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Establishment of Quality Systems and Accreditation in Health Laboratories

Report of an Intercountry Workshop
Thailand, 9-13 October 2006

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Contents

1. Introduction

With advancements in technologies, health laboratories are more than ever assisting physicians and public health programme managers to make informed decisions. Concurrently, the expectations for quality laboratory results have also greatly increased.

The concept of quality has been comprehensively elaborated and an international consensus on the quality certification process obtained through the efforts of the International Organization for Standardization (ISO). Quality systems are now globally recognized as an integral part of health laboratories. Assurance of quality covers all matters that individually or collectively influence the quality of a product or service. It is the totality of the arrangements made so that the product is of the quality required for its intended use. It denotes a dynamic system to improve reliability, efficiency and optimum use of products and services. The implementation of a quality system requires continuous monitoring and periodic evaluation through various tools of assessment.

WHO has consistently advocated implementation and assessment of quality in health laboratories. In order to provide technical assistance to Member States to strengthen their quality systems and establish an accreditation mechanism, an intercountry workshop was organized in Bangkok, Thailand from 9 to 13 October 2006. Fifteen participants from eight Member countries of the South-East Asia Region (Bangladesh, Bhutan, India, Indonesia, Maldives, Nepal, Sri Lanka and Thailand) attended the workshop. It was facilitated by experts from the Bureau of Laboratory Quality Standards, Ministry of Public Health, Thailand (WHO Collaborating Centre on Strengthening Quality Systems in Health Laboratories) and the National Blood Centre, Thai Red Cross Society, Bangkok (WHO Collaborating Centre on Training in Quality for Blood Transfusion Services). The list of participants and programme of work are provided at Annex 1 and 2 respectively.

2. Objectives

The objectives of the workshop were:

- to review existing mechanisms for the establishment of quality systems in health laboratories and discuss ways for improvements;
- to discuss the key elements of accreditation of health laboratories and mechanisms for their implementation;
- to formulate a framework for the establishment of national external quality assessment schemes in health laboratories; and
- to visit laboratories at provincial level that have a functional quality system, and review their role within the national network.

The workshop comprised a presentation of country reports to review the existing health laboratory capacity; sessions to disseminate new information; field visits to regional and provincial laboratories; and group work to formulate a generic plan to establish a mechanism of accreditation.

3. Inaugural session

On behalf of Dr Paijit Warachit, Director General, Department of Medical Sciences, Ministry of Public Health, Thailand, the workshop was inaugurated by Dr Kanchana Kanchananithi, Deputy Director General. She presented the Bureau of Laboratory Quality Standards (BLQS) as the nodal national agency for implementation of the quality system. The international standards ISO/IEC 17025 and ISO 15189 were used to "test" laboratories and health laboratories respectively. Under a Royal Decree, BLQS acts as the national accreditation body, supporting and promoting the accreditation system by providing training courses, facilitating the calibration and maintenance of analytical instruments and acting as the quality information centre.

Dr Kanchana explained that BLQS also organizes the external quality assessment scheme (EQAS) for medical laboratories throughout Thailand. Additionally, in 2002 and 2003, BLQS has signed a Mutual Recognition Agreement with the Asia Pacific Laboratory Accreditation Cooperation, and another with the International Laboratory Accreditation Cooperation. Furthermore, EQAS and BLQS have been accredited by the National

Association of Testing Authority (NATA), Australia in accordance with ILAC G-13 since 23 November 2002. As a WHO Collaborating Centre, BLQS can provide technical support and training to countries other than Thailand.

On behalf of WHO, Dr P.T. Jayawickramarajah, WHO Representative to Thailand welcomed participants and thanked the Ministry of Public Health, Thailand for hosting this workshop. Dr Jayawickarmarajah emphasized the need to strengthen laboratory services and encourage them to ensure quality by adhering to accepted standards. He highlighted the need for accreditation of health laboratories whereby an independent and authorized agency certifies their quality and competence on the basis of predefined standards. In developed countries, no laboratory is allowed to function without obtaining accreditation from the designated agency. This is yet to be established widely in the South-East Asia Region, where only Thailand has had the technical know-how and infrastructure to initiate and sustain the process.

Dr Jayawickramarajah echoed the important role that BLQS can play as the WHO Collaborating Centre for Strengthening Quality Systems in Health Laboratories. Designation as a WHO Collaborating Centre is an indication of the technical capacity of an institute and the commitment of its management to work with WHO to strengthen that of others.

4. Plenary sessions

4.1 Accreditation and certification

Accreditation is a procedure by which an authoritative body gives formal recognition that an institute (laboratory) or person (signatory) is competent to carry out specific tasks (scope). Accreditation has verified that procedures and results are technically valid, that laboratory staff are competent, and confirms that the laboratory conforms to a quality management system.

Accreditation provides confidence in the results, has public and industry acceptance, meets purchaser or regulatory specifications, accords national and international recognition, increases competitiveness and market share, provides assurance to customers of good laboratory practices, ensures better support in the event of legal challenge and saves money by getting it right the first time and every time.

Accreditation within a country can have international recognition through Mutual Recognition Agreements whereby the work of accredited laboratories is recognized as equivalent around the world.

Certification is a procedure by which a third party (certification body) gives a written assurance that a product, process or service (of an organization) conforms to specified requirements. While it confirms conformity of the quality management system, it does not confer technical credibility on the test results.

Accreditation of laboratories in Thailand

BLQS is the designated authority for providing accreditation of health products testing laboratories according to ISO/IEC 17025 and accrediting medical laboratories according to ISO 15189. BLQS is a full member of the APLAC and ILAC, and has mutual recognition agreements with other government organizations such as the Food and Drug Administration and the National Bureau of Agricultural Commodity and Food Standards, who use the services of BLQS-accredited laboratories when evaluating the competence of other laboratories.

BLQS provides accreditation to both government and private laboratories without discrimination. The number and type of operational laboratories in Thailand are:

Ministry of Public Health Regional Hospital Laboratory	25
Provincial Hospital Laboratory	67
Community Hospital Laboratory	712
University Hospital	10
Other Government Hospital	50
Private Hospital	453
Total	1317

BLQS has set up an organizational structure, including sub-committees and a decision-making committee, and procedures to ensure the impartiality, independence and integrity of assessors. All BLQS

assessors are professionals in the relevant fields, and have successfully participated in training courses. They are recruited from government organizations and universities. When selecting assessors, only those that have no potential conflict of interest with the organization to be assessed are selected.

A pre-requisite for granting accreditation to a laboratory is satisfactory performance in at least one proficiency testing activity, where available. An accredited laboratory is required to take part in proficiency testing activities that are relevant to its scope of accreditation, every year.

The assessment or surveillance visit is conducted at the laboratory premises by the appointed assessment team. Conformity with ISO 15189 and general and specific criteria of BLQS are reviewed by the assessment team and a summary of the findings, including details of any non-conformities, are recorded in the assessment report. This report is given to the laboratory before the assessment team leaves. For new accreditation and scope extension, a summary report is submitted to the Technical Sub-committee, which considers in detail each field of tests before presenting the annotated summary report to the Laboratory Accreditation Committee for an accreditation decision.

Surveillance visits are conducted during the first and second years after granting accreditation, and reassessment is conducted at three-yearly intervals. BLQS publishes a directory of accredited laboratories in the Royal Decree Gazette.

4.2 Quality standards

Health laboratories are the core function in the health quality system. The result of a test is an essential and life-saving support within the health care system. Therefore, quality-assured testing of all patient samples is vital

International standards are now widely used in implementing quality. Of these, ISO/IEC 17025:2005 pertains to general requirements for the competence of Testing and Calibration Laboratories and ISO 15189:2003 specifically addresses Medical Laboratories - Particular Requirements for Quality and Competence.

In developing countries, national standards need to be developed and implemented. This requires the following step-wise approach:

- Identify a national focal point for laboratories
- Draft national quality standards through a core group
- Build national consensus by peer review
- Ensure ratification/notification by the national authorities
- Identify and strengthen an implementing agency/institute
- Sensitize and train the participating institutes
- Facilitate the adoption of national standards
- Monitor and evaluate the process.

Once the national standards have been implemented, laboratories are in a better position to meet the requirements of international standards. Thailand adopted this approach with a high degree of success.

Implementation of national standards in Thailand: A novel approach

Thailand developed National Laboratory Standards in 2001. The Bureau of Laboratory Quality and Standards in the Ministry of Public Health was entrusted with the task of developing and implementing these standards in the country. The standards have the following 10 key elements or categories.

- Organization and management
- Personnel
- Laboratory instruments and equipment
- Procurement and external services
- Process control
- Document control
- Control of nonconformities
- Internal audits
- Continual quality improvement
- Client management

The implementation process was accomplished in the following stages:

Stage 1 Appointment of a steering committee comprising all stakeholders of the network and identification of roles and responsibilities

Stage 2 Identification of the quality standards for the participating (voluntary) laboratories

Stage 3 Establishment of the developmental steps and preparation of a checklist and scoring system

Stage 4 Establishment of the implementation approach for self-evaluation and development

Stage 5 Coordination of project implementation within a defined geographical area and establishment of a clear timeframe

Stage 6 Submission by each region of the appropriate detailed activities for budget request

Stage 7 Signing of the project agreement by all parties concerned

Stage 8 Transfer of the budget for project implementation. Progress reports are submitted every six months

Stage 9 Appraisal of the evaluations reported by the committee, management concerned and all stakeholders at the year-end meeting.

Stage 10 Results analysis and plan adjustment for next year

The Thai experience has been documented by WHO/SEARO (see "Quality Standards in Health Laboratories, Implementation in Thailand: A Novel Approach", publication no. SEA-HLM-386, 2005, or at www.searo.who.int/LinkFiles/Publications SEA-HLM-386 a4 2 .pdf).

Role of External Quality Assessment Schemes (EQAS)

EQAS is a schematic external assessment of a laboratory's performance in testing of known but undisclosed content and comparing the results with those of other participating laboratories. It is designed to raise standards of performance in any type of laboratory. A test result is supporting data for clinicians for make decisions on treatment, monitoring a disease or prevention. Therefore, no error or mistake should be tolerated.

Implementation of the quality system is a functional tool to reduce errors and mistakes in laboratories. However, a quality system does not function by itself and needs to be monitored. Self-monitoring, such as an internal audit or quality control, is not sufficient to guarantee the quality of test results. Continuous quality improvement requires ongoing assessment and review of the effectiveness of all elements of the quality system, using both internal and external mechanisms, to ensure that the defined quality standards are being met consistently.

EQAS plays an important role in the quality management system, especially in health laboratories, and is a very specific and specialized part of the monitoring process. Additionally, formal EQAS provides a regular, independent assessment of performance of participating laboratories by a recognized body to identify problems and weaknesses. The aim is to improve performance, ensure the test results and provide the laboratory with an objective view of its performance relative to other participating laboratories.

Even if a formal quality system is not in place, EQAS can still be introduced into laboratory practice as part of a process for quality improvement. However, EQAS should not be used to assess individual staff competency (which should be assessed against the performance of each SOP carried out by the staff member). Rather, information generated by EQAS should be used to identify laboratory errors and implement measures to prevent their recurrence. The establishment of even a simple scheme can have a significant impact in raising laboratory standards. When establishing an EQAS, the most clinically important tests should be included first; a range of tests can then be expanded as the scheme is further developed.

The benefits of EQAS for health and regulatory authorities are the establishment of a network of health laboratories with known standards of performance; the availability of useful information to assist in setting standards, reviewing testing strategies, using resources effectively, improving public confidence in the health laboratories, and supporting systems of accreditation.

Scope of accreditation for the health laboratory

Laboratories can be categorized into two broad types: testing or calibration laboratories. The testing laboratories analyse materials such as food

samples, pharmaceuticals or cosmetic products in order to characterize the specified composition of the sample or detect its contaminants. Health laboratories examine materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease or assessment of health status.

The international standards ISO/IEC 17025:2005 and ISO 15189:2003 are issued for laboratories. ISO 15189 includes 15 major elements (52 clauses) on management and 8 major elements (84 clauses) related to technical requirements. Using both management and technical requirements, the laboratory develops its own documents structure. A typical quality management system document hierarchy generally includes a Quality Manual, Management Procedures, Testing Procedures or Work Instructions and Supporting Documents such as Worksheets, Forms or Log Books.

The quality manual is unique to each laboratory. It should convey accurately, completely and concisely the quality policy, objectives; refer to the next level of documentation such as procedure or work instruction; and address the management responsibilities of the laboratory. All documents must be communicated to all relevant personnel. It is the responsibility of the management to ensure that the documents are understood and implemented at all times.

A laboratory should appoint at least the following staff:

- Technical Manager with overall responsibility for the technical operations and provision of resources needed to ensure the required quality of laboratory procedures;
- Quality Manager who has responsibility and authority to oversee compliance with the requirements of the quality management system, reporting directly to the top management; and
- Document Control Officer, who manages all final documents and information that pertain to the quality system.

Medical laboratories may use ISO 15190 as a guideline for preparing a written laboratory safety procedure, including training staff on safety precaution techniques (e.g. not to drink or eat in laboratory, but to wear gloves, mask and a gown when working with infective materials). A laboratory should note the need to perform certain tests in a bio-safety cabinet class 2 or using a fume hood, where necessary.

5. Country reports

5.1 Bangladesh

Health laboratory services in Bangladesh are functional in the public sector under various ministries, autonomous medical universities, semi-government hospitals, nongovernmental organizations and in the private sector.

The public sector comprises the Institute of Public Health (IPH), 13 regional laboratories in medical colleges, 64 district level laboratories, and peripheral laboratories in most of the 490 thanas (sub-district units). The IPH consists of the departments of microbiology, poliomyelitis, epidemiology, food and water testing, drug testing, and production units where intravenous fluid, blood bags, laboratory reagents and antisera are produced.

In the medical college laboratories, all branches of laboratory medicine are in operation. The district laboratories perform microscopic examinations and a few clinical chemistry investigations but no culture for isolation of pathogens is carried out. At the Thana complex laboratories, minimal microscopy and clinical pathology is done. Networking between laboratories for referral of samples, training support and supervisory visits is not in place.

Internal Quality Control is not being followed in the public health laboratories. A National External Quality Assessment Service (NEQAS) in clinical microbiology has not yet started. None of the public sector laboratories is participating in an International External Quality Assessment Scheme (IEQAS) in microbiology.

There are many laboratories in the private sector although their exact number and work profile are not known. In Dhaka alone, around 2000 private laboratories are in operation, and an estimated 4000 in the rest of the country.

The International Centre for Diarrhoeal Diseases Research (ICDDR-B) in Dhaka has acted as a reference centre for diarrhoeal pathogens since the 1970s, and coordinates with the Government of Bangladesh in investigations on diarrhoeal diseases.

A reference laboratory for safe blood transfusion has been established at the Dhaka Medical College.

There is neither a national policy for laboratories nor a scheme for their accreditation.

5.2 Bhutan

The Bhutan health care system is focused on primary health care services, which are provided through basic health units, district hospitals, regional referral centres and a national referral hospital.

The absence of national standards, a shortage of human and financial resources, a lack of training facilities, inadequate equipment and erratic supplies of reagents are major constraints in ensuring access to quality laboratory services.

Diversification of diagnostic services has recently started. Future plans include the standardization of laboratory services at each level of health facilities; standardization of test methodology, development of standard operating procedures (SOP) for each laboratory test; identification of normal ranges for quantitative tests for the Bhutanese population and enhancing staff proficiency. It is also planned to emphasize total quality management in health laboratories.

5.3 India

The National Accreditation Board for Testing and Calibration Laboratories (NABL) was established as an autonomous body under the aegis of the Department of Science and Technology, Government of India in 1994 to accredit testing, calibrating and clinical laboratories. It started following ISO Guide 58 and ISO 17025 for testing and calibration laboratories, and has now adopted ISO standards for clinical laboratories. NABL is a full member of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the International Laboratory Accreditation Cooperation (ILAC).

NABL has conducted over 50 awareness programmes or workshops in major cities, nine of which exclusively for medical laboratories. Several State governments are considering recommending mandatory accreditation. NABL started accreditation of medical (formerly clinical) testing laboratories in 1998 using ISO/IEC Guide 25. The first certificate was issued on 7 July 1999. The standard was later changed to ISO/IEC 17025: 1999 and then to ISO 15189: 2003. A checklist for the audit of collection centres was issued in 2006.

To date, 74 medical laboratories have been accredited, 21 of which have been issued certificates confirming compliance with ISO 15189:2003. At present 50 additional laboratories are in various stages to meet the new ISO standard.

NABL has also conducted three training workshops that have led to 76 trained assessors.

Major constraints in accreditation in India include the absence of a national laboratory policy, and national standards for accreditation except for blood banks. Accreditation is still voluntary and there is therefore poor participation of public sector laboratories.

5.4 Indonesia

The Government sector has 27 Health Laboratory Offices, 27 Food and Drugs Supervision Offices, 10 Environmental Health Technique Offices, 44 Public Hospital Laboratories, one national research lab (NIHRD), and 1671 sub district laboratories. In the private sector, 599 clinical laboratories are operational.

The laboratories are manned by trained and qualified staff, SOPs are available and used, equipment and reagents validated and maintenance of equipment assured.

The Ministry of Health develops national standards for health laboratories on microbiology, clinical chemistry, pathology and immunology and imparts technical training for laboratory technical staff of hospitals. NEQAS are being organized for clinical chemistry, haematology, microbiology, bacteriology (acid-fast staining) and parasitology (microscopy for malaria).

The National Accreditation Committee (KAN) is the accrediting agency and to date four laboratories in Jakarta, Surabaya, Bandung and Palembang have been accredited.

5.5 Maldives

Maldives has 40 laboratories in the public sector and 14 in the private sector. No national laboratory quality manager has been designated. The Indira Gandhi Memorial Hospital in Male and the Central Medical Hospital supply material to all the laboratories. No accreditation of laboratories is

being undertaken, although a mechanism for registration and licensing of all private laboratories is in place.

The laboratories are manned by trained and qualified staff, SOPs are available and used, equipment and reagents validated and maintenance of equipment is assured. Reagents and kits are checked at the time of receipt. National standards for health laboratories have been drafted and plans for their implementation and for accreditation formulated.

5.6 Nepal

A Quality Assurance Unit was established in the National Public Health Laboratory, Kathmandu (NPHL) in 1997. The important functions being performed by this unit include: development of quality assurance training materials, production and distribution of quality control samples (three times a year), assessment of results, feedback to the participating laboratories, field visits (supervision) to PHC/district/zonal/sub-regional/ regional and central level laboratories, and organization of quality assurance training courses.

The NPHL also organizes NEQAS for a variety of analytes. In the beginning 22 laboratories took part from the central region. Gradually this has been expanded to participants from the whole country with an increasing number of analytes. By August 2006 a total of 380 laboratories were participating in the programme.

5.7 Sri Lanka

Sri Lanka has a functional network of laboratories spread out over the whole country. The number of laboratories at various levels is as given below:

Teaching hospitals	18
General hospitals	16
Base hospitals	30
District and rural hospitals	250

The Medical Research Institute conducts NEQAS in biochemistry and bacteriology with 55 and 25 participating laboratories respectively.

A National Laboratory Policy is awaiting formal approval, and a 10-year plan for granting accreditation has been developed by the Ministry of Science and Technology using ISO 15189.

6. Field visits

Participants visited the Maharaj Nakhon Rachasima Hospital, the Regional Medical Sciences Centre and the Mahasarakam Hospital at provincial and peripheral levels in Thailand. A brief introduction of the institute was provided by the Head of the Laboratory before being taken on a tour of the laboratories. Extensive interaction between participants and the laboratory staff was encouraged to have a better understanding of the concepts of the quality systems applied in provincial laboratories.

7. Action plan for accreditation

The participants were briefed on the need for planning and how to develop an action plan. The parameters to be considered included the specific activities, time frame, type of activity, persons designated to undertake the activity and the resources required to accomplish it. Participants then developed their respective country-specific generic action plan for initiation of accreditation of health laboratories. The plans of a few countries were presented and discussed in a plenary session. Various technical and managerial problems raised by the participants were discussed and solutions suggested. These discussions led to the formulation of the recommendations noted below.

8. Recommendations

(1) Member countries should

- establish national quality standards for health laboratories;
- initiate a process of accreditation of health laboratories.

(2) WHO should

- prepare and disseminate guidelines for the establishment of a national accreditation mechanism for health laboratories;
- facilitate participation of national health laboratories in international external quality assessment schemes (IEQAS).

Annex 1

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Annex 2

Programme

9 October 2006

09.00-09.30	Welcome Address	WR Thailand
	Opening Address	Director General of Department of Medical Sciences
09.45-11.00	Presentations on current status of health laboratories quality system in SEAR countries, including discussion	Moderator: Dr Rajesh Bhatia
11.00-12.00	Establishment of a quality system and accreditation in health laboratories for SEAR countries	Dr Panadda Silva
13.00-14.00	Roles of EQAS for supporting the health laboratory quality system	Dr Patravee Soisangwan
14.00	Field visits to BLQS, DMSc, MOPH, Nonthaburi	
15.00-16.00	Thai-NEQAS Demonstration	Dr Patravee Soisangwan
16.00-17.00	Demonstration on the Mobile Laboratory for Bird Flu Diagnosis (BSL 2/3)	Dr Wattana Auwanit

10 October 2006

08.30-10.00	Scope of Accreditation in a Health Laboratory	Mrs Siripan Wongwanich Mrs Partoompit Wimonwattrawatee
10.30-13.00	Promoting the health laboratory quality system: Thailand experiences	Dr Panadda Silva
14.00-17.00	Implementation of the quality system networking in Northeastern Region, Thailand	Mrs Mathuros Chaivoraporn Mr Prayuth Keawmalung

11 October 2006

10.00-13.00	Visit to the ISO 15189 accredited Maharaj Nakhon Rachasima Hospital, Blood Banking and Clinical Microbiology Laboratory (Regional Hospital Level) and Regional Medical Sciences Centre of Nakhon Rachasima	Directors of institutes Mrs Mathuros Chaivoraporn, Mrs Jarugorn Visansawat Mrs Sasitorn Husawathee
15.30-17.30	Visit the Pimai Laboratory (community hospital level); laboratory networking demonstration	Director, and Head of Pimai Laboratory and Mrs Mathuros Chaivoraporn

12 October 2006

a.m.	Visit to the Mahasarakam Laboratory (provincial hospital level); under Promoting the Health Laboratories Quality System Project	Director, and Head of Laboratory
p.m.	Working group discussions	

13 October 2006

08.30-10.00	Action plan preparation and presentation	Country representatives
10.30-12.00	Wrap up discussion and closing remarks	Dr Panadda Silva Dr Rajesh Bhatia Prof. Dr Pimol Chiewsilp
12.00-13.00	Visit to the RMSC of Nakhonrachasima	Director of RMSC of Nakhonrachasima