



Laboratory Accreditation Experience in LATAM

Rosa SIERRA-AMOR, PhD
Regional Representative at IFCC.

Latin American Confederation of Clinical Biochemistry



Background

- **ISO 15189 “first version”** landed in Latin American countries in 2013.
- The ministries of economy through its institutes of normalization and societies of professionals were **responsible for translating** the standard nationwide.
- The accrediting bodies in each country spread and put in place.
- **Stakeholders:** The clinical laboratory professional societies, accrediting bodies and institutes of metrology of the countries of Latin America.

Purpose of the Project

- To determine the level of implementation of ISO 15189 in Latin American countries.
- To learn the main difficulties and needs that laboratories have to carry out to implement the accreditation for medical laboratories.
- To strengthen the communication between the **medical laboratories** and the **accreditation body**, with the purpose of **unifying the criteria for the interpretation of the technical requirements of the ISO 15189**

1º. Workshop: 2014 on-site

- **Workshop:** Exploring avenues of support to the improvement of traceability in the clinical laboratory in Latin America and the Caribbean. Organized by the Chilean society of clinical chemistry and the PTB of Germany. **Santiago de Chile, August 7-8, 2014**
 - Participants, representatives from professional societies, of agencies of accreditation and metrology institutes discussed the subject, providing information on the current status of accreditation in their countries of origin, its regulations and laws.
 - **Participating countries:** Argentina, Barbados, Chile, Ecuador, Guatemala, Mexico, Paraguay, Peru, Uruguay and Venezuela

2º Workshop: 2015 on-site

- **Workshop:** "Exchange of experiences about the interpretation of Norma ISO 15189", organized by the Working Group of clinical laboratories of IAAC, and the society of microbiologists of Guatemala and the PTB of Germany.
Guatemala City, May 12-15, 2015

Objectives

- To review the key requirements of the ISO 15189 standard with the aim to harmonize the interpretation and implementation, allowing and enhancing the skills of the participants.
- To promote the link between accreditation and scientific organizations in the field of clinical laboratories to achieve the standard ISO 15189.

2º Workshop: 2015 on-site

Topics discussed

- Organization and Management of Medical Laboratories
- Pre-Analytical, Analytical, and Post-Analytical Process
- Information Management
- Practical establishment of laboratory accreditation requirements in the Clinical Laboratory
- **Participating countries:** Argentina, Colombia, Costa Rica, Cuba, Chile, Ecuador, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Paraguay, Peru and Uruguay.

3º Workshop: 2016 on *live stream*

- **Workshop** "Interpretation of the critical requirements of ISO 15189". Organized by the Chilean society of clinical chemistry and the PTB of Germany. **Santiago de Chile**, Octubre 14-15, 2016,



TALLER REGIONAL LATINOAMERICA Y EL CARIBE - ECUADOR 2018
INTERPRETACIÓN DE REQUISITOS CRÍTICOS DE LA ISO 15189-2012
26-28 Septiembre 2018
QUITO, ECUADOR

LATIN AMERICA AND CARIBBEAN REGIONAL WORKSHOP - ECUADOR 2018
INTERPRETATION OF CRITICAL REQUIREMENTS OF ISO 15189-2012
26-28 September 2018
QUITO, ECUADOR

**LIVE
STREAM**
TRANSMISIÓN
EN WVD



3rd Workshop: 2016 on *live stream*

Topics discussed

- Requirements: **5.4 pre-examination process; 5.5 review process; 5.6 quality assurance results; 5.7 post-examination process.**
- A survey was sent to countries requesting comments, concerns or questions on how to address these requirements.
 - **Participating countries:** Argentina, Barbados, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Paraguay, Peru, Uruguay and Venezuela

3rd Workshop: 2016 on *live stream*

Obtain consensus among participants resulting in the best interpretation and approach by the clinical laboratory, accrediting organization and metrology institute.

- 99 questions total, agreed upon emerging issues that should be discussed in a following workshop.

4º Workshop: 2018 on live stream

- **Taller “Implementation of the concept of traceability in the medical laboratories in Latin America”** . Organized by the Ecuadorian Society of Clinical Biochemistry and PTB Germany. **Quito**, Ecuador, 25 -26 de Setiembre de 2018



4^o Workshop: 2018 on live stream

- **Topics discussed:** uncertainty of measurement, traceability, certified reference materials, responsibility of the manufacturers of reagents for diagnosis, and the trials of aptitude, the evaluator competencies requirements, suppliers.
- Survey: 1) accredited clinical laboratories, and 2) and no accredited.

Countries which have at least one accredited clinical laboratory based on ISO 15189



<http://www.iaac.org.mx/Spanish/MembersListFull.php>

Accreditation agencies from LATAM participating ...



<http://www.....>

Survey to Accredited Laboratories

- Type of laboratory
- Type of population
- Number of tests performed
- Certification as an added value
- Accreditation process accessible
- Will you recomed to be accredited ?
- Information accesible at Accreditation bodies
- Experience of assessors
- Planification of the visit
- Accreditation used for publicity


Laboratories Participating..



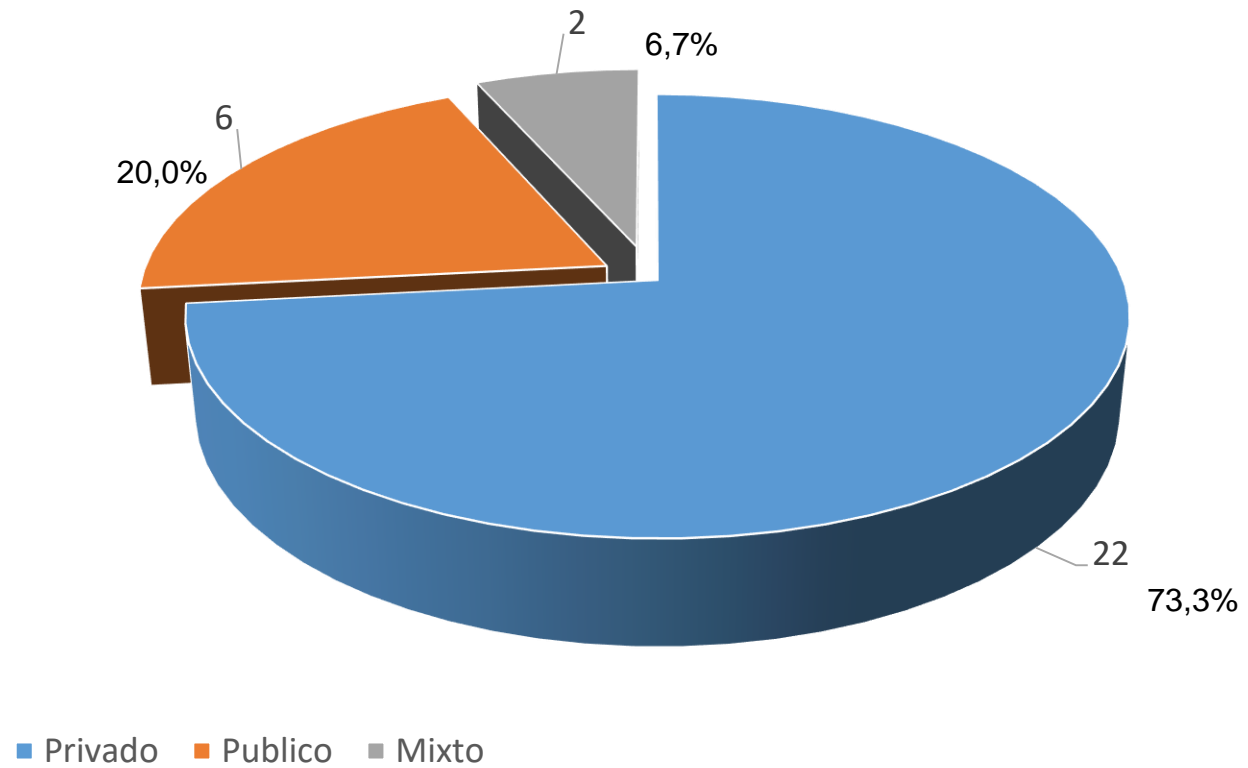
148 Accredited laboratories based on ISO 15189 in LATAM

30 Responses:20,3%

LABORATORIES THAT DID NOT REPLY:

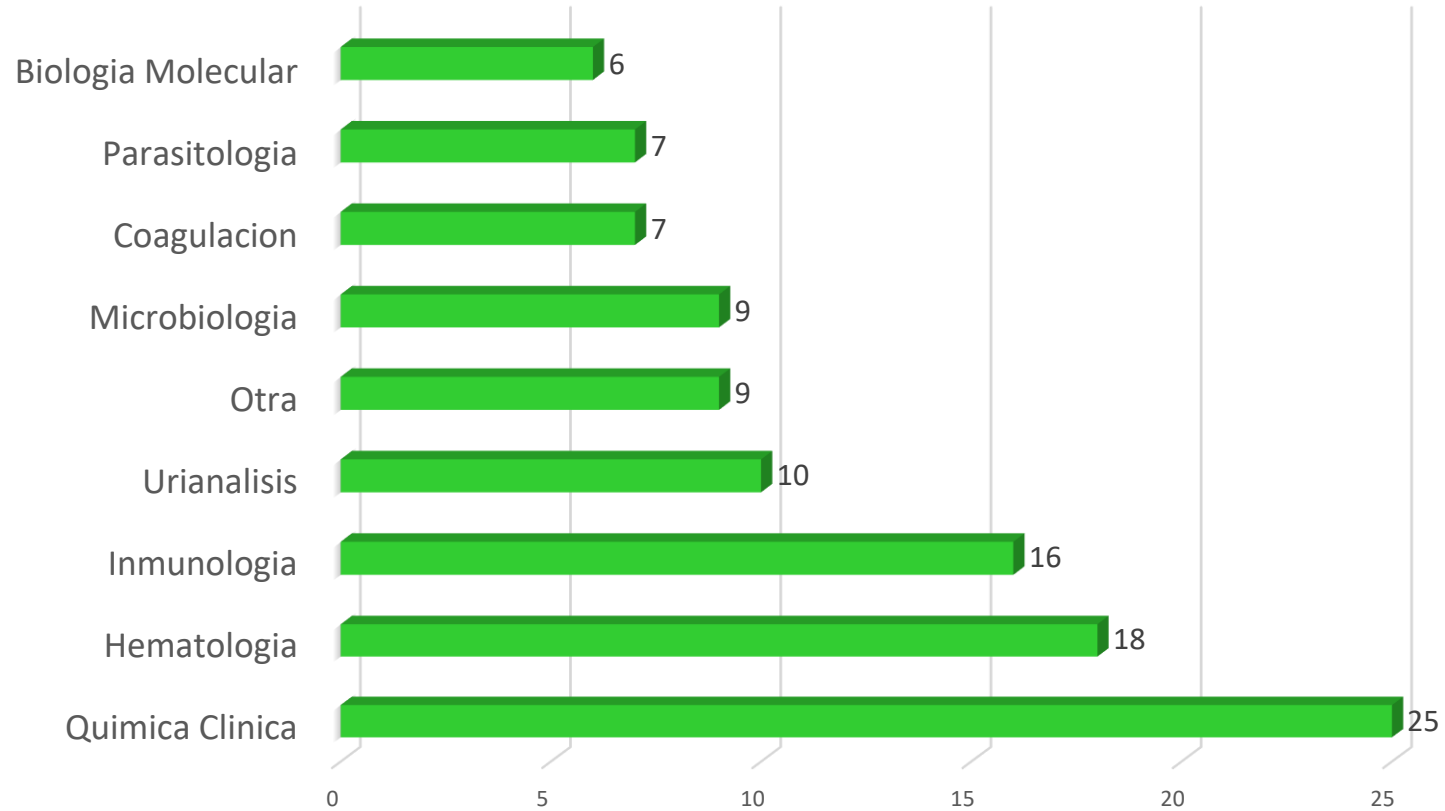
<input type="checkbox"/> Argentina		9
<input type="checkbox"/> Guatemala		6
<input type="checkbox"/> Colombia		3
<input type="checkbox"/> Brasil		3
<input type="checkbox"/> El Salvador		1
<input type="checkbox"/> Uruguay		1
<input type="checkbox"/> Peru		1
<input type="checkbox"/> Venezuela		1

Type of Clinical Laboratory



Responses: 30

What are the disciplines accredited by your laboratory ?



Responses 108



What else is needed?

- **Courses on ISO 15189** through professional societies and accreditation entities.
- Make **synergy with health authorities**, accreditation bodies, and metrology institutes to collaborate on the best strategy to promote the accreditation of clinical laboratories in Latin America.
- **Promote the training of assessors** and technical experts under a same pattern of excellence and in specific subjects in the clinical laboratory.

What else is needed?...

- Create **regional working groups** to know and implement the international standard.
- Organize medical laboratories based on their **level of complexity** to meet the standard ISO 15189.
- Include issues of **metrology and uncertainty in the curricula of universities** at the undergraduate and graduate level.
- Carry out **joint meetings** with the industry of in vitro diagnostics to faithfully meet the traceability of the methods.

5º Workshop: 2020 by LIVE STREAM



TALLER REGIONAL LATINOAMERICA Y EL CARIBE - ECUADOR 2018
INTERPRETACIÓN DE REQUISITOS CRÍTICOS DE LA ISO 15189-2012
26-28 Septiembre 2018
QUITO, ECUADOR

LATIN AMERICA AND CARIBBEAN REGIONAL WORKSHOP - ECUADOR 2018
INTERPRETATION OF CRITICAL REQUIREMENTS OF ISO 15189-2012
26-28 September 2018
QUITO, ECUADOR



- **"Topic to be defined", "venue to be confirmed"**
 - probably CENAM, in Querétaro Mexico.
- The technical part of the transmission live will be in charge of the Faculty of chemistry and biology, University of Santiago de Chile (USACH) and the Chilean National University Network (REUNA).
- Organizers, Chilean society of clinical chemistry, CENAM and the Physikalisch-Technische Bundesanstalt, PTB of Germany.

Publications

- IFCC eNews Jan-Feb 2017 page 19, Latin American Regional and Caribbean Regional Workshop.
- IFCC eNews Feb 2019 page 35, 3rd Regional Workshop ISO 15189 for Latin America and the Caribbean

Summary

- Gradually, accreditation bodies, institutes of metrology together with professional societies interact and resolve on the need to work together for the better understanding of the ISO 15189 standard, its implementation and improves.
- Specialists should participate more actively in their accreditation bodies' CT 212 in parallel to participate in the development of this international standard.
- **The support of institutions like IFCC, ILAC, COLABIOCLI, IAAC, CLSI,** to name a few, will be helpful in the implementation of the clinical laboratory based on ISO 15189 accreditation.

Acknowledge with thanks to:

- Thamara ANDRADE (Ecuador)
- Milena MONARI (Chile)
- Roberto CARBONI (Chile)
- Manfred Kindler (Germany)
- Leonardo AGUIRRE (Chile)
- Sandra QUINTANA (Mexico)
- Klever SAENZ (Ecuador)
- Carlos ROZAS (University of Santiago de Chile (USACH)/Chilean National University Network (REUNA)).

¡Merci-Thank you-Gracias!

email: rosa.sierra.amor@Gmail.com

VERA
CRUZ
500

