

TRAINING REPORT

Workshop: Implementing ISO IEC 17034: Challenges for Quality Infrastructure Organizations in Latin America & the Caribbean

Date: December 4 to 6, 2017

Place: San Salvador, El Salvador

Instructor(s): Kelly Black of Neptune and Company, Inc. USA and Robert Knake of A2LA, USA.

Addressed to:

Reference materials experts belonging to the “Sistema Interamericano de Metrología” (SIM) and “InterAmerican Accreditation Cooperation” (IAAC) including:

- NMI’s peer evaluators
- Delegates to the SIM Quality System Task Force (QSTF)
- IAAC Accreditation Bodies’ staff and assessors,
- IAAC peer evaluators

The workshop was well attended with 34 participants including the two instructors. A listing of attendees is included at the end of this report.

Background:

In 2014 COPANT, IAAC and SIM formalized their cooperation creating the Quality Infrastructure Council for the Americas (QICA). Its aim is to promote a shared vision for mutual support in standards, accreditation and scientific, industrial and legal metrology. The German Cooperation supports QICA joint activities through PTB with a special fund. Some of the activities that QICA jointly proposed are:

- Offering joint seminars and training courses on priority areas;
- Carrying out joint meetings to address matters of common interest.

A topic of common interest to IAAC and SIM and their members is the implementation of the ISO 17034:2016 standard “General requirements for the competence of reference material producers”

ISO 17034:2016 specifies general requirements for the consistent operation of reference material producers and sets out the requirements in accordance with which reference materials are produced. It covers the production of all reference materials, including certified reference materials

There is a special interest of IAAC and SIM in this topic, as ISO 17034:2016 has recently been published as a result of the revision of ISO Guide 34:2009, in November 2016. Now both organizations aim to train the staff of national metrology institutes (NMIs) and accreditation bodies (ABs) in the application of the new standard.

Objective:

- Train Accreditation Bodies' staff, assessors and IAAC peer evaluators on the standard.
- Train NMI experts to understand specifically and in depth the ISO 17034 standard requirements
- Exchange opinions and expectations regarding the implementation of the ISO 17034
- Identify specific topics in its implementation which could become critical

Training and organization improvements:

The training was conducted over three days and included an introductory quiz to gauge attendee's knowledge of the standard, instructor lecture, presentation slides, group exercises and interactive discussion regarding common scenarios associated with the implementation of the ISO 17034:2016 standard. The audience included participants with varying levels of knowledge of the standard. Some of the Accreditation Bodies (AB) in attendance did not currently have an accreditation scheme for reference material producers and others had very mature systems. The National Metrology Institutes (NMI) in attendance all had experience with reference material production and implementation of the requirements of the standard. Overall, the instructors were very impressed with the level of knowledge and expertise that the participants brought to the workshop as it demonstrated a strong backbone for future growth in the availability of quality reference materials in the Americas region.

As the workshop progressed participants demonstrated increased knowledge with the application of the standard and associated principals, such as statistical techniques associated with homogeneity, stability, and uncertainty approaches. There was also an increased understanding of the associated ISO Guides 30, 31 and 35 and how they were incorporated into ISO 17043:2016. A significant amount of time was spent discussing the transition from ISO Guide 34 to ISO 17043:2016 and the impact that has had on reference material producers and accreditation bodies. Most of the accreditation bodies in attendance had already started the implementation of the new standard if they offered an accreditation scheme for reference material producers.

The workshop also addressed the application of the ISO obligatory language regarding the Option A/B management system requirements. There was not consensus as to what was an acceptable approach regarding accepting an ISO 9001 certification in lieu of evaluating the management system requirements of ISO 17034:2016. The general consensus seemed to be that it would not be acceptable to accept a 9001 certification and that the requirements of Section 8 must be evaluated regardless. However, some participants felt it would be appropriate to use a 9001 certification as a means of supporting compliance to Section 8, but most stated there would need to be caveats associated with that approach.

This is an area that need further discussion and guidance from IAAC as currently there isn't consensus and the Option A/B impacts other standards under the Multilateral Recognition Arrangement.

The workshop concluded with a discussion of publication of ISO/IEC 17011:2017 and how that will impact the accreditation of reference material producer accreditation. Also included in this discussion was the requirements of IAAC MD028 and Asia Pacific Laboratory Accreditation Cooperation (APLAC) TC008. The purpose of the discussion was to discuss the need for harmonization amongst accreditation bodies, not only in the IAAC region but globally.

The revision of 17011:2017 will require an evaluation and likely revision of IAAC MD028. APLAC TC008 is currently under revision and will likely be published in soon which should increase harmonization across the regions. Also, with ISO 17034 accreditation being added to the ILAC MRA, ideally in 2018 there will be a need for ILAC level policy to be developed. There is a need to improve consistency in areas including assessment of statistical techniques, representation of scopes of accreditation and application of the standard. There may be need for a future workshop to address these issues when ILAC has adopted ISO 17034 accreditation to the ILAC MRA.

The workshop ended with general question and answer session where participants provided specific questions and with the instructors and fellow participants offering their advice and opinions. As the workshop had a general focus on all areas of reference material production and implementation ISO 17034:2016 there wasn't much time spent on questions related to production of any specific type or types of reference materials. It would likely be beneficial to survey IAAC membership to see what specific technical training would be of the most use to the members and organize a future workshop.

Conclusion and Recommendations for Future Activities:

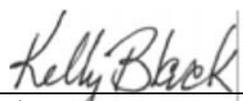
The workshop was very successful and the knowledge of the participants made for a very interactive workshop with sharing of expertise and real-life knowledge of implementation of a system that meets the requirements of the ISO 17034:2016 standard. There is more work to be done and a summary of recommended future activities can be found below:

- **Survey of IAAC Members to see what areas of more specific technical RMP training would be beneficial.**
- **IAAC to work in coordination with ILAC to create a formal policy on the implementation and assessment of Section 8 Option A/B regarding evaluation of management system requirements.**
- **Hold a workshop to discuss the revision of ISO/IEC 17011:2017 and assess its impact on IAAC documents and accreditation. This should take place after ISO 17034 is added to the ILAC MRA and done in coordination with other regions such as APLAC or EA, if possible.**

Sincerely,



Instructor



Instructor



Group Photo



Workshop Schedule

Time	Activity	Responsible	Method/Used Material
First Day: 12/04			
08:30	Registration		
9:00-10:15	<ul style="list-style-type: none"> • Welcome and Introductions • Discussion on participants' goals of course • Purpose and expectations of the course • Discussion on transition to 17034 and new structure 	R. Knake and K. Black	Lecture
10:15-10:30	<i>Morning Break</i>		
10:30-12:15	<ul style="list-style-type: none"> • Introductory "Quiz" • ISO 17034 – General and Structural Requirements • ISO 17034 – Resource Requirements 	R. Knake and K. Black	Quiz, lecture, slide presentation, review of the standard
12:15-13:30	Lunch		
13:30-15:15	<ul style="list-style-type: none"> • ISO 17034 – Technical & Production Requirements • ISO 17034 Requirements – Homogeneity 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.

Time	Activity	Responsible	Method/Used Material
15:15-15:30	Afternoon Break		
15:30-17:00	<ul style="list-style-type: none"> ISO 17034 Requirements – Technical & Production Requirements 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.
Second Day: 12/05			
8:30-10:15	<ul style="list-style-type: none"> ISO 17034 Requirements – Technical & Production Requirements (continued) 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.
10:15-10:30	Morning Break		
10:30-12:15	<ul style="list-style-type: none"> ISO 17034 Requirements – Stability ISO 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.
12:15-13:30	Lunch		
13:30-15:15	<ul style="list-style-type: none"> 17034 Requirements – Assignment of Property Values, Measurement Uncertainty ISO Guide 35 Discussion 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.
15:15-15:30	Afternoon Break		
15:30-17:00	<ul style="list-style-type: none"> ISO 17034 Requirements – Characterization, Certificates 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.

Time	Activity	Responsible	Method/Used Material
Third Day: 12/06			
8:30-10:15	<ul style="list-style-type: none"> • ISO 17034 - Management System Requirements • Break 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.
10:15-10:30	Morning Break		
10:30-12:15	<ul style="list-style-type: none"> • ISO 17034 - Management System Requirements • Break 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.
12:15-13:30	Lunch		
13:30-15:15	<ul style="list-style-type: none"> • Inter-relationship between ISO 17034 and other ISO REMCO documents • ISO Guide 30 • ISO Guide 31 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.
15:15-15:30	Afternoon Break		
15:30-17:00	<ul style="list-style-type: none"> • Formulating scope of accreditation for RMP • Application of IAAC MD 028 to the scope of accreditation • Revision of ISO/IEC 17011 – Potential impact on RMPs' scope and accreditation 	R. Knake and K. Black	Interactive discussion with attendees on current challenges and/or best practices. Lecture, slide presentation, review of the standard and exercises.
17:00-17:30	Wrap up and question and answer session Recommendations for IAAC, SIM, ILAC		

Workshop Attendees:

N	Surname	Name	Country	Company
1	Gaytan Ramirez	Enrique	Argentina	Organismo Argentino de Acreditacion
2	Toscana	Maria Silvia	Argentina	Instituto Nacional de Tecnologia Industrial
3	Barbiere Gonzaga	Fabiano	Brazil - Rio de Janeiro	INMETRO
4	Marques Rodrigues Caixeiro	Janaina	Brazil - Rio de Janeiro	INMETRO
5	Perez Calderon	Ruth Angelica	Canada - Ottawa	National Research Council of Canada
6	Caceres	Catherine	Chile	Public Health Institute of Chile
7	Arias Cortes	Maria Mercedes	Colombia	Instituto Nacional de Metrologia de Colombia
8	Prieto Navarrera	Lyndia Patricia	Colombia	Organismo Nacional de Acreditacion de Colombia
9	Jose Humberto	Mora Murillo	Costa Rica	ECA
10	Rodriguez Araya	Luis Damian	Costa Rica	LACOMET
11	Batista Ovalle	Grace Lucydiana	Dominican Republic	Organismo Dominicano de Acreditacion
12	Rodriguez Martinez	Roshiny del Carmen	Dominican Republic	Organismo Dominicano de Acreditacion
13	Apontez	Eduardo	El Salvador	OSA
14	B. Vispute	Jitendra	El Salvador	APLAC
15	Gutierrez	Karen	El Salvador	CIM
16	Regalado	Wendy	El Salvador	OSA
17	Vasquez	Claudia	El Salvador	OSA
18	Caceres Enamorado	Madelin Mariel	Honduras	Centro Hondureno de Metrologia
19	Chinchilla Osorio	Wendy Lilieth	Honduras	Centro Hondureno de Metrologia
20	Melendez Martinez	Fatima Gabriela	Honduras	OHA
21	Osorto Lainez	Oscar Mauricio	Honduras	OHA

N	Surname	Name	Country	Company
22	Tatiana Atenea	Ortega Alcantara	Mexico	CENAM
23	Trujillo Juarez	Sonia	Mexico	CENAM
24	Orochena	Samuel	Nicaragua	ONA
25	Vado	Brenda	Nicaragua	ONA
26	Lopez	Edilma	Panama	ACODECO
27	Torres Molinares	Cecibel Itzel	Panama	Ministry of Commerce and Industry - Council Accreditation National
28	Caballero Moreno	Maria Yrene	Paraguay	ONA-Paraguay
29	Medina Ferreira	Derlis	Paraguay	INTN
30	Riveros Llano	Cesar	Paraguay	INTN
31	Black	Kelly	United States	A2LA
32	Knake	Robert Lee	United States	A2LA
33	Ferreira	Maria Elizabeth	Uruguay	LATU
34	Perez Zambra	Ramiro	Uruguay	LATU