

**USP-PQM Ethiopia Equipment Assessment, Maintenance and Training:
Ethiopia PQAD Laboratory**

**Addis Ababa, Ethiopia
May 18-24, 2012**

Trip Report

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Executive Summary

PQM contracted Mr. Per Sima and Mr. David Ramsamy from Valendor, an ISO 17025-accredited company that performs quality testing services according to international standards, to assess the condom testing equipment at Ethiopia's Product Quality Assessment Directorate (PQAD) laboratory. They provided maintenance for some equipment, calibrated other pieces, conducted training for eight of the PQAD lab analysts, and made the following comments and recommendation:

- The Valendor equipment is now functional and calibrated. The staff know how to use it and can perform regular maintenance and troubleshooting. Some additional accessories will be needed.

Calibration certificates will be issued for all the calibrated equipment and training certificates will be issued for all those who participated in the various trainings.

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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 assistance 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.

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Acronyms

AIS	Accurate Inflation System
DQI	Drug Quality and Information Program
EHT	Electric Hole Tester
FPP	Finished Pharmaceutical Product
GLP	Good Laboratory Practices
HIV/AIDS	Human immunodeficiency virus/ acquired immune deficiency syndrome
OOS	Out of Service
PEPFAR	President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PQM	Promoting the Quality of Medicines
PW	Water Purification
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
SOP	Standard Operating Procedure
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization
WLT	Water Leakage Tester
WVB	Water Vacuum Bowl

Background

The U.S. Agency for International Development (USAID) and U.S. Pharmacopeia (USP) have been providing technical assistance to Ethiopia since 2008, through the Promoting the Quality of Medicines (PQM) program. At that time, PQM received funding from the President's Emergency Plan for AIDS Relief (PEPFAR) program through USAID/Ethiopia to strengthen the capacity of the Food, Medicine and Health Care Administration and Control Authority (FMHACA). A critical component of PQM's technical assistance has been to strengthen the Product Quality Assessment Directorate (PQAD) laboratory's compliance with international quality management system (QMS) standards.

With technical assistance from PQM, in 2011 the Ethiopia PQAD attained the internationally recognized ISO/IEC 17025:2005 accreditation for testing and calibration laboratories for on seven analytical techniques. Dedicated to continuous improvement, the lab has been working to expand its scope of accredited services, including that for condom testing; however, the PQAD's system has not been functional due to worn or defective parts. PQM arranged for Valendor to assess the condom testing system, make needed repairs, and train the staff on the equipment's use as well as calibrate this and other Valendor equipment.

Purpose of Trip

- Assess condition of equipment; make repairs as possible so lab is operational.
- Refurbish testers with updated parts and calibrate other existing equipment.
- Train PQAD lab staff to maintain equipment and troubleshoot problems.

Overview of Activities

The visit was undertaken to repair non-operational equipment, perform maintenance where needed, calibrate all equipment to international standards, and train the staff to maintain the equipment in the future. The PQM consultants were asked to determine the status of equipment and give recommendations for further improvements and necessary adaptations of the facility.

PQM contracted Mr. Per Sima, General Manager of Valendor AB (Sweden) and Chairman of the Swedish Technical Committee for Condom Standardisation, and Mr. David Ramsamy, Assistant Technical Manager of Valendor (Mauritius) Ltd., to conduct this assessment, calibration, and training to maintain the integrity of the Valendor equipment used in the PQAD laboratory. Mr. Zelalem Mamo, Quality Control Manager, USP-PQM Ethiopia, accompanied the consultants throughout their visit. Below are the findings and actions taken during this trip.

Equipment	Action Taken
Initial Assessment	Of the equipment supplied from Valendor, the following were found to be out of service: <ul style="list-style-type: none">– Electric Hole Tester– Accurate Inflation System– Water Leakage Tester– Water Vacuum Bowl (WVB)

	<p>The crate with spare parts and tools was opened and the goods were inventoried. All items were accounted for per the supply contract; however, it appeared that the crate had been treated roughly during the final transport.</p> <p>The goods, parts and tools were unpacked.</p> <p>The lab does not have a calibrated stainless steel rule for calibration of length. This is required.</p>
<p>Electric Hole Tester (EHT)</p>	<p>The malfunctioning EHT was removed from the wall and new fixing points for the new casing were drilled with the tools provided. Also, new fixing points for the lower tank were installed. The rubber grips from the old EHT were too damaged to be used; however, Mr. Sima carried a new set with him (for emergencies); with approval from the PQM representative, the new set was installed at a price of EUR 400 each. All functions of the EHT were checked and it is now operational.</p> <p>The Old EHT computer was re-configured for use with the AIS and new software was installed. The system is now operational again.</p>
<p>Accurate Inflation System (AIS)</p>	<p>The AIS was determined to contain a virus that corrupted the software for testing. A re-installation of the files was successful but the new files were infected again within 15 minutes.</p> <p>The AIS was maintained for settings and two grip levers were replaced. All locking screws were replaced with new stainless steel screws to facilitate switching to Female Condom adapters.</p> <p>All pressure gauges were re-set manually for zero settings. The clamp slip force check was verified; inflation length was set; and the cylinder speed and force was set. The AIS heads were calibrated and a rehearsal training of conversion of the heads for Female Condom testing was performed.</p> <p>Standard operating procedures (SOP) for the use of the system, already in place, were reviewed.</p>
<p>Water Leakage Tester (WLT)</p>	<p>The WLT was checked, the friction brake was adjusted, and the equipment was calibrated. The check revealed that several of the grips for male condoms were damaged and a replacement set is needed.</p>
<p>Water Vacuum Bowl (WVB)</p>	<p>The WVB for package integrity was repaired with the spare parts provided and was again functional. A table for reading the vacuum at different altitudes was provided.</p>

Enersol Equipment	All of the Enersol equipment was out of use. The calibration of this equipment cannot be checked until it has been repaired. The Valendor staff refrained from trying to repair their competitor's equipment since that might void any warranty, and their company could not be responsible for it.
Digital Thickness Gauge (DTG)	Calibration was performed on the DTG and an SOP was created.
Training	<p>Three lectures were given that covered:</p> <ul style="list-style-type: none"> – Use of standards in the fight against HIV/AIDS – ISO 4074 standards for Male Latex Condoms and what new parameters might be included in the coming revision – WHO 2010 Specifications and its applicability for use with ISO 4074
	<p>The lab staff were trained on SOPs, settings, maintenance, and troubleshooting for the EHT. This training was quite extensive since the operators were not familiar with the machine. The machine was calibrated in the process.</p>
	<p>A training and skills check of the participants was conducted by oral exam and hands-on instruction. Mr. Per Sima and Mr. David Ramsamy determined that the analysts have the appropriate knowledge of maintenance issues, calibration procedures, and SOPs on the equipment in the lab for condom testing.</p>
Conclusion	<p>The Enersol equipment needs to be serviced. According to the staff, the compressor capacity is insufficient for running all of the equipment at the same time.</p> <p>The Valendor equipment is now functional and calibrated. The staff knows how to use it and can perform regular maintenance and troubleshooting. Some additional accessories will be needed.</p> <p>Calibration certificates will be issued by the end of this week for all the calibrated equipment and training certificates will be issued at the same time for all those who participated in the various trainings.</p>
Recommendations	<p>▶ <u>Preventive service contract</u> Valendor proposed a preventive service contract, where Valendor staff visits the laboratory on a regular basis to verify the maintenance status of the equipment and to repair and replace parts that may become a problem. USP-PQM Ethiopia will take this under consideration for next year's workplan.</p>

	<ul style="list-style-type: none">▶ <u>Calibration visits with traceable certificates issued</u> Valendor also proposes a calibration visit contract. This will ensure that all equipment has been calibrated by an external qualified person and the calibration will result in calibration certificates which are traceable. This is quoted separately.▶ <u>Training</u> In order to achieve ISO 17025 accreditation for male condom testing, a Quality Management System is needed. Valendor recommended that the lab director, supervisors, and senior analysts be trained on Quality Systems and procedures in order to prepare for accreditation. PQM will take it under consideration in preparing future workplans.
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Next Steps

1. USP-PQM Ethiopia is making arrangements for a technician from Enersol to visit PQAD to service the Enersol condom testing equipment, providing repair, preventative maintenance, and calibration. This is expected to be completed by August 2012.
2. PQM and USP-PQM Ethiopia staffs will continue to assist the PQAD lab so that it will be eligible for ISO accreditation and WHO prequalification.



ANNEX 1

Per Sima
22 May 2012

Zelalem Mamo
USP-PQM Ethiopia
QC Manager

PQAD Director

Re: Visit report and recommendations

Dear Sirs,

The visit was performed as a repair, maintenance, calibration and training visit. Further to determine the status of equipments and give recommendations for further improvements and necessary adaptations of the facility.

The visit was performed by: Per Sima, General Manager of Valendor Sweden and Chairman of the Swedish Technical Committee for Condom Standardisation and Mr. David Ramsamy, Assistant Technical Manager of Valendor (Mauritius) Ltd.

Friday May 18:

We could determine that from the equipment supplied from Valendor; the EHT was out of service as expected but also the Water Leakage Tester (WLT) The Accurate Inflation System (AIS) as well as the Water Vacuum Bowl (WVB).

The crate with spares and tools was opened and the goods were inventoried. All items were as per supply contract, but it had been treated roughly during the final transport.

The goods, parts and tools where unpacked.

The AIS was determined to contain virus that corrupted the software for testing. A re-installation of the files was successful but the new files were infected again after 15 minutes.

The WVB for package integrity was repaired with the spares and was again functional.

Saturday May 19:

The malfunctioning EHT was removed from the wall and new fixing points for the new casing was drilled with the tools provided. Also new fixing points for the lower tank was installed. It was deemed that the old rubber grips from the old EHT could not be used since they were too damaged. Per Sima had a set of 4 pcs. new with him for emergencies at a price of EUR 400 each. Permission to use these was asked of the USp representative and approval was granted. All functions of the EHT was checked and it was now operational.

The Old EHT computer was re-configured for use with the AIS and a new software was installed. Now the system was operational again.



Monday May 21:

The Enersol equipment was all out of use. It was deemed that there could be no calibration check for these equipments until they have been repaired. Valendor would not go into a competitors equipment and try to repair, since we cannot take responsibility for it.

Training for the EHT was performed. SOP, settings, maintenance and trouble shooting. This was quite extensive training since the operators was not familiar with the machine. Finally the machine was calibrated.

Tuesday May 22:

The AIS was maintained for settings and two grip levers was replaced. All locking screws were replaced with new stainless screws to facilitate switch to Female Condom adapters. All pressure gauges was re-set for manual zero settings. Clamp slip force check was verified. Inflation length was set. Cylinder speed and force was set. And calibration was initiated and performed for some of the heads. Also a rehearsal training of conversion of the heads for Female Condom testing was performed.

Wednesday May 23:

Continued calibration of the AIS and it was finalised. SOP for the use of the system.

WLT was checked and the friction brake was adjusted and calibration of the equipment performed. It was revealed that several of the grips for male condoms was damaged and a replacement set is required.

WVB- training and check of the equipment. In operation. A table for reading vacuum at different altitudes was provided.

Digital Thickness Gauge- Calibration was performed and SOP for procedures.

The lab does not have a calibrated stainless steel rule for calibration of length. This is required.

Thursday May 24:

A training and skills check of the trainees was performed in oral exam and also a practical manner. It was deemed that the analysts have appropriate knowledge of maintenance issues, calibration procedures and also the SOP of the equipment in the lab for condom testing.

Three lectures was given in the library using computer and power point slides. These slides were left with the lab management for rehearsal at a later date.

One of the lectures covered the use of standards in the fight against HIV/AIDS. The second covered ISO 4074 standard for Male Latex Condoms and what new parameters that are worked with in the coming revision. The third lecture covered WHO 2010 Specification and its applicability for use together with ISO 4074.



Summary:

Enersol equipment needs to be serviced. The compressor capacity is not enough for running all the equipment at the same time according to the staff.

The Valendor equipment is now functional and calibrated. The staff knows how to use it and can perform maintenance and trouble shooting. There are some additional accessories needed. A calibrated steel rule. A set of male condom grips for the WLT and a service kit for the Air supply system (replacement filters and tune up kit for the compressor)

Calibration certificates will be issued for all the calibrated equipment and training certificates issued for all participants in the various trainings.

Recommendations

Pro active actions:

Preventive service contract

We propose a preventive service contract, where Valendor staff visits the laboratory on a regular basis to verify the maintenance status of the equipment and to repair and replace parts that is about to become a problem. This is quoted separately.

Calibration visits with certificates issued that are traceable

We also propose a calibration visit contract. This will ensure that all equipment has been calibrated by an external qualified person and the calibration will result in calibration certificates which are traceable. This is quoted separately.

Training:

In order to achieve accreditation according to ISO 17025 for male condom testing there is a Quality System and Management needed. We recommend that the director of the lab together with supervisors and senior analysts take a 6 day training course at Valendor (Mauritius) Ltd. focusing on Quality System and procedures in order to prepare for accreditation. Valendor (Mauritius) is accredited by SWEDAC the Swedish accreditation authority and is performing testing for the major NGOs.

Sincerely yours,

Per Sima

Valendor AB