COUNTRY VISIT REPORT – Dominican Republic

NOVEMBER 2009

CROSQ/EDF Project

Caribbean Laboratory Accreditation Service

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Executive Summary

The CROSQ-EDF-CLAS Project working in coordination with the Inter American Accreditation Cooperation (IAAC) and the Direccion General de Normas y Sistema (DIGENOR) hosted a seminar/workshop on Laboratory Quality Management systems for Clinical Labs According to the requirements of ISO 15189. Funding for participants and workshop logistics was shared between European Union funding under CROSQ and OAS funding under IAAC. In total there were 52 participants from 24 different countries of Latin America and the Caribbean. This consisted of a mix of professionals from the public and private sector working in Clinical Laboratories, Hospitals, Accreditation Bodies, Bureaux of Standards and as Consultants. Presentation materials were provided in both Spanish and English, and simultaneous translation was available for the duration of the event.

This was the first time the majority of participants were introduced to ISO 15189 and the principles of Quality Management. The seminar consisted of presentations, group exercises, scenarios and class discussion across a mix of topics ranging from the basic concepts of Quality, requirements of the ISO 15189 Standard, Safety in Medical Labs and Strategic planning for Accreditation. A representative of the World Health Organisation also presented their training toolkit and provided electronic copies for all participants.

The seminar evaluation showed that over 80% of the participants agreed that the objectives had been met at the end of the activity. In terms of impact of the workshop, it allowed DIGENOR to reach out to its stakeholders and raise awareness about the benefits of Accreditation in Clinical Labs. As such the local participants agreed to form an LQMS group which meets monthly to support each other with Quality improvements and Documentation.

The seminar also allowed participants from a wide variety of organisations and countries to network and share exeriences and solutions in Quality Management. Additionally, this was the first bilingual activity which CROSQ held in conjunction with the Dominican Republic, or in conjunction with Latin America. It provided a unique opportunuity to raise the profile of CROSQ and to communicate its mission and objectives in the region and with respect to a promoting a harmonised Regional Accreditation system.

The comments recieved from the evaluation of participants at the end of the program will be used to continuously improve the conduct of future Seminars/Workshops and determine future needs of the Regional laboratories in preparation for Accreditation.

A follow up visit to Dominican Republic can be planed after 6 months to evaluate the progress made over this period and assist with future planning to meet the Quality Management Goals

CLAS Project Background

Laboratory Accreditation is a process which gives formal recognition to the technical competence of a laboratory to perform specific tests or calibrations. The process requires the maintenance of a documented quality management system (QMS) and identification of personnel qualified and authorized to perform tasks related to the scope of accreditation. The added value of accreditation far outweighs the necessary investment in human resources, finances and time, since it is an independent method of monitoring laboratory competence and performance, and assures the validity of results to users. Accreditation therefore provides assurance to trading partners that an exporting country is competent to test, inspect or certify to the trading partners' requirements,

while at the same time overcoming trade barriers by assuring compliance to the World Trade Organisation (WTO) Technical Barriers to Trade (TBT) Agreement.

The main objective of CLAS is to build a framework that would facilitate co-ordination of regional laboratory accreditation in a manner that leverages regional capacity and harmonises processes and procedures while being cost-effective and internationally recognised. It is envisioned that this will create a platform for:

- strengthening regional communication,
- human resource capacity building,
- consensus building & negotiation through coordination as well as forging strong linkages and relationships with stakeholders
- enabling the smaller countries of the region to participate in and access expertise and services in Accreditation.

Overall it will strengthen and improve regional capacity for the continued functioning of the Laboratory Accreditation infrastructure. CLAS would amongst other things:

- Provide the forum for the development of laboratory legislation for enactment by individual member states
- Assist with and support the coordination of activities of the national accreditation bodies in the region, aimed at avoiding duplication and promoting transfer of knowledge; and ensuring an internationally recognised accreditation infrastructure in the Caribbean;
- Promote interaction among the National Accreditation Focal points (NAFPs) for multiplication of benefits;
- Facilitate access to international expertise by the NAFPs;
- Facilitate access to proficiency testing programs by the NAFPs;
- Facilitate access to training programs for Labs and Assessors by the NAFPs;
- Provide a structure to uphold the principles of Cross frontier Accreditation (ILAC G21)[1] and ensure that confidence in the Caribbean Accreditation infrastructure is not eroded by foreign Accreditation Bodies.

Summary of the Activities

Aim:

To provide participants with an understanding of the concepts, tools and techniques of Laboratory Quality Management leading to Accreditation against the requirements of the ISO 15189 – *Medical Laboratories* –

[1] "Cross-frontier accreditation principles for avoiding duplication" a code of good practice for ILAC member bodies. This approach will serve to strengthen the international network of laboratory accreditation bodies provided through ILAC and will assist the WTO/TBT objective of facilitating international trade by removing technical barriers to trade through mutual recognition between the nationally based conformity assessment systems.

Particular requirements for Quality and Competence. In addition to training in the development, use and updating of Quality Management system documents for the implementation of a QMS for the laboratory

Learning Objectives

- To raise the awareness about the importance of Quality Management systems to the operation of labs.
- To raise awareness about the requirements of the ISO 15189 Standard for labs
- To review and interpret the clauses of ISO 15189
- To relate the requirements of the clauses to the processes in the lab

At the end of this course, participants will be able to:

- Explain the basic Quality Management concepts.
- Describe and apply the clauses and requirements of the ISO 15189.
- Develop the required documents which comprise a Quality Management system.

Course Description: QUALITY MANAGEMENT SYSTEM FOR THE LAB (ISO 15189)

This course introduces participants to the general concepts of Quality Management with specific emphasis on the medical laboratory and reasons for Accreditation of testing activities. The relationship among other management system models. It instructs the participants in the application of the Standard ISO 15189 including the management and technical requirements, with emphasis on the changes in the standard, the requirements for the Quality system, Management commitment, continual improvement, pre-Examination, Examination and Post Examination procedures, methods of assuring the quality of tests, calibration of equipment, traceability, policies, procedures and records. The course also provide a brief overview of the ISO 15190 Standard for Safety in Medical Laboratories.

ISO 15189 requires that a laboratory develop a Quality Management System which entails incooparing all the process and programs necessary for producing high quality results and meeting customer requirements. Implementation of such a system is often difficult because the lab does not have an action plan to guide its development.

Documentation of Requirements: Documents required for the quality system, including Quality Manual, Standard Operating procedures, test methods, and records. Methods of control and review of such documents and reporting of results.

Training Material:

All material needed for the duration of the course:

1. ISO 15189 *Medical Laboratories – Particular requirements for Quality and Competence* laboratories (Participants to bring their own)
2. Power point presentations (Handouts, See list below)
3. Sample documents (Handouts)
4. Course CD with additional resources

Target Participants:

Accreditation Body staff, Lab Staff, Supervisors, Quality Managers, Technical Officers with responsibility for lab and quality Improvement. The list of particpants was extremely varied and consisted of persons from laboratories, Accreditation Bodies, Standards Bureaus and the Centre for Disease Control.

The countries represented were a cross section of Latin American, Caribbean and local persons from Dominican Republic.

Course Description

In keeping with the objectives defined the course was conducted according to the following schedule:

1.	Introduction and Principles of Laboratory Quality Management Systems	1 day
2.	Management and Technical Requirements	1 day
3.	Safety, Annexes, Strategic Planning for Accreditation	1 day
TOTAL		3 days

Overview:

This course introduced participants to the Concepts of Quality Management with specific emphasis on the Clinical laboratory. It instructed the participants in the application and understanding of the tools and techniques available in Quality Management that could readily be applied to improve the operational effectiveness of the Public and Private Laboratories.

The workshop was conducted using a combination of lectures, case studies, power point presentations, group exercises, scenarios and class discussion.

Evaluation of participants at the end of the program

- A customised evaluation form was distributed to the participants. They were asked to rank the course content, training material, facilitator and overall level of the program. Their feedback was also solicited in a narrative format, to be used to improve the conduct of future sessions and determine future needs of the laboratories in preparation for Accreditation.

Facilitator report of the activities, results and evaluation of the workshop provided after the conduct of the workshop.

- A report was prepared by the facilitator at the end of the session which, containing the workshop evaluation, feedback from participants and suggestions for improvement. The report will be given to IAAC for distribution to concerned parties involved in the planning and conduct of the workshop.

Facilitator Profile

Terms of Reference

To meet the objectives of the workshop the facilitator will be required to:

1. Train in the interpretation of the standard ISO 15189:2007 – *Medical Laboratories – Particular requirements for quality and competence* and its use in the accreditation of the laboratory.
2. Train in the use of Quality Management system documents for the implementation of a QMS for the

laboratory.
3. Provide practical examples to enforce learning in the use of the Quality Management system for organizational improvement.

The Facilitator is expected to have training and extensive experience in Quality Management systems for Laboratories, having worked in the field for at least 5 years, including development of procedures and criteria required for Accreditation. To function as an effective trainer the person contracted should have extensive knowledge of the ISO 15189 Standard. Prior experience as a trainer is required.

In order to achieve the objectives of the training program the Facilitator will:

a. Develop and prepare the training material and teaching aids to be delivered in the proposed workshop (including the agenda, handouts, power point presentations and examples).

b. Provide the training material to IAAC at least two weeks before the start of the workshop.

c. Assist with the development of an informative CD to be given to participants at the end of the workshops.

d. Develop a list of equipment and materials necessary for carrying out the training sessions

e. Collaborate with IAAC as necessary to complete logistical arrangements in preparation for workshops

f. Deliver the program at the venue chosen

g. Deal with questions presented by the participants in the conduct of the workshop to clarify their concerns and ensure understanding of the material, where necessary.

h. Review the final report prepared by IAAC within ten (10) days of the end of the program (the main learning points of the training interventions, conclusions and recommendations based on lessons learned for future interventions.)

NOTES OF LABORATORY ACCREDITATION GROUP, DOMINICAN REPUBLIC

Below is a summary of the agreements reached at the first meeting of the Working Group for Clinical Laboratory Accreditation to ISO 15189, on Friday 13 at the Hotel V Centenario, Santo Domingo.

CLAS

1. Support from CLAS for ISO 15189:
2. Training (4 per year)
    a. Seminar for the elaboration of the Quality Manual,
    b. validation of methods,
    c. Assessor Training on ISO 15189,
    d. Consulting for ISO 15189
3. Technical Assistance (Consulting)
4. Proficiency Testing rounds

5. Calibration
6. Internships

Prepare and Send documents to implement the critical path for the creation of the QMS and attaining Accreditation. Identify Stakeholders for Accreditation of the Clinical Lab component and conduct a survey to identify the needs of the sector. Based on these data to develop a work plan for the year 2010 to meet the needs of Stakeholders

World Health Organisation

DIGENOR and the Working Group for ISO 15189 can apply for support to the Organization of the UN Industrial Development Organization (UNIDO) to develop the activities of the Work Plan 2010. Dr. Kojima will send the data needed for contacts with UNIDO.

Rebeca del Castillo – CAREC Project Trainee

In the year 2003 was the first phase of CLAS (the CAREC EU Project). At this time a GAP analysis was performed to determine the needs of stakeholders. This document will be presented at the next meeting of WG. 2.

From 26 to 28 November the Bioanalysts Dominican Congress will be held, dedicated to the Quality at the Hotel Jaragua and Dr. Santana has been invited to attend a lecture on Dominican System for Quality and Accreditation focused on the creation of the Accreditation Body for DR. Dr. Santana has assured his participation.

Next Meeting: Thursday, 19 November, from 9:00 to 1:00 pm, in the 4th. floor of the Library UNPHU.

Annex 1 – Agenda Opening Ceremony

IAAC/OAS/CROSQ/EDF/DIGENOR

Medical Laboratory Accreditation – Promoting Health and National Development

11th November, 2009 *Time: 8.30 am to 10.30 am* Venue – Santo Domingo, Dominican Republic

Objectives:

i. *To raise awareness among key stakeholders about the importance of Laboratory Accreditation to National and Regional Development.*

ii. *To inform stakeholders about the benefits of the Clinical Laboratory Accreditation in assuring National Development.*

iii. *To raise awareness about the importance of Quality Management systems to the efficient operation of clinical laboratories.*

iv. *To officially open the workshop for Medical Laboratories*

Target Audience

Ministry of Health, Ministry of Trade and Industry, Ministry of Agriculture, Medical Laboratories, Medical Laboratories, Testing Laboratories, Tourism Board, Public Health officials, Food Safety Organisations, Water Authority, Chambers of Commerce, Manufacturers Association, Consumer Groups, Export Associations, Academia, Accreditation Focal Points and other relevant stakeholders.

Welcome and Opening Remarks	9:00 - 9:10am	DIGENOR
ANDELAB Network	9.10 – 9.20am	DIGENOR
Presentation on CROSQ	9:20 - 9:40am	Chairperson, CROSQ
Presentation on IAAC and Objectives of Workshop	9.40- 10.00 am	Project Coordinator, CLAS Project
Guest Speaker	10:00 - 10:20am	World Health Organisation
Vote of Thanks	10:20 -10:25am	DIGENOR

COFFEE BREAK

Annex 2 – Agenda Quality Management Seminar

DAY 1	Duration	**Facilitator – Carolina Richter**
AM	2 hours	**OPENING CEREMONY**
	1 hour	INTRODUCTION: ISO 15189 – Overview, Related Standards, Management Systems, Certification, Accreditation Terms and Definitions (3.0)
		QMS PLANNING Organization and Administration (4.1) Quality Management System (4.2)
	45 min	Introduction to the WHO Training Toolkit
PM	1 hour	QMS DOCUMENTATION Document Control (4.3) Quality and technical records (4.13) Contract Review (4.4) Examinations conducted by test samples or to refer patients (4.5)
	1 hour	GROUP ACTIVITY (1,2,3,4,5,6)

DAY 2	**Duration**	
AM	45 min	MANAGEMENT PROCESS
	1 hour	Supply Chain Management External Services and supplies (4.6) Advisory Services (4.7)
		STRENGTHENING AND IMPROVEMENT Complaints Resolution (4.8) Identification and control of nonconformities (4.9) Corrective Action (4.10) Preventive Action (4.11) Continuous Improvement (4.12) Internal Audit (4.14) Management Review (4.15)
	1.5 hours	GROUP ACTIVITY (7,8,9,10,11)
		TECHNICAL REQUIREMENTS
PM	1 hour	Personnel (5.3) 5.3 Organization and Personnel Management, Selection, Training.
		Accommodation and environmental conditions (5.2) equipment (5.3)
		Laboratory pre-analytical phase (5.4) analysis procedure (5.5)
	1 hour	GROUP ACTIVITY (12,13, 14, 15, 16)

DAY 3	Duration	
AM	45 min	Biological Variability and Uncertainty
	45 min.	Quality assurance of analytical procedures (5.6) Post-analysis procedures (5.7) Report of Results (5.8)
	45 min	Quality Indicators
	45 min.	ANNEX A: INFORMATION PROTECTION SYSTEM ANNEX B: ETHICS
PM		ISO 15190 – MEDICAL LABORATORIES – REQUREMENTS FOR SAFETY
		GROUP ACTIVITY (17): Action Plan.
		CONCLUSIONS, RECOMMENDATIONS
		COURSE EVALUATION

Annex 3 – List of Group Activities

QUALITY PLANNING SYSTEM	
ACTIVITY1	Is there a quality policy at your institution? Do you know it? Develop a quality policy.
ACTIVITY2	Identify the two sectors identified as the main by customers of the laboratory, and specify the methods considered most appropriate to meet the quality expectations with respect to products or services that are offered
ACTIVITY3	Select one of the most important barriers to change in the laboratory, identify those people (and functions) you believe are in a position to overcome that barrier and propose an action plan required for change to occur.
ACTIVITY4	The implementation of laboratory quality system involves the commitment of all staff and is a highly interdisciplinary work. For this reason it is desirable to have different people who are competent and willing to take responsibility and lead the project. Identify at least three key functions in the laboratory and the leadership characteristics most suitable for each.
ACTIVITY5	Explain what you think are the functions of the Quality Management Committee (Committee on Infections, Training Committee, Committee for Scientific Research, etc.).
ACTIVITY6	What is the situation with regard to the levels of documentation provided for a quality management system?
ACTIVITY7	Identify the processes that take place in your laboratory, indicating in each case whether the support is key, and explain which of the technical and administrative functions involved represent critical steps for the proper development of these processes.
ACTIVITY8	Identify the different records that are kept in your laboratory and indicate for which of them there are legal requirements and what is the period of retention required
ACTIVITY9	Analyze the quality requirements of the supply chain and identify areas it considers critical. Explain your answers. What are the most common mistakes?
ACTIVITY10	Identify any non-compliance which occurred during the past year in your specific area of work in the laboratory and conduct a detailed analysis of the causes
ACTIVITY11	Describe the current complaint management system in the lab and discuss the benefits of having a nonconformance report. If you do not have a complaints handling system what strategy would you implement for this purpose.
ACTIVITY12	Make an Organisational chart of the laboratory. Include how it relates with the entire institution
ACTIVITY13	Choose a laboratory area and define the required job profiles for the technical and administrative staff.
ACTIVITY14	Describe how to assess training needs
ACTIVITY15	Develop an SOP for designing and budgeting a preventive maintenance program for your laboratory equipment
ACTIVITY16	Develop an SOP for the receipt, acceptance or rejection of supplies purchased by the laboratory
ACTIVITY17	ACTION PLAN: Develop an action plan for implementing a QMS. Identify key personnel, key activities, estimating time and performance indicators.

Annex 4 – Participant list – Quality Management Seminar

Name	Institution	Country
1.Richard Hadeed	Biohealth Medical Laboratory,	Antigua
2. Samantha Cooper	Ministry of Health,	Belize
3. Arlene Archibald	Ministry of Health,	Grenada
4. Raymond Samuels	Ministry of Health,	Montserrat
5. Dr. Marc Anthony Germain	GHESKIO,	Haiti
6. Marie Magalie Stanislas	Laboratoire National de la Santé Publique	Haiti
7. Dr Elsy Michel	Hospital de l'Universiite D'etat D'Haiti,	Haiti
8. Candelle Walcott Botswick	Guyana National Bureau of Standards	Guyana
9. Ucklin Stephanie Hector	Public Health Laboratory,	Barbados
10. Haidi Tjon Kon Fat Bronstein	Ministry of Health,	Suriname
11. Andrea Williams	JNF Hospital,	St. Kitts
12. Brenda Jn Baptiste	Victoria Hospital,	St. Lucia
13. Ellison Floyd	TTLABS,	Trinidad
14. Karlene Lewis	TTLABS,	Trinidad
15. Estela Contreras	INDECOPI,	Peru
16. Mitzi Mota	Entidad Mexicana de Accreditacion	Mexico
17. Miguel Mondragon	CNA,	Panama
18. Alejandra Guevara	ECA,	Costa Rica
19. Rocio Montes	ONAC,	Colombia
20. Diego Moya	IBMETRO,	Bolivia
21. Danelia Garcia Pineda	ONA,	Nicaragua
22.Rodolfo Aquino	COPLACES,	El Salvador
23.Maria Amelia Acuña	OAA,	Argentina
24.Julia de Saldivar	ONA,	Paraguay
25. Norma Batista Profamilia	CDC	Dominican Republic
26. Justina Pinales Trinidad	DIGENOR	Dominican Republic

27.José del Carmen Valenzuela	PROCONSUMIDOR	República Dominicana
28.Joselyn Alt. Rodríguez Rodríguez	Laboratorio Brito	República Dominicana
29. Alba Roque	Inst. De Dermatologia	República Dominicana
30. Mariolga Roques Ortiz	Lab. Roques	República Dominicana
31.Dennis Grullón de Calzada	Lab. Clinico Bion	República Dominicana
32. Sandra Encarnación	Inst. Dom. De Estudios Biologicos, IDEV-CDC	República Dominicana
33.Marcia Reyes Concepción	Lab. Clinico Referencia	República Dominicana
34.José Alberto Pérez		República Dominicana
35.Wilma Dalila Pérez	Centers for Disease Control (CDC)	República Dominicana
36.Mc Kinney Sulamita	CDC – LNSPDD	República Dominicana
37.Belkis Alt. Laburd,	CDC- Clinica de Familia	República Dominicana
38. Ana Virginia Malla	CDC	República Dominicana
39. Rosa Mayra Tejeda Reyes	CDC	República Dominicana
40. Amarilis Durán	Lab. Referencias	República Dominicana
41. Patricia Pereyra	DIGENOR	República Dominicana
42.Maria F. Sánchez	DIGENOR	República Dominicana
43.Adriana Valerio	DIGENOR	República Dominicana
44. Hector Martinez	DIGENOR	República Dominicana
45.Maria Acosta	DIGENOR	República Dominicana
46.Maria del Castillo	Consejo Nacional C	República Dominicana
47.Oracio Tavera	CNC	República Dominicana
48. Claribel Lopez Rodriguez	M.B	República Dominicana
49. Carmen Baez	DIGENOR	República Dominicana
50.Angela Brito	ANDELAP	República Dominicana
51. Dianne Lalla Rodrigues	ABBS	Antigua and Barbuda
52. Carolina Richter	OGA	Guatemala

53. Kazunobu Kojima	World Health Organisation	Lyon, France

Annex 5 – Participant list – Stakeholder Meeting

13th November 2009

Dirección General de Normas y Sistemas de Calidad (DIGENOR)

1ra. Reunión del Comité de Trabajo del Organismo Dominicano de Acreditación (ODAC),

Republica Dominicana

Nov 13/2009

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Annex 6 – List of presentations

Spanish folder	English folder	Document type
01 INTRODUCCION TERMINOS Y DEFINICIONES ORGANIZACIÓN SGC	01 QMS INTRODUCTION AND DEFINITIONS	Powerpoint presentation
02 GC DOCUMENTACION (4.3 – 4.5, 4.13)	02 QM4.3 TO 4.5 DOCUMENTATION	Powerpoint presentation
03 GESTION POR PROCESOS	03 MANAGEMENT OF PROCESS	Powerpoint presentation
04 (4.6 – 4.15) PROVEEDORES Y MEJORA	04 PROVIDERS AND IMPROVEMENTS	Powerpoint presentation
05 REQUISITOS TECNICOS (5.1 – 5.8)	05 TECHNICAL REQUIREMENTS	Powerpoint presentation
06 VARIABILIDAD BIOLOGICA E INCERTIDUMBRE	06 BIOLOGICAL VARIABILITY PRE ANAL	Powerpoint presentation
07 INDICADORES DE GESTION DE LA CALIDAD	07 INDICATORS OF QUALITY MANAGEMENT	Powerpoint presentation
08 ANEXOS	08 ANNEXES	Powerpoint presentation
09 ISO 15190	09 ISO 15190	Powerpoint presentation
Crawford Handout – Key Differences between 15189 and 17025	Crawford Handout – Key Differences between 15189 and 17025	Pdf document

Annex 7 – Participant comments on the Seminar

11th to 13th November 2009 Venue –Santo Domingo, Dominican Republic

1. Do you require further information on any topic discussed?
   - Uncertainty of measurement and audits
   - Checklist for the standard
   - About Ethics and safety
   - Some topics seemed a bit rushed but this might have been due to time constraints
   - Validation of methods, motivation of staff
   - Examples of Intercomparison prorams
   - Proficiency testing Providers for clinical analysis
   - More knowledge about the ISO 15190
   - Biological variability
   - Need information about all the steps to develop an Accreditation plan

2. Any other comments/recommendations?

   - The translations for the English material should have been completed
   - The presenter clearly showed that she knew the ISO 15189 and she was able to bring that across to the group
   - Workshop need to be more practical with many examples included, presentation of actual documents taken from already accredited lab, presentation of workshop needs to be conducted by both examiner and someone who actually completed the process of accreditation, bias towards Directors/Managers rather than personnel of a clinical/analytical institute or company
   - Very good programme
   - In order to ensure continuity towards Accreditation, there should be follow up meetings to assess where the respective organizations are and where they need to be and how to overcome obstacles to get there
   - It would have been beneficial if those countries that are far ahead in the process help/share to guide the others with lessons learnt/mistakes and way forward, as a recommendation from CROSQ or brought out in the presentations
   - The follow up has to be done. Put names in a pool for other workshop programmes
   - Help us find ISO 17025 and ISO 15190
   - Presenter was pleasant and patient. Manual could have been supplied in an electronic form to save on paper. CD
   - toolkit was a very good idea and very helpful
   - Bringing together participants from different areas (Accreditation body, private & public labs, etc) was a good to share experiences. Workshop was well organised
   - The quality of the translation was decidedly poor for about 50% of the workshop, so that put the English speakers at a disadvantage
   - My goal is to make my department a model department by implementing a QMS for that Department, towards a total QMS for my lab
   - I Suggest to develop a course on the standard with specific emphasis on Measurement uncertainty and the parts which cover that theme specifically
   - Implementation of the Quality System in the Clinical Lab should be the theme for the next workshop
   - Congratulations to the organization team for an excellent workshop
   - I considered the course very good, applicable and explanatory
   - Continue developing these types of courses in the countries of the region. Develop courses in validation and uncertainty
   - Excellent comments on experience in laboratories by the facilitator
   - There will be much value in a course about auditing the QMS for clinical labs

Annex 8 – Quality Management Seminar Dominican Republic – Analysis of participant responses

Medical Laboratory QM Seminar – Dominican Republic	Participants in the evaluation
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		Excellent		Very Good		Good		Fair		Poor		No answer
1	What is your overall impression of the workshop?	26	56.5%	16	34.8%	3	6.5%	1	2.2%	0	0.0%	4
2	How would you rate the quality of the presentations?	23	50.0%	18	39.1%	5	10.9%	0	0.0%	0	0.0%	4
3	How effective was the use of equipment/training tools/techniques?	19	41.3%	22	47.8%	5	10.9%	0	0.0%	0	0.0%	4

As a result of this workshop are you able to:		Yes		No		Remarks	No answer
4	Explain the basic Quality Management concepts?	45	98.0%	1	2.2%		4
5	Describe the clauses and requirements of the ISO 15189?	40	87.0%	6	13.0%		4
6	Apply the clauses and requirements of the ISO 15189 to the laboratory and Accreditation process?	42	91.3%	4	8.7%		4
7	Develop the required documents which comprise a Quality Management system?	41	89.1%	5	10.9%		4

END OF DOCUMENT