

# Evaluation of the Laboratory Quality Management System: Bureau of Drugs and Narcotics (BDN)

Nonthaburi, Thailand  
February 26, 2013

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## *Trip Report*

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PROMOTING THE QUALITY OF MEDICINES

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## **Executive Summary**

Dr. Charles, Dr. Phanouvong, and Mr. Roth traveled to Thailand to review the Bureau of Drugs and Narcotics' (BDN) established priorities and method based accreditation plan and further develop the laboratory ISO 17025 and WHO prequalification implementation plans. PQM reviewed the current QMS information, toured the lab, determined the condition of the equipment, and discussed flexible accreditation scope expansion with BDN.

BDN is ready to formally request scope expansion under ISO 17025:2005 with their accreditation body. PQM suggested two methods (Sterility and Bioburden) for future scope expansion during their next surveillance or full reaccreditation assessment. PQM also suggested that the laboratory will need to develop a sustainability and maintenance plan to maintain the amount of current equipment and potential sample loads being tested. When the laboratory adds more methods to their scope, the laboratory will likely need to delegate resources to handle new business and accreditation opportunities.

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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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- Dr. Aye Aye Thwin, Director; Dr. Wayne Stinson, Regional Malaria Advisor; Mr. Christopher Barrett, Deputy Director; and Ms. Sharlene Bagga-Taves, Health Officer, Office of Public Health, USAID/Thailand
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- PQM administrative staff and editors for their assistance with logistical arrangements and for editing the trip report

## ACRONYMS

BDN	Bureau of Drugs and Narcotics
DQI	Drug Quality and Information Program
MOH	Ministry of Health
NOMCOL	Network of Medicine Quality Control Laboratories
PMI	President's Malaria Initiative
PQM	Promoting the Quality of Medicines Program
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RDMA	Regional Development Mission for Asia
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

## **Background**

With financial support from the U.S. Agency for International Development (USAID), the U.S. Pharmacopeia (USP) has been providing technical assistance to Thailand since 2002. In Thailand, activities have focused on three main areas to improve the quality of medicines, namely, strengthening the capacity of the Bureau of Drugs and Narcotics (BDN) by providing training on post-marketing surveillance, laboratory techniques, and ISO 17025 Quality Management System (QMS) awareness.

BDN's goal is to strengthen their capabilities as a quality control (QC) laboratory by broadening their current ISO 17025:2005 scope of accreditation and becoming prequalified by the World Health Organization (WHO) Prequalification Program.

## **Purpose of Trip**

The purpose of this visit is to review the established priorities and method based accreditation plan and further develop the ISO 17025 and WHO prequalification implementation plans. PQM will review the current QMS information, tour the lab, determine the condition of the equipment, and discuss flexible scope expansion with their current accreditation body.

## **Source of Funding**

These activities were supported by the President's Malaria Initiative (PMI) through the Regional Development Mission for Asia (RDMA).

## **Overview of Activities**

The full agenda of the trip is included in *Annex 1*, a list of participants in *Annex 2*, and additional photographs of the lab in *Annex 3*.

During Dr. Charles' visit to BDN, there were five objectives:

- Discuss flexible scope expansion with current accreditation body
- Evaluate the current QMS
- Tour the laboratory
- Evaluate the equipment in the laboratory
- Discuss ISO Standards

Discussions regarding various aspects of QMS and other relevant topics were held with BDN staff. Some of the discussions focused on:

- Flexible scope expansion
- Audit trails with older equipment
- Adding microbiological methods to the scope of accreditation
- Reinforcing proficiency and inter-laboratory testing in support of the Network of Medicine Quality Control Laboratories (NOMCOL)-Asia
- Sustainability and maintenance after accreditation
- Renovation of the microbiology lab, which BDN has been keen to undertake to comply with international standards in terms of lab facility and operation. BDN needs technical assistance from PQM to provide input for the design of the lab.

The BDN staff asked several questions during the session about documentation, microbiological methodology, measurement uncertainty, and equipment issues.

PQM identified two ISO 17025 accredited organizations: TechMasters Electronics in Thailand and Davison Instruments in the U.S. as potential providers for combination pressure and temperature data loggers calibration support.

The laboratory stated that they would like to expand their scope of accreditation to the microbiological area. PQM suggested two methods (Sterility and Bioburden) for future scope expansion during their next surveillance or full reaccreditation assessment. The laboratory also expressed that while they are able to maintain their current sample testing load, they do not have the resources to accept all new business at this time. PQM suggested that the laboratory will need to develop a sustainability and maintenance plan to maintain the amount of current equipment and potential sample loads being tested. When the laboratory adds more methods to their scope, the laboratory must delegate resources to handle new business and accreditation opportunities.



## Conclusion

BDN is ready to formally request scope expansion under ISO 17025:2005 with their accreditation body. Based on discussions, if the accreditation body does not allow further expansion by method without documenting the products tested, the laboratory may investigate a new accreditation body, possibly ACLASS in the U.S.

## Next Steps

- BDN will decide which methods will be updated for future flexible scope expansion before or during their full re-accreditation
- BDN will prepare all documentation and equipment for flexible scope expansion to be submitted to the current accreditation body within the Physical Chemistry area.
  - Suggested Methods:
    - pH
    - KF
    - UV
    - LOD
    - Dissolution
    - Content Uniformity
- Prior to proceeding through the 2013-2014 accreditation cycle, the laboratory will need to develop a sustainability and maintenance plan to maintain the amount of current equipment and potential sample loads being tested
- During the full reaccreditation assessment in 2014, BDN will add 2-3 of the most used methods of the microbiology group to the proposed scope of accreditation

**PQM Trip Agenda**

Bureau of Drug and Narcotic  
 Nonthaburi, Thailand  
 February 26, 2013

<b>Time/Date</b>	<b>Activity</b>
0900	Arrival, opening meeting; introductions
ISO Section 4 Review	
1000	Scope discussion and expansion, flexible method based scopes Discuss any issues in the following areas: Management Requirements including management reviews, internal audit corrective actions, non-conforming work, complaints, client services, preventive actions, request tender and contract, subcontracting, purchasing services, measurement uncertainty, document control, measurement uncertainty, record control, job descriptions and responsibilities, personnel training, PT testing and other quality system elements
1200-1300	Lunch
ISO Section 5 Review	
	Discussion of equipment, Chemical Testing (Weight, pH, LOD and Microbiological methods) Discuss ISO 17025 Calibration Providers in the region Discussion ISO 17043 providers in the region Review of equipment and test discussion
1300-1500	BDN follow-up and briefing with Dr. Souly continued
1500-1600	Laboratory Tour Lab and Equipment Inspection
1600-1800	Wrap Up, Discuss Open Issues and feedback
1800	Depart

**PQM Trip: Lists of Participants**

Bureau of Drug and Narcotic  
 Nonthaburi, Thailand  
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**February, 2013 – Opening and Closing Meeting with Management and PQM Review**

<b>Participant</b>	<b>Institution</b>
Nidapan Ruangrittinon	BDN-Director Laboratory
Wiyada Akarawut	BDN-Deputy Director Laboratory
Suratchanee Savetsila	BDN-QA Manager
Dhaweessap Chaisomboonpan	BDN-Senior Pharmacist
Maytinee Limsiriwong	BDN-Senior Pharmacist
Orapin Tanankut	BDN
Sasida Yusook	BDN-Senior Pharmacist
Sirichai Krabisri	BDN-Senior Pharmacist
Somsak Sunthornphanich	BDN-Senior Pharmacist
Supanee Duangteraprecha	BDN-Senior Pharmacist
Witinee Kongsook	BDN-Senior Pharmacist
Donnell Charles	PQM
Souly Phanouvong	PQM
Lukas Roth	PQM

**PQM Laboratory Tour**

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**BDN Laboratory - Reference Standard Areas**



**BDN Laboratory - Dissolution Areas**



**BDN Laboratory - HPLC Areas**



**BDN Laboratory- Microbiological Areas**