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# Accreditation of Health Laboratories in the Countries of the SEA Region

Report of a Regional Consultation Bangkok, Thailand, 6-10 October 2003

WHO Project: ICP BCT 001



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# 1. INTRODUCTION

Accreditation of health laboratories is the process by which an independent and authorized agency certifies the quality and competence of a laboratory on the basis of certain predefined standards. This is done at regular intervals to ensure maintenance of standards and reliability of results generated to support clinical and public health activities by the laboratories. In developed countries, no laboratory can function without obtaining accreditation from the designated agency. The accreditation process requires identification of an authoritative body, adoption of standards and institution of a mechanism of inspection of laboratories to certify their compliance with standards. With the notable exception of India and Thailand, most of the countries in the Region do not have the technical know-how or infrastructure to initiate and sustain the process of accreditation. The accreditation of laboratories gives confidence to the user in availing their services.

WHO has supported quality assurance in health laboratory services has been supported by WHO for many years. Technical discussion on this subject took place at the fiftieth session of the Regional Consultation. Various activities have been undertaken at intercountry and country level to strengthen the quality system and assessment mechanism. Technical staff participating in various activities have been provided orientation on an independent certification mechanism for quality in an institution. The next logical step is to orient the national managers, so that they could initiate the process of accreditation, and provide them with a broad framework to facilitate the implementation process. However, since the Member Countries do not have adequate technical skills in implementing the accreditation, a Regional Consultation was organized at Bangkok, Thailand from 6 -10 October 2003 to orient national focal points in all the countries to the concept and process of accreditation in the Region and to develop a broad framework to facilitate the implementation process which could be utilized by the Member Countries in formulating their respective guidelines.

Seventeen participants from all Member Countries of SEAR, except Democratic Republic of Korea and Timor-Leste and one from the United Kingdom attended this consultation. Dr JJS Snell, from the United Kingdom was elected as the Chairperson and Dr Panadda Silva, Director, Bureau of Laboratories Quality and Standards, Bangkok, Thailand as Co-chairperson of the consultation (See Annexes 1 and 2 for the detailed programme and list of participants).

# 2. OBJECTIVES

The objectives of the consultation were as follows:

- (1) To orient national programme managers in implementation of accreditation of health laboratories;
- (2) To review the genesis and status of accreditation of health laboratories in India and Thailand;
- (3) To formulate a framework on accreditation of health laboratory services, and
- (4) To develop a model Plan of Action for implementation of accreditation in the countries of the Region.

# 3. INAUGURAL SESSION

Dr Panadda Silva, Director, Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health, Government of Thailand, welcomed the participants of the consultation. Dr Somsong Rugpoa, Director General, Department of Medical Sciences, Ministry of Public Health, Government of Thailand, briefed the participants about the steps initiated in Thailand for quality assurance in laboratories. He assured the participants that they would benefit immensely from the deliberations of various experts as well as visit to the Bureau of Laboratory Quality Standards which would help them in implementing similar steps in their respective countries.

Dr S Kumari, Regional Adviser, Blood Safety and Clinical Technology, WHO Regional Office for South-East Asia, described the background for the conduct of this consultation, its objectives and expected outcome. She also read out the address of Dr Uton Muchtar Rafei, Regional Director, WHO/SEARO, New Delhi. The Regional Director said that health laboratories were now being utilized more often at present than in the past. Unreliable laboratory results might, therefore, have serious consequences for the health of individuals as well as the community. In this context, it was crucial for laboratories to ensure quality in their results.

He reiterated that quality assurance was a wide-ranging concept which covered all matters that individually or collectively influenced the quality of a product. Quality assurance encompassed the totality of the arrangements made to ensure that the product was of the quality required for its intended use. It denoted a system for continuously improving reliability, efficiency, and utilization of products and services. It rested on implementation of various measures within the laboratory that helped the staff in deciding whether the results were reliable enough to be released. The implementation of quality warranted its continuous monitoring and periodic evaluation through various tools of assessment.

Dr Uton emphasized that laboratories should be encouraged to ensure quality and also undergo independent evaluation periodically. The laboratories which performed as per the accepted standards needed to be recognized through a well-defined process, of accreditation. WHO had consistently advocated to promote implementation and assessment of quality in the health laboratories of the countries of the South-East Asia Region during the past few years and this consultation was another step taken to provide technical support to the countries to initiate the process of accreditation and assure quality of laboratory results.

# 4. **PROCEEDINGS**

# 4.1 Review of Status of Quality Assurance in the Countries of SEA Region

## 4.1.1 Regional perspectives

Dr Sudarshan Kumari presented the status of quality assurance in the Member Countries of South-East Asia. She stressed that quality assurance was important in health laboratories, which provided considerable support to the quality of health care, especially in the area of communicable diseases and non-communicable diseases that had imposed a stupendous burden on health services and communities. There were a variety of health laboratories in the SEA Region and their number ran in thousands. However, the quality of results generated by most of these laboratories was questionable. Only three countries (Indonesia, Myanmar and Nepal) in the SEA Region had a national laboratory policy and two (Thailand and India) had initiated the process of accreditation. As far back as in 1974, the Twenty-seventh World Health Assembly had adopted Resolution WHA 27.62 on Laboratory Technology urging Member States to pay special attention to the issue of quality control in laboratories. The WHO Regional Committee for South-East Asia also recommended various steps to assure quality of laboratory results.

WHO had organized Intercountry consultations and workshops on various facets of quality assurance in the recent past. Many laboratory personnel from the Member Countries of SEA Region were imparted training on quality assurance. Member Countries were also provided with the services of international consultants to develop their quality systems. WHO undertook similar activities for providing technical support to Member Countries in the area of blood safety which had become a priority area since the emergence of HIV/AIDS and viral hepatitis as major public health problems. Dr Kumari identified various lacunae in the implementation of quality in the health laboratories in the Region and urged the participants to develop an efficient quality management programme in their countries.

# 4.1.2 Accreditation in Thailand

Dr Panadda Silva traced the history of accreditation and its implementation in Thailand and informed that ISO Guide 25 was the initial document used. Subsequently, ISO Guide 17025 provided useful information in establishing a mechanism for accreditation. International standards were currently available in ISO 15189 which were exclusively for medical health laboratories. Thailand had also developed national standards that were applicable across the country. All standards included management and technical requirements. Implementation of standards was through a quality assurance system that comprised of trained personnel, validated equipment and reagents, appropriate methodology, and documentation. Utilizing the expertise and infrastructure already available within the country or internationally, could facilitate implementation of accreditation. The external quality assessment scheme (EQAS) should precede accreditation, since apart from a tool for assessing quality, the data generated by an ongoing scheme should also provide indication about the status of the quality and improvements that might have been brought about. The strategic plan for accreditation should include national consensus on locally effective mechanisms for accreditation, commitment of national governments, availability of adequate resources, and willingness of the laboratory professionals to participate in this scheme. Subsequently, an infrastructure should be created to initiate accreditation. The accreditation of blood transfusion services in Thailand was described by Dr Pimol Chiewsilp. From 2004, the blood banks in Thailand would be following the standards as envisaged earlier by the American Association of Blood Banks (AABB).

## 4.1.3 Accreditation in India

Dr Kanagasabapathy described the genesis and activities of accreditation body of India. The National Accreditation Board for Laboratories (NABL) of India was established as an autonomous body under Department of Science and Technology, Government of India in 1994 to accredit testing, calibrating and clinical laboratories. Ten disciplines of clinical laboratories were included in the scope of NABL accreditation. It followed ISO Guide 58 and ISO 17025 and was gradually moving to adopt the ISO standards for clinical laboratories. NABL was one of the 16 (Asia Pacific Laboratory Accreditation Cooperation) APLAC partners. NABL organized five-day training courses twice a year based on APLAC guidelines through which 45 assessors had been trained. It also organised training courses on laboratory quality system, management and internal audit four times a year and 50 had been trained to date. Accreditation in India was so far voluntary and participation in EQAS was a prerequisite for applying to NABL. Till date, NABL had accredited 34 clinical laboratories and an additional 25 were under process.

# 4.1.4 Status of accreditation in other SEAR countries

Apart from India, Thailand and to some extent Indonesia, other countries do not have any process of accreditation. Indonesia initiated a process of accreditation since 2002 under which standards were formulated. An assessor's guideline for evaluating conformation to standards by a scoring method based upon inspection of documentation, observation and interview with selected members of laboratories was also prepared. Though all private laboratories had to be mandatorily accredited, the process had just begun and to date, no laboratory had been granted accreditation. Myanmar was initiating legislation which would demand laboratories in the private sector to participate in EQAS run by National Health Laboratory, Yangon before licensing. Nepal had a national laboratory policy and around 120 laboratories were currently participating in EQAS. The laboratories in the private sector were also being encouraged to participate in EQAS. Maldives was planning for accreditation of its food processing laboratory, since the economy of the country depended to a large extent upon export of seafood, and most of the other edible items were imported into the country. Sri Lanka had been advocating guality assurance in its health laboratory services and may soon start accreditation. Bhutan was having discussions on initiating mandatory accreditation of the laboratories as well as other health care services. Some of its laboratories were already participating in various International EQAS.

Bangladesh had large number of laboratories, most of which were not even registered with any government agency. Some of these were manned by unskilled workers. A law was enacted in 1982 to regulate health laboratories, but the same was not being implemented. All the countries were of the view that accreditation, as and when initiated, should be on a voluntary basis. They also opined that licensing may be the first step in moving towards the goal of accreditation.

## 4.2 Orientation on Quality System and Accreditation

An overview of quality, quality assurance and quality system was provided by Dr Rajesh Bhatia, WHO/SEARO, New Delhi. The importance of International Standards Organization (ISO) in disseminating international standards was highlighted. Dr Bhatia said that the objective of a quality system was to continuously generate reliable data on the basis of accurate and precise testing of the clinical and other materials. A quality system had five key elements, viz organization and management, documentation, standards, training and assessment. The assessment could be continuous and concurrent (monitoring) or periodic and retrospective (evaluation). It could be undertaken through man (audit) or by sending material (EQAS and internal quality assessment scheme). Accreditation was a tool that recognized the existence of a quality system in a laboratory.

Dr Pimol Chiewsilp, Quality Manager, National Blood Centre, Bangkok, Thailand described the utility and mechanism of internal audits. She introduced the aims of audit, classification, characteristics, and types of quality audit and described the mechanism for undertaking audit. The main purpose of audit is to determine conformance to specified requirements and determination of effectiveness of quality system in meeting quality objectives, as well as to provide the auditee with an opportunity to improve quality system. A quality audit should observe actual practices and compare these with planned practices; must be independent and objective; performed by competent staff with the cooperation of auditee and its report should be shared with top management to quality.

Dr JJS Snell spelt out the requirements of the accreditation process. Accreditation stimulates improvements in standards, provides measures of competence, and provides criteria for licensing. He stated that an accreditation system should be built on the strong foundation of quality system and quality assurance programme. Countries which do not have a sound quality system in place may not benefit from accreditation until quality assurance in terms of good laboratory practices, internal quality control, audit, validation, internal quality assessment, and participation in EQAS was strengthened. Every country should decide its priorities and adopt standards which should be followed by all its laboratories. While setting standards, the country may opt to aim at not very stringent standards to begin with. As quality improves, standards can be elevated. The process of accreditation cost money to the accreditation board as well as to the laboratory seeking accreditation. The cost was towards capital, time of staff, calibration, consumables and training. However, in the long run these costs overweighed the cost of poor quality.

# 4.3 Initiation of Accreditation

Dr Panadda Silva discussed the establishment of the process of accreditation which required national consensus on various issues. These may be grouped under the following:

- > Identification of standards that will be used in the country
- Areas that will be covered by this scheme: some or all of great public health importance
- Identification of stakeholders: Government, private sector, regulatory agency, laboratory professionals and users
- Development on linkages with international agencies viz. ILAC and APLAC
- > Establishment of procedures for accreditation and accreditation body
- > Characterization of concepts of accreditation body
  - Conflict of interest
  - Impartiality
  - Confidentiality
- > Identification of customer and delineation of relationship with them
- ➢ Resources
  - Infrastructure
  - Personnel: management and technical; assessor
  - Documentation
- > Setting up a process of accreditation and giving it wide publicity.



# 4.3.1 Preparation by laboratories for accreditation

Dr Chongdee Wongpinairat enumerated the steps a laboratory should undertake to obtain accreditation from a national or international body. The laboratory should understand the requirements of the accreditation body and undertake an internal audit to perform a self inspection. Broadly, these requirements will fall into organization and management, documentation (quality manual, quality policy, SOP, reports) and their control, internal quality controls, requirements of technical functions of the laboratory (personnel, equipment calibration and traceability, availability of quality reagents, validation mechanism for material, machine and methodology, participation in EQAS, records and reports). Once the laboratories had sufficient confidence in their quality system, they may apply to an Accreditation Board which appoints an assessor to evaluate the quality system of the laboratories against predefined standards.

## 4.3.2 Guidelines for assessors

Assessment of quality system requires on-site inspection by assessors. Professor Pradeep Seth highlighted the need for the conduct of a consistent and thorough assessment and availability of guidelines for same. The guidelines must ensure application of uniform standards. Assessment may require two visits-one for pre-assessment in which the methodology of assessment is explained, checking the preparedness of laboratory, studying the scope of accreditation and fixing the duration of the assessment and the number of assessors. The assessors conduct on-site assessment of the applicant laboratory, make recommendations to the Accreditation Body and obtain evidence on conformance with respect to criteria as approved by Accreditation Body while maintaining confidentiality on matters related to the applicant laboratory. The assessor's check-list includes laboratory design, personnel, collection and handling of specimens, safety in laboratory including waste disposal, availability of documents (e.g. standard operating procedures, records, statistical process controls), guality of reagents, storage facilities, test procedure, internal audit and assessment of quality through audits and EQAS. After inspection, the assessor prepares a report and submits to Accreditation Board.

## 4.3.3 Framework for accreditation

Based upon the experience with the accreditation process in the United Kingdom, Dr Snell briefed the participants about the process of accreditation.

He also described various types of audits (vertical, horizontal and witness) that could help the management in ascertaining whether the organization was functioning the way it was envisaged to operate. He also suggested that standards should be realistic and framework and could be borrowed from ISO 15189.

Dr Snell discussed the intricacies of accreditting small laboratories which were large in number and providing invaluable support to national programmes and diagnosis of diseases such as tuberculosis, malaria, anaemia, and diarrhoeal diseases etc. Dr Panadda supported and supplemented his views by incorporating the experience of Thailand. She said that Thailand placed greater emphasis on internal quality control and was developing a manual to assure quality for use in smaller laboratories. Participation in EQAS was a must and the organizer of EQAS provided technical support to the laboratories and training for those whose performance was not up to the desired mark. Regular monitoring visits (at least twice a year) also ensured continuous monitoring and interaction with the staff of small laboratories.

The participants discussed the framework in group work to develop a generic plan for initiation of accreditation and finalized a generic roadmap for the development of the process of accreditation. In the plenary session, they made various suggestions to implement the process in the diverse conditions of the countries of the SEA Region.

# 4.4 Visit to Bureau of Laboratory Quality Standards, Thailand

The participants visited the Bureau of Laboratory Quality Standards, Department of Medical Sciences, Ministry of Public Health, Nonthaburi, Thailand. They observed the infrastructure for accreditation of laboratories in Thailand. The Director and the faculty of the Institute showed them various types of documentation and data management related to accreditation.

# 4.5 Development of Plan of Action for Implementation of Quality System and a Follow-up Mechanism

Dr Sudarshan Kumari briefed the participants on the need of planning and the method of development of an action plan with specific activities, taking into consideration various parameters such as activity; time-frame, type of activity, person designated to undertake the same and the resources required to accomplish it. The participants were divided into two groups to have in-depth

discussion and exchange of information. Both the groups developed generic action plans in group work and presented these in a plenary session.

Various issues that need to be considered by the participants in implementation of accreditation in their own settings were thoroughly discussed in a plenary session. The technical problems raised by the participants were discussed and various solutions suggested. Extensive discussions led to the formulation of recommendations that are described hereunder.

# 5. **RECOMMENDATIONS**

The participants unanimously agreed that quality in health laboratory services in the countries of SEA Region required considerable improvement and accreditation was one of the tools to assess this quality and bring about an improvement to support quality of care. They were also aware of the fact that the process of accreditation demanded resources and commitment from the top administrators of the countries and would take considerable time and efforts to make it a functional and efficient tool. To achieve the basic goal of initiating accreditation, they made the following recommendations:

## 5.1 To Member Countries

The Member Countries should:

- (1) Develop, on priority, a national health laboratory policy emphasizing the importance of a quality system. The national policy should be backed up with appropriate legislation and allocation of adequate resources for its efficient implementation.
- (2) Register and license all health care laboratories in the public and private sectors with the help of uniform standards drafted by the health ministry in consultation with national experts.
- (3) Undertake a situation analysis of quality systems in the health laboratories, strengthen areas that require support to assure a functional quality system in all health laboratories and create awareness about availability and utilization of ISO standards.
- (4) Set its goal vis a vis accreditation of health laboratory services with a defined realistic time frame and based upon standards developed by International Standards Organization (IS:15189). This goal should

address application of the process of accreditation to specific geographical regions; inclusion of one or more disciplines of laboratories from public or private sectors alone or together through mandatory or voluntary accreditation.

- (5) Develop and implement a national programme by creating appropriate infrastructure (viz. Accreditation Body) for according accreditation. The process of accreditation should be overseen by a broad based group comprising various stakeholders such as laboratory professionals, regulators, consumer-protection groups, legal experts, academics, opinion-makers etc.
- (6) Seek technical cooperation from other countries for getting the laboratories accredited through a bilateral agreement or through technical support from international agencies such as WHO, till the accreditation infrastructure is created or becomes feasible in the country.

# 5.2 To WHO

WHO should:

- (1) Develop minimum standards for licensing and registration of different disciplines of laboratories and blood transfusion services.
- (2) Undertake advocacy with the national health authorities to ensure adoption of minimal standards for health laboratories for registration and licensing and to improve the quality of their services.
- (3) Provide technical support to countries in strengthening their quality system and initiation of accreditation with emphasis on development of infrastructure and training of human resources.
- (4) Facilitate accreditation of health laboratories from accreditation authorities of other countries of the SEA Region for Member Countries who desire it.
- (5) Develop a follow-up mechanism to monitor the progress made by the countries in implementing accreditation and provide continuous technical support through an established accreditation body.
- (6) Organize a review meeting every two years to ascertain the progress made in strengthening quality systems and initiation of accreditation, so that countries could learn from the experiences of others and build up their programmes.

# 6. CONCLUDING SESSION

The concluding session was chaired by Dr S Kumari who thanked the organizers and the facilitators for making the consultation a success. She expressed her satisfaction at the Consultation having met its stated objectives and hoped the participants would be able to translate the knowledge gained in strengthening quality assurance practices in their own settings. She assured continuation of WHO support in this area.

# Annex 1

# PROGRAMME

# Day 1 - 06 October 2003

0900 hrs.	<ul> <li>Registration</li> <li>Introduction</li> <li>Objectives</li> <li>RD's address</li> <li>Election of chair</li> <li>Approval of agenda</li> </ul>					
1000 hrs.	Overview of quality assurance activities in SEAR and need for accreditation	Dr S Kumari				
1030 hrs.	Overview of quality system-implementation of quality	Dr Rajesh Bhatia				
1130 hrs.	Overview of quality system-assessment of quality	Dr Rajesh Bhatia				
1200 hrs.	Internal audit	Dr Pimol Chiewsilp				
1400 hrs.	Accreditation-Concepts and constraints	Dr JJ Snell				
1445 hrs.	Accreditation in Thailand-Genesis, status and future prospects	Dr Panadda Silva				
1600 hrs.	Accreditation in India-Genesis, status and future prospects	Dr Kanagasabapathy				
1645 hrs.	Open session for views of country representatives on accreditation	Chairman				
Day 2 - 07 October 2003						
0900 hrs.	Organization of accreditation scheme at national level: – How to initiate – Infrastructural requirements	Dr Panadda Silva				
1000 hrs.	Accreditation-Standards and process and the UK experience	Dr Snell				
1130 hrs.	Guidelines for inspection	Dr Pradeep Seth				

1215 hrs.	Preparation by laboratories	Dr Chongdee						
1400 hrs.	Voluntary or mandatory accreditation Country opinion	Chairman						
1445 hrs.	Accreditation of blood banks: Thai experience	Dr Pimol						
1600 hrs.	Accreditation for clinical chemistry laboratories: additional requirements	Dr Kanagasabapathy						
1630 hrs.	Accreditation for haematology: additional requirements	Dr Sood						
Day 3 - 08 October 2003								
0900 hrs.	Draft framework for accreditation Group discussions	Dr Snell to introduce the subject and lead discussion						
1400 hrs.	Formulation of framework of accreditation Two groups: Group 1: Labs dealing with communicable diseases Group 2: Labs with BTS, clinical chemistry and haematology							
Dav 4 - 09 October 2003								

# Day 4 - 09 October 2003

0900 hrs. Presentation of group work and discuss	sions
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- 1100 hrs. Finalization of framework
- 1400 hrs. Recommendations for accreditation of laboratories in the SEA Region

# Day 5 - 10 October 2003

0900 hrs.	Briefing on plan of action	Dr Kumari
0930 hrs.	Development of model plan of action for imple- mentation of accreditation in member countries Group I and II	
1200 hrs.	Presentation of plan of action	
1400 hrs.	Finalization of recommendations, framework, plan of action	
1500 hrs.	Valedictory and adoption of recommendations	

## Annex 2

# LIST OF PARTICIPANTS

#### Bangladesh

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