claimed uncertainty), could lead to better availability of PT when there are fewer than 20 interested participants.

Recommendation adoption where possible of reference values, if sufficiently traceable, and with criteria for performance determined by defensible external criteria.

d. Accreditation of PTP in more member countries might help regional acceptance. There could also be regional cooperation in technical assessors or experts. For example, some Workshop participants demonstrated good understanding of statistical methods for PT; this expertise could be shared regionally, as data analysts, assessors or trainers.

e. An understanding that the ISO standards and ILAC policies are not clear on all points should lead to greater flexibility in designs for PT schemes. This would place reliance on technical judgment for appropriate design and performance criteria, rather than statistical methods for consensus that might not be appropriate or are not reliable for small numbers of participants. The need for technical expertise applies also to the accreditation bodies, if they are to assess the appropriateness of the design.

Recommendation: Accreditation bodies should have technical expertise in statistical methods for proficiency testing, in assessing for conformity to ISO/IEC 17043, or for reviewing the adequacy of a scheme for a group of laboratories. This could require contracting with regional experts.

f. There is a lack of comprehensive information on schemes offered within the IAAC region, or international schemes that are feasible and relevant.

Recommendation: To conduct a survey of SIM and IAAC (one response per country) on schemes that are approved for use, schemes conducted within the countries. This is to provide a comprehensive listing of available PTs, for sharing information, and to assist in promotion for new programs.



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**Annex A Schedule** (modified from plan, to reflect what occurred)

ISO/IEC 17043:2010 *Conformity assessment – general requirements for proficiency testing* and  
 ISO 13528:2015 *Statistical Methods for Proficiency Testing by Interlaboratory Comparisons*  
 Three day workshop on proficiency testing, Panama City, 20-22-23 March, 2017

<b>Day 1</b>	<b>Monday, 20 March</b>
8:30-10:15	Session 1.1 – Introduction to Workshop
	<ul style="list-style-type: none"> <li>Welcome</li> <li>Introduction of organizer and presenter</li> <li>Introduction of participants: areas of particular interest, experience, and needs regarding PT.</li> <li>Use of the ISO documents by IAAC and SIM (includes IAAC/SIM cooperation)</li> <li>Purpose and expectation of the training course</li> </ul>
10:15-10:30	Break
10:30-12:15	Session 1.2 – Introduction to ISO PT documents
	<ul style="list-style-type: none"> <li>Purposes of documents, current uses</li> <li>Purposes for Interlaboratory comparisons</li> <li>Objectives for PT scheme</li> <li>Consensus or accuracy/goal-based evaluation of performance.</li> <li>Appropriate statistical methods</li> </ul>
12:15-13:30	Lunch
13:30-15:15	Session 1.3 – Design of PT Scheme
	<ul style="list-style-type: none"> <li>Requirements for organization, equipment, personnel</li> <li>Requirements for design of PT</li> <li>Requirements for statistical design</li> </ul>
15:15-15:30	Break
15:30-16:15	Session 1.4 – Preparation of PT items
	<ul style="list-style-type: none"> <li>Requirements for preparation of PT items</li> <li>Homogeneity and stability assessment</li> <li>Statistical methods for homogeneity and stability assessment (will include exercise from ISO 13528)</li> </ul>
16:15-17:00	Session 1.5 – Technical requirements for operation of PT schemes
	<ul style="list-style-type: none"> <li>Policies and procedures when different measurement methods are used</li> <li>Instructions, handling, storage</li> <li>Records</li> </ul>
17:00	Close Day 1
<b>Day 2</b>	<b>Tuesday, 21 March</b>
8:30-10:15	Session 2.1 – Assigned values
	<ul style="list-style-type: none"> <li>Requirements for assigned values</li> <li>Procedures for determining assigned values</li> <li>Uncertainty of assigned values</li> </ul>
10:15-10:30	Break
10:30-12:15	Session 2.2 – Evaluation of performance
	<ul style="list-style-type: none"> <li>Requirements for evaluation of performance</li> <li>Procedures for determining evaluation criteria</li> </ul>



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	<ul style="list-style-type: none"> <li>• Performance statistics (including exercise from ISO 13528)</li> </ul>
12:15-13:30	Lunch
13:30-15:15	Session 2.3 - Exercise on PT scheme designs ...breakout groups
	Breakout groups produce scheme designs <ul style="list-style-type: none"> <li>• Calibration: Pressure</li> <li>• Food: Vegetable Oil</li> <li>• Environmental: Pesticide in water</li> <li>• Medical: Cholesterol and Triglyceride</li> <li>• Minerals: Copper Oxide</li> </ul>
15:15-15:30	Break
15:30-16:15	Session 2.3 (continued) Report on group designs
16:15-17:00	Session 2.4 – Performance statistics
	<ul style="list-style-type: none"> <li>• Requirements for evaluation of performance</li> <li>• Procedures for determining evaluation criteria</li> <li>• Performance statistics (including exercise from ISO 13528)</li> </ul>
17:00	Close Day 2
<b>Day 3</b>	<b>Wednesday, 22 March</b>
8:30-10:15	Session 3.1 – Performance statistics and evaluation criteris
	<ul style="list-style-type: none"> <li>• Criteria for uncertainty of assigned values</li> <li>• Alternative approaches when criteria not met</li> </ul>
10:15-10:30	Break
10:30-12:15	Session 3.2 – Statistical analysis
	<ul style="list-style-type: none"> <li>• Statistical techniques for small numbers of participants</li> <li>• Robust statistical techniques</li> <li>• Examples in ISO 13528</li> </ul>
12:15-13:30	Lunch
13:30- 15:30	Session 3.3 – Additional topics
	<ul style="list-style-type: none"> <li>• Qualitative measurands and statistical analysis</li> <li>• Statistical expertise at PTP and AB,</li> <li>• Needs for AB reviewers, etc.</li> </ul>
15:30-16:00	Break
16:00-17:30	Session 3.4 – QICA planning
	<ul style="list-style-type: none"> <li>• Action plans for participant bodies.</li> <li>• Plans for NMI and AB regarding PT availability and approval.</li> <li>• Recommendations for IAAC, SIM, ILAC</li> </ul>
17:30	Close



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### Annex B: Attendees (pdf follows)

Number		Name		Country, Organization
1	Mr.	Tholen	Daniel William	United States - im Übrigen,
2	Mrs.	Gutierrez de Monzon	Karen	El Salvador, Centro de Investigaciones de Metrología
3	Mr.	Quiroga	Aldo	Peru, INACAL
4	Mrs.	Valenzuela Aldana	María Lourdes	Paraguay, INTN
5	Mr.	De Oliveira Araujo	Thiago	Brazil - Rio de Janeiro, INMETRO
6	Mrs.	Palacios	Ivana Marisa	Argentina, INTI
7	Mrs.	Nápoli	Romina	Uruguay, LATU
8	Mrs.	De Oliveira	Estela María	Brazil - Rio de Janeiro, Instituto de Radioproteção e Dosimetria
9	Mrs.	Bruce	Sally	United States - Washington, D.C., NIST
10	Mr.	Molina Castro	Gabriel Ignacio	Costa Rica, LACOMET
11	Mr.	Salguero Salvador	Rómulo Enock	Guatemala, CENAME
12	Mr.	Garrido	Oscar	Chile, INN
13	Mrs.	Gamiño Galindo	Maricela	Mexico, CENAM
14	Mrs.	De la Guardia	Gabriela	Panama, CENAMEP
15	Mrs.	Lewis	Karlene	Trinidad and Tobago, TTBS
16	Mr.	Macea Selmo	Joel Abel	Dominican Republic, INDOCAL
17	Mrs.	Zuta Chong	María Imilce	Peru, PTB
18	Mr.	Mora Murillo	José Humberto	Costa Rica, ECA
19	Mr.	Greenaway	Anthony	Jamaica, Jamaica National Agency for Accreditation
20	Mr.	Gaytan Ramírez	Enrique	Argentina, OAA
21	Mrs.	Barillas de Hernández	Vilanova Duberly	Guatemala, Oficina Guatemalteca de Acreditación
22	Mrs.	Madrid Flores	Liza Maria	Honduras, OHA
23	Mrs.	Caballero Moreno	María Yrene	Paraguay, ONA
24	Mrs.	Galeano Rivas	Nilsa Marisol	Paraguay, ONA
25	Mrs.	Vasquez Gonzalez	Claudia Elizabeth	El Salvador, OSA
26	Mr.	Medina de la Barra	Milton Andrés	Ecuador, Servicio de Acreditación Ecuatoriano
27	Mrs.	Torres	Cecibel	Panama, Consejo Nacional de Acreditación
28	Mrs.	Osejo Baca	Rosa Angela	Nicaragua, ONA
29	Mr.	Aguilar Aliaga	Marcelo Edilberto	Peru, SGCAN – RED ANDINA DE ACREDITACIÓN
30	Mr.	Collazo Palacio	Adalberto	Cuba, ONARC
31	Mr.	Fernandes da Silva	Mario Antonio	Brazil - Rio de Janeiro, Cgcre
32	Mr.	Vega	Guillermo	Panama