Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin
Nationales Metrologieinstitut

TECHNICAL COOPERATION

Expert Report

Expert Report

Sectorial Project: Support of the Quality Infrastructure: sectorial, national, regional
Project Nro 95257 / BMZ No. 2012.22967

Technical Cooperation with **IAAC**
Country | region: Latin America and Caribbean
Objective: Workshop: “Exchange of Experiences about the Interpretation of the ISO 15189:2012”
City | country: Guatemala City, Guatemala
Duration: 12th- 15th May 2015

Reporter: Imilce Zuta
Function: Expert/No. contract 4500094549t
Date: August 2015

Abbreviations | Explanation of terms used

AB	Accreditation Body
CCE	Control de Calidad Externo
CCI	Control de Calidad Interno
CLIA	Clinical Laboratory Improvement Amendments
CV	Coeficiente de Variación
ema	Entidad Mexicana de Acreditación
GA	General Assembly
IAAC	Interamerican Accreditation Cooperation
IEC	International Electrotechnical Commission
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
ILAC	International Laboratory Accreditation
LSC	Laboratory SubCommittee
MU	Measurement Uncertainty
OA	Organismo de Acreditación
OAA	Organismo Argentino de Acreditación
OGA	Oficina Guatemalteca de Acreditación
PECC	Programa Externo de Control de Calidad
PTB	Physikalisch-Technische Bundesanstalt
PT	Proficiency Testing
QI	Quality Infrastructure
SCHQC	Sociedad Chilena de Química Clínica
TC	Technical Cooperation
TSC	Training Sub-Committee
WG	Working Group

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1. PRELIMINARY REMARKS

On 7 – 8th, August 2014 it was developed the "Workshop: Exploring Avenues to Support the Improvement of Traceability in Laboratory Medicine in Latin America and the Caribbean" in Santiago de Chile. Based on this activity it was proposed a plan of activities with two main subjects to be addressed:

a) Developing of reference material for the clinical sector in the region as a support of the metrological traceability

b) Harmonization of the interpretation of the ISO 15189 by the region,

Both of them, aimed to get a reliable measurement in the clinical sector.

So this activity has been developed as a demand identified in the workshop in Chile..

2. SUMMARY (IF NECESSARY, IN WORKING LANGUAGE)

Summary (if necessary, in working language)

3. OBJECTIVE

- Review the key requirements established in the ISO 15189 standard aimed to the harmonization of their interpretation and application in order that let us the developing and improvement of the competence of the participants.
- Promote the link between the accreditation bodies and the scientific societies in clinical laboratories as pillars of the accreditation of clinical laboratories according to the ISO 15189:2012 Standard.

4. IMPORTANT RESULTS OF THE EXPERT MISSION

- Link between the representative of the accreditation body and the representative of the scientific society in the region. (countries which attended the workshop)
- Potential initiation of a joint plan of work for each country or its continuation in case it exists.
- Identification of some technical aspects in which it would be necessary to deepen in order to strengthen the technical competence of the community related to clinical laboratories.
- Training proposal for 2016 – 2017 aimed to having a harmonized criteria during the assessments which could be supplemented with technical workshops with the objective to strengthen the technical competence of the personnel of the clinical laboratory accreditation program and the own members of the scientific societies in the region.
- Identification of improvement opportunities by the clinical laboratories which were visited
- Better understanding of the ISO 15189 applicable for clinical laboratories, exchanging experiences towards a common understanding.
- Dissemination of the workshops realized in 2014, in Santiago de Chile and in 2015 in Guatemala City related to the Traceability and Accreditation Programmes in Clinical Laboratories in the **"IFCC e-news"** (***page 8 of this e-link: http://www.ifcc.org/media/322234/IFCCeNewsJuly2015.pdf***)

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4.1 GENERAL COMMENTS ON THE CURRENT SITUATION

The Workshop was held on the Hotel Howard Johnson Inn Guatemala City, Ave Reforma 4-22 Zona 9 Guatemala City, during the workshop we had the participation of

- Mrs. María Amelia Acuña, OAA (Argentine Accreditation Body)
- Mrs. Milena Monari, SCHQC (Chilean Scientific Society)
- Rosa Sierra Amor, (IFCC – International Federation of Clinical Chemistry and Laboratory Medicine)
- Sandra Quintana, technical expert of ema (Mexican Accreditation Body)
- Javier Gella, Biosystems (Spanish Scientific Society)
- Imilce Zuta, PTB

The host institutions was OGA, the Accreditation Body from Guatemala, whose director is Mr. Alexander Pineda.

The countries that attended the workshop were: Argentina, Colombia, Costa Rica, Cuba, Chile, Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Mexico (only presenters), Paraguay, Peru and Uruguay

The number of participants was **43**, which exceeds the expected figure, however we managed the workshop in order to balance the participation and cover the key points of the standard in the two days.

4.2 DESCRIPTION OF THE CENTRAL ACTIVITIES AND RESULTS

The first two days we had the dissertation of the key subjects of the ISO 15189 Standard according to the programme. The outcomes of the discussion we have got of the workshop are shown in the **Table 1,** in Spanish

Table 1

Requisito	Tema	Comentario
4.1.1.3 a) y b)	Conducta ética	Establecimiento de principios en el marco del cual opera el laboratorio clínico (LCLI) Es importante que se tenga en cuenta lo requerido por la ley y regulación vigente aplicable en el país en torno al accionar del LCLI.
4.1.1.3 c)	Conflictos de interés	Analizar y demostrar la ausencia o potencial existencia de conflictos de intereses y en este último caso, mencionar medidas adoptadas

		para evitar que se produzcan y la efectividad de la adopción de las mismas.
4.1.1.3 e)	Confidencialidad de la información	Mantener la confidencialidad de la información (resultados) respecto a la data del paciente para potenciales futuras investigaciones. Mantener en reserva la identidad del paciente respecto a los resultados de una prueba de HIV a la que se sometió
4.1.2.1 b)	Política de la Calidad	El LCLI tiene una política de la calidad establecida cuando es conocida y comprendida por el personal del laboratorio a todo nivel
4.1.2.1 e)	Responsabilidad, autoridad e interrelaciones	Una forma de demostrarlo es a través de un organigrama y el manual de organización y funciones
4.4.1	Servicios de laboratorio, definidos, documentados y comprendidos	En algunos países de la región tales como en México, el LCLI puede atender al paciente ambulatorio, en estos casos es importante que se le otorgue información correcta y completa acerca de los métodos de ensayo involucrados en el servicio de análisis clínico, sus rangos de variabilidad biológica, entre otros. Al término de brindar esta información, el paciente firma la solicitud de servicio o documento equivalente, establecido por el LCLI, en señal de estar de acuerdo con el servicio. En el contexto de lo expuesto, la competencia del personal que atiende al paciente ambulatorio y le otorga la información relativa al servicio de análisis
4.5.1.	Derivación	El LCLI deriva a) Métodos de ensayo **comprendidos en su alcance de acreditación** a Laboratorios Clínicos acreditados con base en la norma ISO 15189 o que demuestren que cumplen con los requisitos de esta norma, en la aplicación de dichos métodos de ensayo. b) Métodos de ensayo **no comprendidos en su alcance de acreditación**, pero cuyos resultados **tienen un vínculo o relación en un servicio clínico que involucra métodos acreditados,** a

		Laboratorios Clínicos acreditados con base en la norma ISO 15189 o que demuestren que cumplen con los requisitos de esta norma, en la aplicación de dichos métodos de ensayo. c) Método de ensayo **no comprendidos en su alcance de acreditación**, cuyos resultados **NO tienen vinculación alguna con servicio clínico que contenga métodos acreditados.** En este caso, el LCLI puede derivar en Laboratorios Clínicos acreditados o no con la norma ISO 15189, sin embargo es recomendable que de alguna manera el LCLI se asegure que el laboratorio derivante posea competencia en la realización de los ensayos en cuestión.
	Sobre la acreditación de laboratorios clínicos derivantes	El Organismo de Acreditación (OA) puede acreditar a laboratorios clínicos (LCLI) que son derivantes, es decir que no hacen el proceso pre-analítico, pero sí el proceso analítico, pero debe tener procedimientos acerca de cómo se asegura de la aptitud de la muestra antes de ser ensayada, es decir al momento de recibirla. El OA puede acreditar a LCLI que sólo hacen la pre-analítica, dependiendo si la regulación del país lo permite
4.6	Servicios externos y suministros	Los proveedores de evaluación externa de la calidad (PEEC) deberían cumplir con la norma ISO/IEC 17043 o con un conjunto de requisitos establecidos por el OA a través de un checklist
4.8	Resolución de quejas	Las quejas se colectan, se analizan y evalúan y se valora si: a) Procede, se plantea la corrección y si se genera una NC entones corresponde un plan de acciones correctivas. Eventualmente como fruto de este análisis podría plantearse acciones preventivas b) No procede, no obstante podría evaluarse la situación materia de la queja para valorar la pertinencia del planteamiento de oportunidades de mejora

4.14	Evaluación y auditorias	El equipo auditor interno debe conocer la norma ISO 15189 y los procesos a ser auditados. Sería recomendable que el experto técnico conozca la norma ISO 15189
5.1.6	Evaluación de la competencia	Debería ser efectuada por una persona con competencias al menos similares o mayores a la del personal a ser evaluado.
5.4.6	Recepción de la muestra	Establecer criterios de aceptación y rechazo de la muestra. Usualmente, el laboratorio que deriva el servicio de ensayo clínico, entrega un procedimiento de manipulación, mantenimiento y transporte de muestra, al laboratorio derivante, con el objeto de que éste siga las pautas establecidas en dicho documento.
5.5	Situaciones particulares que se presentan en el laboratorio clínico	Una situación que en ocasiones se suele presentar en el laboratorio clínico se da cuando durante un turno, el sistema de medición no funciona y el analista responsable llama al personal técnico del proveedor, pero éste no se encuentra disponible. Esto provoca que finalmente las muestras no puedan ser analizadas, quedando pendiente de análisis hasta el día siguiente. En el marco de lo expuesto, es importante tener en cuenta el mantenimiento de la validez de la muestra que esta por ser ensayada.
5.6	Aseguramiento de la Calidad	Pre-examen Examen Post-examen
		Utilización de materiales conmutables independientes, adicional al que proporciona el fabricante
		En las concentraciones que contribuyen a los rangos de trabajo del laboratorio
		Definición de la frecuencia de uso de estos materiales con base en sustento técnico y su cumplimiento
		Supervisión del control de calidad
		Empleo de especificaciones de control de calidad, tales como CLIA, Variabilidad Biológica, entre otros.
	Algunas mecanismos alternativos	Materiales de referencia certificados Materiales provenientes de células o tejidos almacenados Muestras analizadas previamente Materiales de control provenientes de PECC

5.6.3	Programas Externos de Control de Calidad (PECC)	Proveedores preferentemente acreditados con base en la norma ISO/IEC 17043
		Que empleen preferentemente materiales de referencia trazables metrológicamente
		Datos del CCI y antecendetes del Paciente

Traceability and commutability
Key previous subjects the clinical laboratory would have to take into account:

- Be sure they are using the measurement instrument or analytic measurement system in an appropriate manner.
- To have clear which are the requirements of the tolerance of the process (the measurement instrument/system would have to be capable to achieve this tolerance)
- To use reference materials in the **highest level of traceability as possible**
- To have clear the accuracy of the measurement
- To determine the correction factor.

The reference material more used by the clinical laboratory are firstly the commercial reference materials and secondly those ones prepared by the own laboratory. It is really unusual they use certified reference material. So the way they have to assure the veracity of the results is comparing with a highest level testing method or participating in intercomparisons organized by institutions different of the measurement system provider.

A key property of the reference material is the commutability, however the commercial reference material are usually only traceable to the corresponding measurement instrument or measurement analytical system, so it is not commutable. By contrast, the certified reference material are usually commutable, because of that are more useful for the clinical laboratories because there is a higher possibility to use it in different testing methods.

Measurement Uncertainty

The Measurement Uncertainty are expressed depending on:

- The CV of the process
- The measurement uncertainty of the calibrator. This MU would not have to vary so much among the batches of the calibrators.
- The measurement uncertainty of the correction factor to correct the systematic error

The lecturer, presented some calculations as examples, however, perhaps a specific course about this subject would be useful.

Assessment Exercise to Clinical Laboratories
The organization host got three clinical centres to be visited by the participants of the workshop, in groups, during the third day. We organized and formed three groups with the corresponding team leaders. The objective of this activity was to give the opportunity to the participants to be part of a team assessment, make questions and collect information in order to discuss them afterwards in a team.
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We made the practical assessment in the following clinical laboratories to which we would like to express our sincere gratitude:

- Herrera Llerandi Hospital
- Sanatorio del Pilar
- Clinical Laboratory of the Mariano Gálvez University

The outcomes developed by the participants are not exposed here, however this information is is being used for the activity related to the harmonization of the interpretation of the ISO 15189 among the accreditation bodies of the region that operate the Clinical Laboratories Accreditation Programme.

The fourth day the groups they presented the outcomes of their practical assessment and we had a fruitful discussion

EXPECTATIONS	
Share experiences	√
Harmonization of the interpretation of requirements between ABs and Scientific Societies	In process
Harmonization of the criteria for the Clinical Laboratory Accreditation Programme	In process
To initiate the Accreditation Programme of Clinical Laboratories in those ABs that has not still begun it.	In process
Deepening on the subjects	√
To know the opinion of others	√
To receive feedback about our opinions	√
To extend our knowledge about the standard	√
To form a team work	√
To address key points of the ISO 15189,	√
Strategic alliances between the representatives of the ABs and the Scientific Societies	√

We, IAAC and Scientific Societies representatives and me, are continue working in those activities which are still in process and according to the plan elaborated on May 2015-.

Group Photo

4.3 NEED FOR ACTION

To develop the future activities mentioned in the Plan of Activities 2015 – 2017, which was sent to the group of participants who attended the workshop and the corresponding PTB Coordinator on May 2015. We are developing the determined activities according to the plan till now and we expect to continue developing them in that way.

The Plan of Activities 2015 – 2017 is attached to this report in other file, however wecould remark it covers Technical Activities for the Clinical Laboratories WG and the Training WG of IAAC

5. CONCLUSIONS

The discussion about the key subjects related to ISO 15189 let to us to realize there are particular situations in the clinical laboratories in the countries of the region.

The different level of the laws and the different level of the regulation in the countries promotes these differences, however this is not the unique reason. The differences in the level of the competence of the professionals of the health sector in the own countries could be considered as another reason.. On the other hand, it is relevant the representatives of the accreditation bodies of the clinical laboratories accreditation programme review and discuss in their own

organizations (as in the Clinical Laboratory Committees) the requirements of the ISO 15189 Standard in order to enrich their own knowledge and comprehension about this standard.

The outcomes of this practice could be recorded in the template we have prepared for the countries in order to collect the comments of the ABs of the region about this standard and the Clinical Laboratories WG (which belongs to the LSC) of IAAC could work in a proposal of harmonized interpretation of the ISO 15189

We continue working in the activities shown in the Plan of Activities 2015-2017 for the Clinical Laboratories WG and Training WG of IAAC.

The subject referred to the traceability would have to be addressed in another workshops in the framework of SIM or IAAC, preferably jointly under the umbrella of any Clinical Chemistry Congress as COLABIOCLI.

6. RECOMMENDATIONS (FUTURE ACTIVITIES, NETWORKING POTENTIAL ETC.)

What	**Name**	**When**
1.Plan of activities proposed – Training Activities	LSC/ TSC/ I.Zuta	2015 **done**
2.Plan of activities proposed – Technical Activities	LSC[1] / I.Zuta	2015 **done**
Coordination with IAAC about follow up and execution of the planned activities	C. Herrera / M. Torres / E. Tejeda (IAAC) I. Zuta (PTB)	2016 – 2017 In process
Presentation of the developed, in process and future activities in IAAC meetings	I.Zuta (PTB)	2016 Done in March 2016 and in process

7. APPENDIX TO THE EXPERT REPORT

7.1 AGENDA

It is attached to this Report”

7.2 CONTACTS

[1] In coordination of I.Zuta

Name	Institution	Position	E-mail
Cristina Herrera	INN	Laboratory Accreditation Programme Responsible	Cristina.herrera@inn.cl

7.3 UPDATE OF THE OPERATIONAL PLAN (OPTIONAL)

Update of the operational plan (optional)

7.4 UPDATE OF RESULTS-BASED MONITORING (OPTIONAL)

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