PQM Report on Evaluation of Capacity and Laboratory Quality Management System: Laboratoire National du Contrôle des Médicaments de Senegal

Dakar, Senegal
September 3-7, 2012

Trip Report

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Cooperative Agreement # GHS-A-00-09-00003-00
Sponsoring USAID Missions: USAID/Senegal, through the President's Malaria Initiative (PMI), and USAID Core funding for Common Agenda
Grantee: Promoting the Quality of Medicines (PQM) Program
Author(s) Name: Latifa El-Hadri and Donnell Charles
Language: English
Date of Publication: November 2012

PROMOTING THE QUALITY OF MEDICINES

This report is made possible by the generous support of the American people through the United States Agency for International Development (USAID), under Cooperative Agreement No. GHS-A-00-09-00003-00, and the President's Malaria Initiative (PMI). The contents are the responsibility of the Promoting the Quality of Medicines Program, implemented by the U. S. Pharmacopeia, and do not necessarily reflect the views of USAID, PMI, or the United States Government.

Executive Summary

The Laboratoire National du Contrôle des Médicaments de Senegal (LNCM) is working towards obtaining ISO/IEC 17025:2005 accreditation and, at a later stage, be incorporated into the list of ISO 17025 accredited testing laboratories. The list is published by each recognized accreditation body, to document and inform potential customers that these laboratories have met the highest standard of quality. To attain this goal, the Promoting the Quality of Medicines (PQM) program planned this trip with two primary objectives:

1. Perform an evaluation of the Quality Management System (QMS) of the Laboratoire National du Contrôle des Médicaments aiming to prepare the lab for a planning visit from an internationally recognized accrediting body; and,
2. Assess the technical capacity of the lab by evaluating the critical equipment and information technology server systems.

PQM performed the assessment of the lab and its QMS according to International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005 (or ISO 17025) standards. The following are the key findings and conclusions:

- LNCM has made little progress progress in implementing a QMS that is compliant with ISO 17025 since the audit performed in September 2010 by the Tunisian National Accreditation Counsel. The PQM evaluation identified relevant non-conformities and provided an action plan on how to address them.
- The QMS documents, particularly the Standard Operating Procedures (SOPs), are satisfactory; however, implementation of these SOPs remains a critical challenge.
- LNCM is not yet ready for a formal ISO 17025 audit.
- Currently, the lab is displays poor internal organizational and a lack of leadership by management. It is missing some major QMS documents and 20 lab SOPs.
- LNCM requires ongoing technical support for their current and future documentation and funding to procure equipment needed for their scope of accreditation in order to implement its ISO 17025 action plan.
- LNCM needs at least 24 months to be ISO 17025 accredited.

PQM has provided details of the nonconformities identified and suggested corrective action(s) and timelines to remediate those nonconformities. PQM will work with LNCM on implementing effective corrective and preventive actions (CAPAs) and will continue to provide technical assistance to strengthen its QMS and improve technical capacities.

Next, PQM will conduct a follow-up visit to assess the progress LNCM is making implementing CAPAs and rectifying the laboratory's critical findings.

TABLE OF CONTENTS

Acknowledgements....3
Acronyms....4
Background....5
Purpose of Trip....5
Source of Funding....5
Overview of Activities....6
Recommendations....10
Next Steps....10
Annex 1: Trip Agenda....11
Annex 2: List of Participants....13
Annex 3: Key Findings of QMS Assessment....14
Annex 4: Lab Inspection....22
Annex 5: ILAC Information and List of Recognized Accreditation Bodies....24

About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID's response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical leadership to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States government. It may be reproduced if credit is given to PQM and USP.

ACKNOWLEDGEMENTS

We would like to thank:

- USAID/Senegal for their support and valuable input
- Special gratitude to the PMI Advisor Dr. Lamine Birame Diouf for his high level of interest and his feedback
- LNCM lab chief and his staff for their motivation and commitment to implementing the ISO 17025 accreditation action plan
- DPM and PNLP for organizing a meeting to formally introduce the PMI advisor for USP PQM to the relevant partners and sharing with him PQM's ongoing and planned activities in Senegal
- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report
- Mr. Anthony Boni and Dr. Maria Miralles at USAID/Washington for their support and advice

ACRONYMS

AM	Antimalarial
ARV	Antiretroviral
ATB	Anti-tuberculosis
CAPA	Corrective and Preventative Action
CDC	Centers for Disease Control and Prevention
DPL	Direction de la Pharmacie et Laboratoires (Department of Pharmacies and Laboratories)
DQI	Drug Quality and Information Program
FY	Fiscal Year
GHIP	Global Health Impact Programs
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
ILAC	the International Laboratory Accreditation Cooperation
LNCM	Laboratoire National de Contrôle des Médicaments (National Quality Control Laboratory)
pH	Measure of how acidic or basic an aqueous solution is
PMI	President's Malarial Initiative
PNA	Pharmacie Nationale d'Approvisionnement (Central Medical Store)
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
TA	Technical Assistance
USAID	United States Agency for International Development
TUNAC	Tunisian Accreditation Council (Conseil National d'Accreditation)
USP	United States Pharmacopeial Convention

Background

Since 2002, the U.S. Agency for International Development (USAID) and the U. S. Pharmacopeial Convention (USP) have been providing technical assistance to Senegal to strengthen their medicines quality assurance (QA) systems—first through the USP Drug Quality and Information (DQI) program and, currently, through the Promoting the Quality of Medicines (PQM) program. The Laboratoire National de Contrôle des Médicaments (LNCM), Senegal's official medicines control laboratory, has been working to obtain ISO/IEC 17025:2005 (ISO 17025) accreditation. In its FY12 work plan, an important component of PQM technical assistance has been to strengthen the lab's compliance of with international quality management system (QMS) standards.

Purpose of Trip

The primary objectives of the trip were to evaluate the QMS of LNCM by performing an assessment (mock audit) according to international standards and to evaluate the LNCM's technical capacity based on ISO 17025 requirements. During this trip, PQM met with the new advisor from the President's Malaria Initiative (PMI) and introduced him both to lab staff and to relevant partners at meeting held at Direction of Pharmacies and Medicines (DPM).

The following were secondary objectives of the trip:

- Provide forms and templates for laboratory Standard Operating Procedures (SOPs), and,
- Discuss the lab's implementation plan toward ISO 17025 accreditation with the LNCM team.

Source of Funding

These activities were funded by USAID/Senegal through the President's Malaria Initiative.

Overview of Activities

The activities conducted during this visit are listed in the Agenda (Annex 1); the main activities are summarized in the table below.

<table>
<tr><th>Item</th><th>Description</th></tr>
<tr><td>Institution Evaluated</td><td>Laboratoire National de Contrôle des Médicaments (LNCM) of Sénégal</td></tr>
<tr><td>Primary Objectives</td><td>The intent of this visit was to:
1. Evaluate the QMS of the LNCM; and,
2. Assess the lab's technical capacity by evaluating the critical equipment and IT back-up server systems.

To fulfill these objectives, PQM used Sections 4 and 5 of the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025:2005 General requirements for the competence of testing and calibration laboratories. PQM staff assessed the QMS of LNCM based on the ISO 17025 standards listed on the following table:
<table>
<tr><th>Procedure</th><th>ISO 17025:2005 Element/Standard</th></tr>
<tr><td>Record Control</td><td>4.13</td></tr>
<tr><td>Internal Audit Reports and Schedule</td><td>4.14</td></tr>
<tr><td>Management Review</td><td>4.15</td></tr>
<tr><td>Document Control</td><td>4.3</td></tr>
<tr><td>Logbook and Notebook Issuance Procedure</td><td>4.13.2.1</td></tr>
<tr><td>Customer Evaluation and Feedback</td><td>4.7</td></tr>
<tr><td>Chemical Inventory</td><td>4.6.2</td></tr>
<tr><td>Nonconforming Work</td><td>4.9</td></tr>
<tr><td>Supplier Evaluation</td><td>4.6.4</td></tr>
<tr><td>Equipment</td><td>5.5</td></tr>
<tr><td>Laboratory Waste and Disposal</td><td>5.3.5</td></tr>
<tr><td>Reference Standard Procedure</td><td>5.6.3.1</td></tr>
</table></td></tr>
<tr><td>Secondary Objectives</td><td>• Provide templates for SOPs and forms.
• Discuss with LNCM team the implementation plan for ISO 17025 accreditation.
• Review with LNCM staff the TUNAC action and amend according to ISO 17025 requirements.
• Prepare LNCM for an official (pre-audit) visit from the International Laboratory Accreditation Cooperation (ILAC); assist with planning. See Annex 5 for more information on ILAC.
• Provide LNCM with the list of ILAC signatory recognized accreditation bodies.</td></tr>
</table>

	• Educate laboratory staff on: - Processes involved with internal auditing techniques for ISO 17025 accreditation; - External audit expectations; and, - Developing effective CAPAs.
Partners	• LNCM • PQM
Evaluators	• Latifa El-Hadri, PQM • Donnell Charles, PQM
Key Personnel	• Yerim Diop • Djubril Fall • Adama Diedhiou • Omarr Sarr • Elhadji Ibrahima Toure See Annex 2 for a complete list of participants.
Agenda	See Annex 1 for a complete visit agenda.
Areas Evaluated	• QMS Documents, focusing on critical Standard Operating Procedures • Laboratory facilities for testing and/or calibration • Handling of test items • Document and records control • Equipment and lab areas • Staff training • Test methods • Reporting and evaluation of test results • Safety and good housekeeping • Corrective and preventive actions • Uncertainty of measurement • Documentation traceability and IT back-up • Electronic records and spreadsheets (worksheets)
Key Findings	• LNCM needs to improve managerial leadership in the lab and define responsibilities. • PQM identified numerous nonconformities in addition to those declared by TUNAC auditors. • LNCM is slowly progressing toward implementing a QMS that is compliant with ISO 17025 standards. The LNCM staff displays enthusiasm and eagerness to start the ISO 17025 accreditation process, but they need to put more effort into implementing CAPAs and comply with ISO 17025 requirements. • Financial resources to implement the ISO 17025 action plan are limited, particularly in terms of procuring lab equipment, providing training, and providing technical assistance to bring the lab up to meet standards. • The technical ability of the lab staff to perform testing according to ISO 17025 standards is limited.

	Details of the QMS nonconformities, suggested corrective actions, and suggested timelines to remediate the nonconformities were documented and presented to the laboratory. More details on key findings are provided in Annex 3 and Annex 4.
Conclusion	• LNCM requires ongoing technical support for their current and future documentation and equipment. • LNCM requires increased funding for the implementation of ISO 17025 and for procuring the equipment needed for their scope of accreditation. • LNCM needs at least 24 months to achieve ISO 17025 accreditation.
Next Steps	PQM will continue working with LNCM to help them comply with ISO 17025 standards by improving their SOPs (providing needed templates) and reviewing draft procedures documents. PQM will provide an action plan on how to remediate both major and minor deficiencies, make the immediate corrective actions, and improve their managerial leadership, roles, and responsibilities.

Meeting with LNCM Staff

Participants: Latifa El-Hadri, Donnell Charles, and LNCM Staff

Dr. El-Hadri introduced Dr. Donnell Charles, Manager of Quality Management Services at USP, to the LNCM staff. She informed the group that she and Dr. Charles will be providing LNCM with technical support during the process of its accreditation. Pr. Yerim, LNCM director, thanked PQM staff for their assistance and for working diligently in addressing LNCM deficiencies that were reported by TUNAC September 2010 audit. PQM staff then presented the trip agenda and underlined the main objectives of the visit.

Meeting with USAID/Senegal (PMI) and LNCM staff

PQM staff briefed Dr. Diouf, USAID-PMI Advisor, during his visit to the lab. PQM introduced him to the lab staff and shared with him the agenda of the trip. Pr. Yerim welcomed Dr. Diouf and thanked USAID for their valuable financial support to the lab. Pr Yerim expressed his gratitude for having PQM accompanying the lab toward ISO 17 025 accreditation. He shared with Dr. Diouf his concerns about the financial and technical challenges that the lab is facing in accomplishing this milestone. They mainly discussed how the lab could obtain additional funding and how to improve the lab staff's analytical skills and managerial responsibilities.

Dr. Diouf and Dr. El-Hadri planned for a roundtable meeting with the relevant partners, mainly governmental entities that deal with the lab directly, including Pharmacie Nationale d'Approvisionnement (PNA), DPM, and major health programs. These agencies are clients of the lab and, as such, need to be aware of the process of ISO accreditation and its requirements. To seek financial contribution from other programs and organization, Dr. Diouf suggested they prepare a document justifying what the lab needs in terms of equipment, training, and technical assistance to share with them at the meeting.

Meetings with lab managers and lab technicians

PQM conducted working sessions with the LNCM director and his staff to:

- Review the major and minor deficiencies reported by TUNAC auditors;
- Discuss the major deficiencies that need to be addressed by higher management;
- Suggest ways of addressing the major and minor issues before the next official audit;
- Provide a tutorial to the LNCM QA manager and staff on "Management Requirements and Technical Requirements" (Sections 4 and 5 of ISO 17025 requirements);
- Outline the need to control Management Review and Internal Audit Process by QA staff;
- Share results of the PQM mock assessment with LNCM staff and review documents related to CAPA, Internal Audit, Management Review, Document and Record Control, Equipment, Personnel Records, and ISO Accreditation.
- Discuss the first steps in the "roadmap"—the documentation review that ensures the laboratory process, procedures, and QMS documentation is complaint with ISO 17025 and the overall plan—of finding and selecting organizations required for ISO 17025 accreditation:
  - ILAC signatory accreditation body for accreditation of the testing laboratories;
  - An ISO 17025:2005 calibration organization for laboratory equipment; and,
  - A Proficiency Test provider.
- Discuss what assays LNCM wants to include in the scope of accreditation.
- Inform the group that laboratory equipment must be operating properly and calibrated or certified by a recognized vendor in order for the assay to be included in the scope.
- Inform the staff that having only one of each piece of equipment may limit their opportunity in the accreditation process.

Debrief Meeting at USAID Mission

Participants: USAID Mission – Mame Diouf, PMI Advisor; Julie Thwing, Malaria Advisor, Centers for Disease Control and Prevention (CDC); Matar Camara, Policy and Health Financing Specialist; PQM – Latifa El-Hadri

Dr. El-Hadri gave an overview of what activities the lab has accomplished and passed on the LNCM director's words of appreciation to the Mission for providing the lab financial support. PQM staff conveyed that LNCM director and his staff are eager to obtain ISO/IEC 17025:2005 accreditation and to be incorporated in the list of ISO 17025 accredited testing laboratories. Dr. El-Hadri explained the importance of achieving this landmark: By attaining working conditions that conform to stringent international standards, LNCM assures that its QC laboratory is capable of producing accurate, valid, and defendable data when testing internal and external samples of various products.

PQM noted that LNCM is in the beginning stages of achieving this goal and that its QMS assessment and lab inspection revealed numerous nonconformities that will need to be addressed. LNCM will require continuous support—technical, training, and equipment—to remediate the deficiencies identified.

Recommendations

- DPL management should continue to be involved in LNCM activities to become ISO 17025 accredited. Active involvement and strong support is integral to achieving success as an internationally recognizable organization.
- LNCM should correct all findings and issues and provide evidence to the internal auditors and registrars to evaluate.
- LNCM needs to complete all CAPAs that PQM provided as follow-up items on the previous visit prior to the assessment.

Next Steps

- PQM will assist LNCM in addressing the issues identified during the PQM mock assessment.
- PQM will assist LNCM in planning its scope preparation for the assessment visit from an accredited organization (within one year) that is required for accreditation.
- Once the physical chemistry laboratory is accredited, PQM will help LNCM begin strategic planning for moving the Microbiology departments towards ISO 17025 accreditation by 2015.
- PQM will provide additional SOP templates based on the lab's progress.
- PQM will assist LNCM in developing a comprehensive implementation plan toward ISO 17025 accreditation based on its QMS assessment and lab inspection.
- LNCM will complete all CAPAs by April 2013).
- LNCM will complete the required documentation and processes for ISO 17025 accreditation by July 2013.

Annex 1

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Quality Management System Assessment and Laboratory Inspection Visit
Laboratoire National de Contrôle des Médicaments du Sénégal

Dakar, Senegal ◆ September 03 – September 07, 2012

Agenda

Date 03 SEP 12	DAY 1-Monday	Responsible
08:30-10:00	• Introduction of Participates • Presentation of the agenda/objective of the visit • Education of the lab staff regarding preparation	LNCM representative USP/PQM representative
10:00-12:00	• TUNAC Audit Discussion o Discuss Major déficiences Activities o Discuss Minor déficiences Activities o Discuss current action plans	LNCM representative USP/PQM representative
12:00-13:00	Lunch	All
13:00-15:00	• Review/ Discussion of PQM audit questions (70 Question sent to LNCM)	LNCM representative USP/PQM representative
15:00-17:00	• Review of Equipment Questions o Discussion of Measurement of Uncertainty o Discussion of Uncertainty Budget o Equipment and Data Sheet Calculations	LNCM representative USP/PQM representative
Date 04 SEP 12	**DAY 2-Tuesday**	**Responsible**
08:30-10:00	• ISO 17025 Section 4 Audit	LNCM representative USP/PQM representative
10:00-12:00	• ISO 17025 Section 5 Audit	LNCM representative USP/PQM representative
12:00-13:00	Lunch	All
13:00-15:00	• Discuss QMS Road Map for ISO 17025 accreditation o Template discussion ▪ Master Document (all documents) ▪ Audit Document ▪ ISO required critical documents	LNCM representative USP/PQM representative

15:00-17:00	• Management Discussion o Discuss Scope of accreditation and capabilities (Human Use) ▪ HPLC (USP General Chapter <621>) ▪ Karl Fisher (USP General Chapter <921>) ▪ Dissolution (USP General Chapter <711>) ▪ UV/VIS (USP General Chapter <851>) ▪ Dosage Uniformity(USP General Chapter <905>) ▪ pH(USP General Chapter <791>) ▪ LOD (USP General Chapter <731>)	LNCM representative USP/PQM representative
Date 05SEP 12	**DAY 3-Wednesday**	**Responsible**
08:30-10:00	• Equipment Record Review Desk Audit o Equipment Software and Manuals o Backup Audit and Recovery	LNCM representative USP/PQM representative
10:00-12:00	• Laboratory Inspection and On-site Equipment Review o Traceability-(Tracebacks) optional procedure	LNCM representative USP/PQM representative
12:00-13:00	**Lunch**	**All**
13:00-15:00	• Management Discussion o Selecting an Accreditation Body o Selecting an Calibration Body -Equipment o Selecting a Proficiency Test Provider	LNCM representative USP/PQM representative
Date 06SEP 12	**DAY 4-Thursday**	**Responsible**
08:30-10:00	• Develop a comprehensive implementation plan toward ISO17025 accreditation based on Management discussion, documentation review, laboratory space review, and equipment review.	LNCM representative USP/PQM representative
10:00-12:00	• Develop a comprehensive implementation plan toward ISO17025 accreditation based on Management discussion, documentation review, laboratory space review, and equipment review continued	LNCM representative USP/PQM representative
12:00-13:00	**Lunch**	**All**
13:00-15:00	• LNCM Remarks • Action items: implementation plan and timeline	LNCM representative USAID representative (if applicable) USP/PQM representative
15:00-17:00	• Assist LNCM in drafting needed SOPs and review drafts o Internal Audit o Management Review o Proficiency Test or ILT o Quality Manual	LNCM representative USP/PQM representative
Date 07SEP 12	**DAY 5-Friday**	**Responsible**
08:30-10:00	Wrap up and closing	USP/PQM representative

Annex 2

PROMOTING THE QUALITY OF MEDICINES

Senegal LNCM Visit ◆ September 7- 13, 2012

List of Participants

Participant	Institution
Latifa El-Hadri	PQM
Donnell Charles	GHIP/PQM
Adama Diedhiou	LNCM
Assane Deng	LNCM
Djibril Fall	LNCM
Elhadji Ibrahima Toure	LNCM
Fatou Ndiaye	LNCM
Ibra Ngom	LNCM
Jean Louis Preira	LNCM
Magatte Diao	LNCM
Mame Ndack Ndiaye	LNCM
Ngom Mamadou	LNCM
Owsmane Niass	LNCM
Sergne Omar Sarr	LNCM
Sokhra Astu G Diop	LNCM
Yerim Diop	LNCM

Annex 3

PROMOTING THE QUALITY OF MEDICINES

Key Findings on Laboratory Inspection And IT Back-up Systems

Senegal LNCM ◆ September 7- 13, 2012

Laboratory Inspection Findings

The objective of the Laboratoire National de Contrôle des Médicaments (LNCM) is to become accredited by 2014 in the following scope:

Dissolution
HPLC
pH
UV-VIS
Uniformity of dosage.

To fulfill this objective, PQM inspected the status of the equipment involved, evaluated how the lab staff works with it, and assessed the lab staff's working area. The main equipment inspected and techniques audited include:

- High Performance Liquid Chromatography (HPLC)
- Potential hydrogen ion test (pH)
- Gas Chromatography (GC)
- Ultraviolet wavelength test (UV)
- Karl Fisher (KF)
- Loss on Drying (LOD)
- Dissolution
- Viscosity
- Chemical Hoods and Biological Safety Cabinets (BSCs)
- Weigh Station, Analytical and Top Loading Balance areas
- Sample Storage and Preparation Areas

The Microbiology Laboratory will not be included in the scope of accreditation; however, the staff, supplies, and space are shared with this group and thus required inspection.

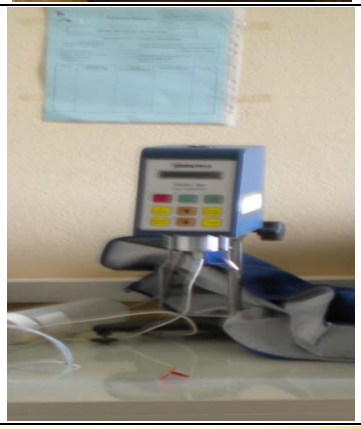
The table below lists the major findings (with pictures) observed during the PQM inspection of the LNCM lab.

The lab staff was given the table below as a quiz to identify the findings that need to be fixed.

Picture from Lab Inspection	Finding
	• Documentation listed as uncontrolled (loose information that can be taken by anyone or be replaced by anyone, could be lost by air draft, etc.)
	• Chemical used to conduct assay – no expiration date • Equipment not verified for use by the equipment group
	• No equipment verification by equipment group • No calibrated thermometer used in equipment • No form or record of use
	• No verified working thermometer in unit to ensure the digital display is accurate

	• Equipment not confirmed for use by equipment group • Equipment not calibrated by an outside party • Equipment not on marble slab
	• Chemicals not listed with expiration dates • Expired chemicals in units • Temperature probes not calibrated • Temperature probes not in glycerol • Equipment cycling from refrigerated to frozen
	• No verified working thermometer in unit to ensure the digital display is accurate. • No equipment verification by equipment group. • No Calibrated thermometer used in equipment. • No form or record of use.
	• Equipment not confirmed for use by equipment group • Equipment not calibrated by an outside party • Probe in unknown solution • pH buffers not a lot from an approved vendor

HOOD 	• Equipment not confirmed for use by equipment group • Equipment not certified by an outside party • Equipment not turned on • Equipment airflow blocked causing environmental exposure • No usage form
	• Equipment not confirmed for use by equipment group • Equipment not calibrated by an outside party • Probe/Desiccate overexposed • KF solution not from an approved vendor
	• Equipment not calibrated by an outside party
	• Equipment not confirmed for use by equipment group • Equipment not calibrated by an outside party • Calibration expired

	• Equipment not confirmed for use by equipment group • Equipment not calibrated by an outside party • No usage form
	• Retains not stored in proper condition • Retains not destroyed or returned to the customer after the customer has approved the final report
	• Equipment not confirmed for use by equipment group • Equipment not calibrated by an outside party • No usage form
	• Equipment not confirmed for use by equipment group • Equipment not calibrated by an outside party

	• Hood used as storage area • Chemical not labeled • Equipment not certified by an outside party • Equipment not turned on • Equipment airflow blocked causing environmental exposure • No usage form

Status of Lab Equipment and Inspection

Reviewer(s) Initial/Date: Donnell Charles, PQM/QMS Manager /05SEPT2012
Latifa El-Hadri, Program Manager

Laboratory: LNCM, Dakar, Senegal

Location or Room(s): Physical Chemistry, Microbiology, and Logistics

Laboratory Observations Number(s): ~24

	Documentation, Supplies, and Samples	Review: Checked (C) Not Checked (NC) Unavailable (U)	Assessment: Satisfactory (S) Not Satisfactory (NS)* Not Applicable (NA)	Comments
1.	Laboratory Specific Equipment: Pipettes and Multi-channel pipettes	U	S	Glass pipettes, Rainin, or Glisson pipettes maybe required in the future.
2.	Laboratory Specific Equipment: Freezers/Refrigerators/Incubators	C	NS	Equipment needs thermometer inside. Not functioning and not repairable from the laboratory.
3.	Laboratory Specific Equipment: Thermometers	C	NS	More working thermometers needed in refrigerators, freezers and incubators.
4.	Laboratory Specific Equipment: BSC/Chemical Hoods	C	S	Cleaning and servicing required for all hoods and BSC.
5.	Laboratory Specific Equipment: Karl Fisher Unit	C	NS	There is no functioning Karl Fischer in the lab owned by LNCM.
6.	Laboratory Specific Equipment: HPLC	C	NS	There are three HPLC's; only one is functioning. Current condition of the functioning HPLC needs to improve or this system will fail also.
7.	Laboratory Specific Equipment: GC and GC/MS	C	NS	GC and GC/MS will need to be evaluated for review. Systems will need to be performance checked prior to use.
8.	All equipment In-Scope, In-Scope: Calibration not Required, Out of Scope, and Out of Service properly labeled.	C	NS	Equipment is not clearly labeled as out-of-service or non-functioning.

	Documentation, Supplies, and Samples	**Review:** Checked (C) Not Checked (NC) Unavailable (U)	**Assessment:** Satisfactory (S) Not Satisfactory (NS)* Not Applicable (NA)	**Comments**
9.	Calibration and Maintenance labels visible and legible.	C	NS	Calibration labels are not visible or satisfactory at this time.
10.	Proper Receipt, Handling and Storage of Samples to be Assayed.	C	NS	Retain samples are stored, but no environmental controls are in place.
11.	Chemicals and supplies labeled and stored properly.	C	NS	Chemical supplies are maintained, but not in correct area.**
12.	Expired Chemicals and Supplies segregated and prepared for disposal.	C	NS	There currently is no chemical disposal process. Microbiological, Chemical, and Physical chemicals are inappropriately discarded. This is an issue.
13.	Reporting and documenting of equipment malfunction and repair.	C	NS	Several pieces of equipment are not functioning and are in need of repair. Equipment and Software needs to be evaluated.
14.	Proper Laboratory Attire/PPE donned.	C	NS	All lab staff are not wearing proper safety PPE. At a minimum, lab coats, glasses, and gloves should be worn in all areas.
15.	Proper Safety Equipment and Records available.	C	NC	
16.	Controlled hard copy binders available.	C	NS	Records need to be consolidated in one area as each lab retains certain records in their own areas.
17.	In-Use Approved Documents are properly initialed and dated.	C	NS	Controlled documents in the laboratory need to be monitored to ensure they will not be lost.
18.	Chart records operating, initialed and dated properly.	C	NS	Control Charts can be better documented as this is only used for certain equipment in the laboratory.
19.	General appearance and cleanliness	C	NS	Lab is basically clean, but two bird's nests were located in the area.
20.	Other: Dissolution Device	C	NS	Two functioning devices need maintenance.
			* Requires Comment	** Storage of Reagents and Standards are adequate but needs to be strengthened in order to maintain control of the material and longevity of the material.

Additional notes and laboratory staff interviewed identified by item and room number.

Comments

Checked:

1. Balance–C, NS–Balances need to be calibrated in place in all areas; the Balance in pass-through area in microbiology is not acceptable.
2. Reference Weights–C, NS–Documentation for weights not reviewed. No working weights found in the laboratory.
3. Reference Thermometer–C, NS–Reference Thermometer not acceptable. Instrument appears to be out of calibration.
4. Check Server–Server exists, but service provider was not on site. Not fully complete at this time. Follow up on the next visit.
5. Check Records Back-up–C, S–Records reviewed on functioning HPLC are sufficient but requires regular back-up.
6. Check Auto-injector: HPLC–C, NS–Instrument's auto-injector is not functioning; injections are made manually.
7. Check Auto-sample: Dissolution–C, NS–Device not used at this time; will need to be evaluated for use.
8. Check Equipment Out-of-Service–C, NS–Labels need to be generated for all equipment in all areas.
9. Autoclave Instrument used for Storage Area–C, NS–Not an acceptable area for storage.
10. Printer–All printers need the proper ink in the laboratory.

Sample Weighing Room Area–There is no control of temperature or humidity in this area. This needs to be reviewed prior to using the equipment in the area.

Annex 4

Key Findings: IT Back-up Systems Inspection

PQM reviewed the software documentation, calibration certification documentation, and manuals for the laboratory equipment. The main findings include:

- The back-up documentation process and retrieval need to be reassessed as it is not sufficient. Further examination is required.
- LNCM does not have an employee or contractor to maintain IT server or supporting systems.
- A new server will be required, as new equipment will require additional server capacity and memory.
- LNCM software used (listed below) is not traceable and cannot be backed-up fully if catastrophic failure occurs:
  - Varian star chromatography workstation system control, version 6.30 (HPLC Varian), (Generating automatically SST)
  - TotalChrom workstation, version 6.3.1 (HPLC PerkinElmer)
  - Wincats planar chromatography manager, version 1.3.4 (CAMAG/HPTLC)
  - Azur, version 4.6 (UV Spectrophotometer Jasco)
  - IP Spectrophotometer
- LNCM failed to prove that records were stored off-site at a reliable facility not affiliated with the laboratory or any adjacent buildings.
- PQM conducted a “trace back” ISO 17025: 4.13.2.1, that is, traced a record back from an HPLC and the lab; LNCM was unable to provide a report document. PQM urged them to work on providing one for the next visit. PQM informed the lab that this type of document is very important and the assessor will definitely inquire about it during an official audit.

Summary of QMS Assessment and Lab Inspection according to ISO 17025 Requirements:

No	Severity of Non-conformity (MAJ, MIN, OFI)	Area of Evaluation	ISO/IEC 17025:2005 Clause
1	MAJ	Corrective Actions	4.11.1
2	MAJ	Control of Records	4.13.2.1 & 4.13.2.2
3	MAJ	Internal Audits	4.14
4	MAJ	Accommodation and Environmental Conditions	5.3

5	**MAJ**	**Control of Data**	**5.4.7**
6	**MAJ**	**Equipment**	**5.5.2, 5.5.5, 5.5.7 & 5.5.8**
7	**MAJ**	**Handling of Test Items**	**5.8.1, 5.8.2 & 5.8.4**

Following the visit, PQM provided LNCM with an action plan including details of each observation, evidence, suggested corrective action(s), and suggested timeline. PQM is working with LNCM on the implementation of this plan.

ANNEX 5

Signatories to the ILAC Mutual Recognition Arrangement[1]

No.	Accreditation Body	Economy		Scope	Original Signing Date
1	Organismo Argentino de Acreditacion (OAA)	Argentina	1	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	11 Aug 2005 11 Aug 2005
2	National Association of Testing Authorities, Australia (NATA)	Australia	2	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
3	Akkreditierung Austria	Austria	3	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	22 Sept 2002 22 Sept 2002 24 Oct 2012
4	**(e) (p)**Belgian Accreditation Structure (BELAC)	Belgium	4	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	01 Aug 2006 01 Aug 2006
5	**(f)**Coordenação Geral de Acreditação General Coordination for Accreditation (CGCRE)	Brazil	5	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000
6	Standards Council of Canada (SCC)	Canada	6	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000
7	**(r)**Canadian Association for Laboratory Accreditation Inc. (CALA)	Canada	6	Testing ISO/IEC 17025	17 Nov 2005
8	Instituto Nacional de Normalización (INN)	Chile	7	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	08 Oct 2010 08 Oct 2010
9	**(b) (o)**China National Accreditation Service for Conformity Assessment (CNAS)	People's Republic of China	8	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
10	Ente Costarricense de Acreditación (ECA)	Costa Rica	9	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	16 Jan 2007 22 Mar 2010 24 Oct 2012
11	Croatian Accreditation Agency (HAA)	Croatia	10	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	29 Apr 2010 29 Apr 2010

[1] Updated November 5, 2012

No.	Accreditation Body	Economy		Scope	Original Signing Date
				Inspection ISO/IEC 17020	24 Oct 2012
12	National Accreditation Body of Republica de Cuba (ONARC)	Cuba	11	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	17 Sept 2005 17 Sept 2005
13	Cyprus Organisation for the Promotion of Quality (CYS) Cyprus Accreditation Body (CYSAB)	Cyprus	12	Testing ISO/IEC 17025 & ISO 15189	18 Oct 2011
14	Czech Accreditation Institute (CAI)	Czech Republic	13	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
15	Danish Accreditation (DANAK)	Denmark	14	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
16	Organismo De Acreditacion Ecuatoriano (OAE)	Ecuador	15	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	03 Dec 2011 03 Dec 2011 24 Oct 2012
17	**(x)**Egyptian Accreditation Council (EGAC)	Egypt	16	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	10 Oct 2009 10 Oct 2009
18	**(g)**Finnish Accreditation Service (FINAS)	Finland	17	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
19	Comite Francais d'Accreditation (COFRAC)	France	18	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
20	**(w)** Deutsche Akkreditierungsstelle GmbH (DakkS)	Germany	19	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
21	**(j)** Hellenic Accreditation System S.A. (ESYD)	Greece	20	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	22 May 2004 22 May 2004
22	Oficina Guatemalteca de Acreditación (OGA)	Guatemala	21	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	26 June 2008 14 Mar 2012
23	Hong Kong Accreditation Service (HKAS)	Hong Kong, China	22	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000

No.	Accreditation Body	Economy		Scope	Original Signing Date
				Inspection ISO/IEC 17020	24 Oct 2012
24	Hungarian Accreditation Board (NAT)	Hungary	23	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	28 Apr 2010 28 Apr 2010 24 Oct 2012
25	National Accreditation Board for Testing and Calibration Laboratories (NABL)	India	24	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000
26	National Accreditation Body of Indonesia (KAN)	Indonesia	25	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	20 June 2001 30 Dec 2003 24 Oct 2012
27	**(h)**Irish National Accreditation Board (INAB)	Ireland	26	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
28	Israel Laboratory Accreditation Authority (ISRAC)	Israel	27	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	03 Nov 2001 03 Nov 2001 24 Oct 2012
29	**(l)** L'Ente Italiano di Accreditamento (ACCREDIA)	Italy	28	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	02 Nov 2000 07 Oct 2010
30	Japan Accreditation Board (JAB)	Japan	29	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 28 July 2003 24 Oct 2012
31	**(a)**International Accreditation Japan (IAJapan)	Japan	29	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000
32	Voluntary EMC Laboratory Accreditation Center INC (VLAC)	Japan	29	Testing ISO/IEC 17025	16 Jan 2007
33	National Centre of Accreditation (NCA)	Kazakhstan	30	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	27 Oct 2010 27 Oct 2010
34	Korea Laboratory Accreditation Scheme (KOLAS)	Republic of Korea	31	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	02 Nov 2000 20 June 2001
35	Office Luxembourgeois d'Accréditation et de Surveillance (OLAS)	Luxembourg	32	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	14 Apr 2011 19 Apr 2012 24 Oct 2012
36	Department of Standards Malaysia	Malaysia	33	Testing ISO/IEC 17025 & ISO 15189	16 Jan 2003

No.	Accreditation Body	Economy		Scope	Original Signing Date
	(Standards Malaysia)			Calibration ISO/IEC 17025	19 Nov 2003
37	entidad mexicana de acreditación a.c. (ema)	Mexico	34	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	17 Nov 2005 17 Nov 2005 24 Oct 2012
38	Mongolian Agency for Standardization and Metrology, Accreditation Department (MNAS)	Mongolia	35	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	07 June 2012 07 June 2012
39	Dutch Accreditation Council (RvA)	The Netherlands	36	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
40	International Accreditation New Zealand (IANZ)	New Zealand	37	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
41	**(k)**Norsk Akkreditering (NA)	Norway	38	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
43	Papua New Guinea Laboratory Accreditation Scheme (PNGLAS)	Papua New Guinea	40	Testing ISO/IEC 17025	12 May 2010
44	Organismo Nacional de Acreditacion (ONA)	Paraguay	41	Testing ISO/IEC 17025	27 April 2012
45	**(q)**Philippine Accreditation Office (PAO)	Philippines	42	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	17 Nov 2005 17 Nov 2005
46	Polish Centre for Accreditation (PCA)	Poland	43	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	19 Jan 2005 19 Jan 2005 24 Oct 2012
47	Instituto Portugues de Acreditacao (IPAC)	Portugal	44	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	10 May 2006 10 May 2006 24 Oct 2012
48	Romanian Accreditation Association (RENAR)	Romania	45	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	22 May 2004 28 May 2009
49	Association of Analytical Centers “Analitica” (AAC “Analitica”)	Russian Federation	46	Testing ISO/IEC 17025	21 May 2009

No.	Accreditation Body	Economy		Scope	Original Signing Date
50	Accreditation Body of Serbia (ATS)	Serbia	47	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	24 May 2012 24 May 2012 24 Oct 2012
51	Singapore Accreditation Council (SAC)	Singapore	48	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
52	Slovak National Accreditation Service (SNAS)	Slovakia	49	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	11 June 2001 11 June 2001 24 Oct 2012
53	Slovenian Accreditation (SA)	Slovenia	50	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	28 Nov 2003 28 Nov 2003 24 Oct 2012
54	South African National Accreditation System (SANAS)	South Africa	51	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
55	Entidad Nacional de Acreditacion (ENAC)	Spain	52	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
56	Sri Lanka Accreditation Board for Conformity Assessment (SLAB)	Sri Lanka	53	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	09 Dec 2009 08 June 2012
57	Swedish Board for Accreditation and Conformity Assessment (SWEDAC)	Sweden	54	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
58	Swiss Accreditation Services (SAS)	Switzerland	55	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000
59	**(d)**Taiwan Accreditation Foundation (TAF)	Chinese Taipei	56	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
60	**(m)**The Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health,	Thailand	57	Testing ISO/IEC 17025 & ISO 15189	04 April 2003

No.	Accreditation Body	Economy		Scope	Original Signing Date
	Thailand (BLQS-DMSc)				
61	**(i) (t)** National Standardization Council of Thailand – Office of the National Accreditation Council (NSC – ONAC)	Thailand	57	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	03 Nov 2001 03 Nov 2001 24 Oct 2012
62	Bureau of Laboratory Accreditation, Department of Science Service, Ministry of Science and Technology (BLA-DSS)	Thailand	57	Testing ISO/IEC 17025	23 Aug 2006
63	The Accreditation Institute of the former Yugoslav Republic of Macedonia (IARM)	The former Yugoslav Republic of Macedonia	58	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	19 Apr 2012 19 Apr 2012 24 Oct 2012
64	Tunisian Accreditation Council (TUNAC)	Tunisia	59	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025	02 Apr 2008 02 Apr 2008
65	Turkish Accreditation Agency (TURKAK)	Turkey	60	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	10 May 2006 10 May 2006 24 Oct 2012
66	Dubai Accreditation Department (DAC)	United Arab Emirates	61	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	18 Oct 2009 18 Oct 2009 24 Oct 2012
67	United Kingdom Accreditation Service (UKAS)	United Kingdom	62	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
68	American Association for Laboratory Accreditation (A2LA)	USA	63	Testing ISO/IEC 17025 & ISO 15189 Calibration ISO/IEC 17025 Inspection ISO/IEC 17020	02 Nov 2000 02 Nov 2000 24 Oct 2012
69	National Voluntary Laboratory Accreditation Program (NVLAP)	USA	63	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	02 Nov 2000 02 Nov 2000
70	**(c)**International Accreditation Service, Inc (IAS)	USA	63	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	02 Nov 2000 09 May 2005
71	**(s)**ANSI-ASQ National Accreditation Board *doing business as* ACLASS **(s)**ANSI-ASQ National Accreditation Board *doing business as* FQS	USA	63	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Testing ISO/IE	

No.	Accreditation Body	Economy		Scope	Original Signing Date
72	Laboratory Accreditation Bureau (L-A-B)	USA	63	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	06 Dec 2007 06 Dec 2007
73	Perry Johnson Laboratory Accreditation, Inc. (PJLA)	USA	63	Testing ISO/IEC 17025 Calibration ISO/IEC 17025	06 June 2008 21 May 2009
74	American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB)	USA	63	Testing ISO/IEC 17025	07 April 2009
75	AIHA Laboratory Accreditation Program, LLC (AIHA-LAP, LLC)	USA	63	Testing ISO/IEC 17025	22 Aug 2010
76	Organismo Uruguayo De Acreditación (OUA)	Uruguay	64	Testing ISO/IEC 17025	22 Oct 2010
77	**(n)**Bureau of Accreditation (BoA)	Vietnam	65	Testing ISO/IEC 17025 Calibration ISO/IEC 17025 Inspection ISO/IEC 170	

(a) IAJapan was formed from a restructure of JCSS and JNLA on 1 April 2002.
(b) CNAL was formed from a restructure of CCIBLAC and CNACL on 20 Feb 2003
(c) IAS was formed from a restructure of ICBO on 1 Dec 2002
(d) TAF was formed from a restructure of CNLA on 16 April 2005
(e) BELTEST and BKO/OBE originally signed the MRA
(f) Diretoria de Credenciamento e Qualidade/Instituto Nacional de Metrologia, Normalizacao e Qualidade Industrial (INMETRO) originally signed the MRA
(g) FINAS, Finnish Accreditation Service Centre for Metrology and Accreditation originally signed the MRA. Their name changed to Finnish Accreditation Service (FINAS)
(h) The Irish National Accreditation Board (NAB) originally signed the MRA. NAB changed their name to Irish National Accreditation Board (INAB)
(i) Thai Laboratory Accreditation Scheme (TLAS) originally signed the MRA. TLAS changed their name to TISI
(j) Hellenic Accreditation Council originally signed the MRA. Hellenic Accreditation Council changed their name to Hellenic Accreditation System S.A. (ESYD)
(k) Norwegian Accreditation originally signed the MRA. Norwegian Accreditation changed their name to Norsk Akkreditering (NA)
(l) Sistema Nazionale per l'Accreditamento originally signed the MRA. Sistema Nazionale per l'Accreditamneto changed their name to Sistema Nazionale per l'Accreditamneto di Laboratori (SINAL).

ACCREDIA was formed as a result of the incorporation of SINAL and SINCERT and was accepted as signatory to the EA MLA on 29 May 2009 for testing only.
SIT (original signing date – 9 April 2003 for calibration only) was incorporated into COPA. EA MLA signatory status was transferred to COPA on 4 November 2009.
Signatory status of COPA to the ILAC MRA was withdrawn effective 21 May 2010 as a result of the termination of COPA's membership in EA as per EA Resolution 2010
(25) 3.
ACCREDIA assumed the responsibilities for the accreditation of calibration laboratories in Italy from July 2010 as
COPA was no longer operational. ACCREDIA was accepted as a signatory to the EA MLA for calibration on 7
October 2010.

(m) Bureau of Laboratory Quality Standards (BLQS) Department of Medical Sciences (DMSc) originally signed the MRA. Their name changed to The Bureau of Laboratory
Quality Standards, Department of Medical Sciences, Ministry of Public Health, Thailand (BLQS-DMSc)

(n) Vietnam Laboratory Accreditation Scheme (VILAS/STAMEQ) originally signed the MRA. Their name changed to
Bureau of Accreditation (BoA)

(o) CNAS was formed from the merger of CNAL and CNAB

(p) BELTEST and BKO/OBE ceased to exist on 1 August 2006

(q) PAO was reinstated as a signatory by the APLAC MRA Council for testing and calibration on 10 December 2008. This follows the suspension as a result of the Resolution
of the APLAC MRA Council on 5 June 2008 whereby the signatory status for calibration and testing for PAO was suspended.

(r) Canadian Association for Environmental Analytical Laboratories (CAEAL) originally signed the MRA. CAEAL changed its name to Canadian Association for Laboratory
Accreditation Inc. (CALA) on 23 June 2008

(s) Assured Calibration and Laboratory Accreditation Select Services was acquired by ANSI-ASQ National Accreditation Board and are now know as ANSI-ASQ National
Accreditation Board *doing business as* ACLASS as of 18 September 08. As of 1 January 2012, ANSI-ASQ National Accreditation Board acquired Forensic Quality Services
(FQS) a signatory to the ILAC MRA for testing since 10 December 2010 and are now known as ANSI-ASQ National Accreditation Board doing business as FQS.

(t) TLAS changed their name to National Standardization Council of Thailand – Office of the National Accreditation Council on 29 January 2009.

(w) DakkS was formed from a merger of DGA and DKD in December 2009.
DGA was formed from a merger of Deutsches Akkreditierungssytem Prufwesen (DAP), Deutsche Akkreditierungsstelle (DACH), and Deutsche Akkreditierungsstelle
Technik in Trägergemeinschaft für Akkreditierung German Association for Accreditation GmbH (DATech in TGA GmbH).

(x) National Laboratories Accreditation Bureau (NLAB) merged into EGAC as of 28 December 2009