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Quality Assurance in Health Laboratory Services: A Status Report

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PREFACE

WHO has been assiduously promoting quality of health care at all levels. The health laboratories provide strategic support to both clinical and public health services in providing quality services. In recent years, excellent progress has been made in various fields of medicine. These developments have revolutionized health laboratory services. The latest molecular tools have greatly enhanced the accuracy of various test procedures. However, this unparalleled progress in the field of diagnostic medicine can benefit humanity only if the laboratory services are accessible to users and the results produced by the laboratories are reliable, reproducible and rapid enough to be useful.

An optimal utilization of health laboratories is possible only when laboratory services are planned meticulously and resources invested judiciously into this area. To achieve this basic prerequisite of the planning process, WHO has been creating a database of the status of health laboratories in the Member Countries of the South-East Asia Region. This information is based on the observations made by large number of international experts during their recent visits to Member Countries.

In many countries of our Region, health laboratories have not been able to contribute optimally because of various reasons, notably: lack of clearly-defined national policies for laboratory services; shortage of trained manpower; poor linkages and communication; obsolescence of health facilities; shortage and inappropriate laboratory equipment; non-availability and hence non-utilization of standard operating procedure manuals in laboratory techniques; poor development of internal quality control methods, and inadequate number of laboratories participating in external quality assessment schemes.

This document is aimed to provide an independent status of health laboratories in Member Countries of South-East Asia Region to the health administrators to support them in developing effective plans for strengthening and utilization of laboratory services.

Dr Sudarshan Kumari
Regional Adviser

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ABBREVIATIONS AND ACRONYMS

AIIMS	All India Institute of Medical Sciences, New Delhi, India
CPHL	Central Public Health Laboratories, Colingdale, London, UK
EQAS	External Quality Assessment Scheme
HBsAg	Hepatitis B surface antigen
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
IEQAS	International External Quality Assessment Scheme
IPH	Institute of Public Health, Dhaka Bangladesh
IOC	Internal Quality Control
MDR	Multi Drug Resistance
MRI	Medical Research Institute, Colombo
NACO	National AIDS Control Organization, India
NEQAS	National External Quality Assessment Scheme
NHL	National Health Laboratories, Yangon

NICD	National Institute of Communicable Diseases, Delhi, India
NICED	National Institute of Cholera and Other Enteric Diseases, Kolkata, India
NIH	National Institute of Health, Bangkok, Thailand
NPHL	National Public Health Laboratories, Kathmandu, Nepal
QA	Quality Assurance
RCPA	Royal College of Pathologists of Australia
RIVM	Rijksinstituut Voor Volksgezondheid en Mileu
SEAR	South-East Asia Region
SOP	Standard Operating Procedure
STC	Short Term Consultant
STD	Sexually Transmitted Diseases

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1. INTRODUCTION

Quality assurance (QA) in health laboratories incorporates all the factors that may influence the generation of reliable results. It comprises two key components. Internal quality control (IQC) includes appropriate measures taken during day-to-day activities to control all possible variables that can influence the outcome of laboratory results. This is a continuous process that operated concurrently with analysis. External quality assessment scheme (EQAS) is the other component. This component is necessary to ensure comparability of results among laboratories. This component is carried out retrospectively and is conducted by an independent agency.

WHO has made considerable efforts during the 1990s to ensure the quality of results produced by laboratories through the application of quality assurance practices. These efforts have included advocacy, capacity building and technical support. The technical discussions at the 49th session of the WHO Regional Committee for South-East Asia focused on quality assurance in laboratory practices. All Member Countries recognized that quality assurance is an important element in the provision of quality patient care and public health services, and endorsed a resolution on the need to improve the quality in health laboratories.

There has recently been a phenomenal increase in the number of health laboratories in the countries of the Region. Awareness about the need for quality services has also been increasing among health care providers.

The Regional Office has provided technical support and assisted in the organization of group educational activities in all countries of the Region. Good laboratory practices have been emphasized. Guidelines on QA for use in peripheral and intermediate laboratories have been published, and a six monthly bulletin on quality assurance is widely disseminated.

Though all Member Countries are making efforts to implement QA practices in health laboratories, their achievements have not been uniform.

Only one country – Thailand has a well running EQAS of microbiology under a national policy of EQAS with well functioning accreditation system of laboratories. A national policy for QA has been drafted in Indonesia and Myanmar. In India, there is no national policy for EQAS as yet, but a programme of networking of laboratories for surveillance of communicable diseases drawn up with the help of WHO has been submitted to the Government of India for implementation. It includes provision of QA as an ongoing activity involving all laboratories in India.

Though India, Indonesia, Myanmar and Sri Lanka have developed relatively good mechanisms for the implementation of QA, provision of EQAS remains largely voluntary. A national policy for QA of laboratories needs to be drawn up and executed in the times to come. Steps have been initiated for accrediting laboratories. Bangladesh, Bhutan, DPR Korea, Maldives and Nepal are in the process of strengthening their infrastructure and standardizing their methodologies.

WHO continues to provide technical support to countries to strengthen IQC and its integration into health laboratories at various levels of the health care system. The Regional Office is also

encouraging the participation of a greater number of laboratories in EQASs, in order to continue to improve the quality of care.

In addition to quality assurance programmes in public health laboratories, Bangladesh, India, Indonesia, Myanmar, Sri Lanka and Thailand are participating in quality assurance programmes in certain subject-specific programmes viz; poliomyelitis laboratories, HIV laboratories, blood banks, and tuberculosis laboratories.

2. SUBJECT- SPECIFIC LABORATORY NETWORKS

2.1 Polio Eradication Programme

Network of polio laboratories in SEAR

With the help of WHO, laboratories in the Region are carrying out polio virus isolation from cases of AFP and also from environment. With impending polio eradication, it is envisaged that these laboratories will take up other national programmes such as measles and dengue control programme.

Sixteen laboratories in SEAR countries constitute the network of polio laboratories. Of these, five serve as reference laboratories. EQASs are currently in operation. The coded samples prepared for the global network of laboratories by Rijksinstituut Voor Volksgezondheid en Milieu (RIVM), Netherlands are distributed.

These laboratories are: IPH in Bangladesh; In India the nine laboratories are: BJ Medical College, Ahmedabad; Sanjay Gandhi Post-graduate Institute, Lucknow; Serologists to Government of India, Kolkatta; National Institute of Virology, Pune; Pasteur Institute of India, Coonoor; King Institute of Preventive Medicine, Chennai; National Institute of Communicable Diseases, Delhi;

Entero-virus Research Centre, Mumbai and Central Research Institute, Kasauli. In Indonesia, Provincial Laboratory, Surabaya; in Myanmar, National Health Laboratory, Yangon; in Sri Lanka, Medical Research Institute, Colombo and National Institute of Health in Bangkok. These laboratories take part in IEQAS conducted by the Netherlands laboratory.

2.2 AIDS Control Programme

Countries of the Region have opened HIV surveillance centres. The quality assurance programmes of blood banks have been linked with AIDS control programmes in most of the countries.

Realizing the need for external quality assessment programme for HIV testing laboratories including blood banks in order to maintain the validity of HIV tests being carried out at various levels, the programme of EQAS in HIV testing is being instituted in all countries. In India, the National Institute of Biologicals (NIB) has been identified by National AIDS Control Organisation (NACO) as the apex institute for initiating an EQAS in HIV testing which will act as the national coordinator of networking. Eleven centers, viz. NICD, Delhi; AIIMS, New Delhi; Indian Institute of Immunohaematology, Mumbai; NICED, Calcutta; School of Tropical Medicine, Calcutta; Madras Medical College, Chennai; National AIDS Research Institute, Pune; Regional Institute of Medical Sciences, Imphal; Christian Medical College Vellore; National Institute of Mental Health and Neuro-Sciences, Bangalore; Dr MGR Medical College, Chennai have been identified for the implementation of the external quality assessment programmes in their areas. The same centres have been asked to conduct EQAS in transfusion transmitted infectious agents in blood banks for HIV, HBsAg, and HCV by NACO.

Similar programmes have been started in other countries of the region viz; Institute of Public Health in Dhaka, Bangladesh; National Public Health Laboratory in Kathmandu, Nepal; Provincial Laboratory, Surabaya, Indonesia; National Health Laboratory, Yangon, Myanmar; Medical Research Institute, Colombo, Sri Lanka, and National Institute of Health, Bangkok, Thailand.

With the help of WHO, selected laboratories in the countries of the Region are regularly participating in IEQAS in HIV serology conducted by Australia and CPHL, London.

2.3 Tuberculosis

With the upsurge in multidrug resistant tuberculosis in the countries of the world, especially in association with AIDS, WHO is conducting an international IEQAS for MDR tuberculosis.

There is a network of five laboratories in India carrying out surveillance of drug resistant tubercle bacilli in selected districts. These laboratories are Tuberculosis Research Centre, Chennai; National Tuberculosis Institute, Bangalore; Lala Ram Swarup TB Hospital, New Delhi; TB Centre, New Delhi and Maharashtra Government Institute of Medical Science, Wardha.

In other countries, the participating laboratories are: Centre Biomedis, Jakarta and Provincial laboratory, Surabaya in Indonesia; NHL, Yangon in Myanmar; MRI, Colombo in Sri Lanka; NIH Bangkok in Thailand; Centre for Epidemic Prevention, Pyongyang in DPRK, and NPHL, Kathmandu in Nepal.

3. CURRENT SITUATION OF QUALITY ASSURANCE IN CLINICAL MICROBIOLOGY IN THE COUNTRIES

The South-East Asia Region has 11 countries, of which India and Indonesia are very large by population and surface area. Medium-sized countries are Thailand, Myanmar, DPR Korea and Bangladesh; while Sri Lanka, Maldives, Bhutan, Nepal are small. Provision of health care services also differs, but is fairly sufficient in most of the countries. Similarly, although health laboratories exist in all countries, quality assurance also differs in most countries. The status of quality assurance in the Member Countries of South-East Asia Region is given in Annex 1.

WHO consultants visited countries of the Region in the last eighteen months to assess the current status of quality assurance in their health laboratory services to identify the major lacunae in effective implementation of internal quality control and external quality assessment schemes. The current situation in the countries presented here is based on these reports.

In spite of continuous endeavours on the part of WHO for implementation of QA programmes in the countries of the Region for more than a decade, WHO's concern is that in most of the countries, the implementation was not as complete as it should have been. Even IQC has not been practised regularly in many laboratories at the intermediate and peripheral levels.

Only one country – Thailand has a well running EQAS of microbiology under a national policy of EQAS with well functioning accreditation system of laboratories. National policy for QA has been drafted in Indonesia and Myanmar. In India, there is no national policy for EQAS as yet. However, provision of QA as an ongoing activity involving all laboratories in India is essential. Accreditation of laboratories on voluntary demand has been started in India.

3.1 Administrative Mechanism

In small countries like Bhutan, Maldives, Nepal and Sri Lanka, the responsibility for health care including laboratory services lies with the central ministry of health. Excepting Bhutan, other countries in this group also have private medical care, which does not come under the purview of the Government.

Among the medium sized countries, in DPR Korea, government authority is absolute and there are no private laboratories in the country. In Myanmar, though government authority is absolute, some private laboratories have come up in Yangon and Mandalay. As and when national policy for QA and accreditation of health laboratories is implemented, it will be mandatory for private laboratories.

In Bangladesh, most of the laboratories are under the control of the provincial and central governments. The private laboratories are absolutely autonomous and as and when national policy for QA and accreditation of health laboratories is implemented, it should be mandatory for private laboratories.

3.2 National Policy for Quality Assurance of Diagnostic Laboratories

The only countries with a national policy for quality assurance are Indonesia and Thailand; of these, Indonesia has just started, but Thailand has been practising it for more than 20 years. In India, a national policy is on the anvil, but it will take some time for it to be implemented. In other countries, there is no sign of planning such a policy.

3.3 National Policy on Accreditation of Diagnostic Laboratories

India and Thailand have introduced accreditation of laboratories. In Thailand it has been going on for several years.

In India, it has just been started on a voluntary basis and largely, private laboratories are coming forward for accreditation. Once a national policy on networking of laboratories is implemented, accreditation of laboratories will become mandatory.

In Indonesia, accreditation policy is in the planning stage, but is likely to be implemented very soon.

None of the other countries viz; Bhutan, Bangladesh, DPR Korea, Maldives, Myanmar, Nepal and Sri Lanka have as yet started planning for accreditation of laboratories.

3.4 Networking of Diagnostic Laboratories

Only in Indonesia and Thailand laboratories in the public sector network. In India, networking of laboratories for surveillance of communicable diseases is in the planning stage.

4. COUNTRY-WISE SITUATION OF LABORATORIES IN SEA REGION

The country-wise situation of laboratories in the South-East Asia Region is given in detail in Annex 2.

4.1 Bangladesh

Health laboratory services structure consists of public sector laboratories under the various ministries, autonomous medical university (Bangabandhu Sheikh Mujib Medical University), semi-government hospital laboratories, nongovernmental organizations (e.g. BIRDEM) and private laboratories.

In the public sector, there is a central laboratory at IPH in Regional laboratories medical college (13), district level laboratories (64) and the most peripheral laboratories are at the Thana Complex (490).

In the Institute of Public Health (IPH) Dhaka, there are microbiology, polio, epidemiology, food and water testing, drug testing, IVF section including blood bag unit, reagent production, antisera production, quality control unit and vaccine laboratories.

In the medical college laboratories, all branches of laboratory medicine are in existence. In the district level laboratories, mainly the microscopy of samples, routine clinical pathology and a few clinical chemistry investigations are done. No culture of samples for isolation of pathogens is done. At Thana complex, laboratory minimal microscopy and clinical pathology is being done. Networking between laboratories for referral of samples, training, support and supervisory visits is not in place.

An International Centre for Diarrhoeal Diseases Research – ICDDR-B is functioning in Dhaka since 1970s. It acts as a reference centre for diarrhoeal pathogens and coordinates with the Government of Bangladesh in investigations on diarrhoeal diseases. The centre is very well-equipped and takes part in IEQAS for enteric pathogens.

There are a large number of laboratories in private sector. Exact numbers are not known. However, it was estimated to be around 2 000. In Dhaka alone, there may be more than 400 laboratories.

A reference centre for safe blood transfusion has been established at Dhaka Medical College with the help of UNDP. The reference centre will provide referral services for 97 blood banks in

the country. Tests for blood-borne infections i.e, HIV, HBsAg, HCV, malaria and syphilis are being conducted. It will also conduct EQAS for blood serology and serology of transfusion-borne infections.

IQC is not being followed in the public health laboratories. NEQAS in clinical microbiology has not yet started. None of the public sector laboratory is participating in IEQAS in microbiology. There is neither a national policy for laboratories nor a scheme for accreditation of laboratories.

The microbiology laboratory of IPH, Dhaka can take up the responsibility of organizing laboratory for NEQAS in clinical microbiology. In the initial phase, NEQAS in microscopy to be introduced followed by culture and antimicrobial susceptibility test samples. Later, some selected district level laboratories may be chosen to undertake NEQAS in microscopy for thana-level laboratories. When the scheme is fully established, private laboratories are also to be included in the scheme. The NEQAS organizing laboratory shall participate in International External Quality Assessment.

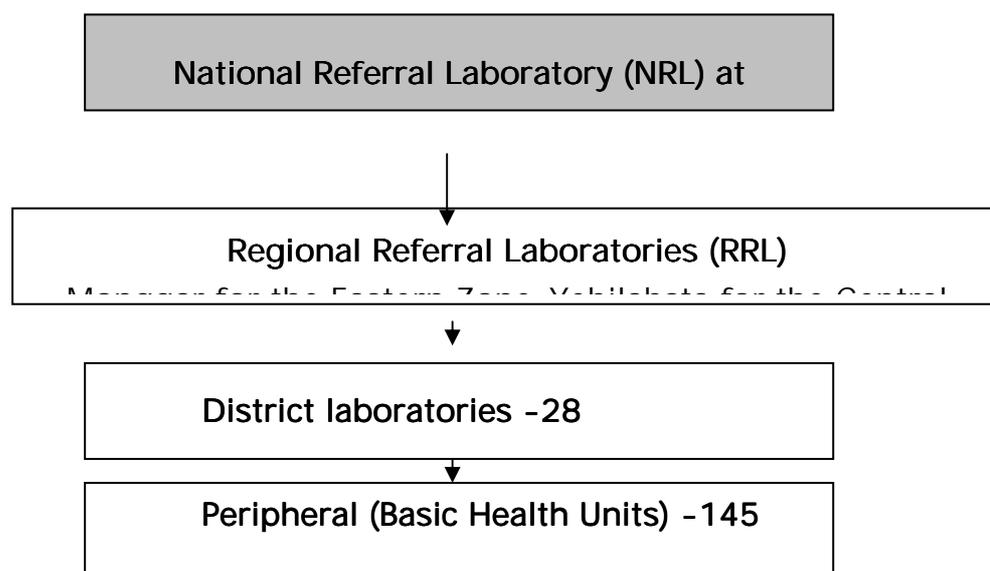
A WHO consultant visited Bangladesh in September 2001 and conducted a orientation course for key trainers in quality assurance. The participants were senior microbiologists from IPH and medical colleges of Bangladesh.

A national policy for Quality assurance and accreditation of laboratories needs to be enunciated and implemented.

4.2 Bhutan

Bhutan has a network of health laboratories at the national, regional and district levels. The administrative authority is the Ministry of Health of Bhutan. The apex of the structure is represented by the National Referral Laboratory (NRL) at Thimphu. Two Regional Referral Laboratories (RRL) are in operation; one at Monggar for the Eastern Zone and another at Yebilabtsa for the Central Zone. In addition, there are twenty district laboratories and eight other hospital laboratories (DHL/OHL).

National guidelines exist for the networking of laboratories with the main aim of ensuring effective supervision. The national referral laboratory supervises and supports the work of the regional referral laboratory which in turn supervises and supports the work of district and sub-district hospital laboratories. These district and sub-district hospital laboratories supervise and support the work of Basic Health Units (BHU).



There is an EQAS for AFB smear microscopy in operation since 1999. NEQAS for other microscopy parameters and cultures and antibiotic sensitivity have not been started.

A WHO consultant had conducted a workshop for carrying out EQAS in clinical microbiology in 1993 and another one in September 2000 to sensitize technical staff for restarting EQAS in clinical microbiology.

Previously, the National Referral Laboratory (NRL) at Thimphu was taking part in IEQAS conducted by RCPA (Australia). It has been stopped in 1999 due to problems in postage regulations and financial difficulties.

A national policy for quality assurance and accreditation of laboratories needs to be enunciated and implemented.

4.3 DPR Korea

DPR Korea has well-structured government health laboratory services. There are two streams of such laboratories. The stream of public health laboratories function as laboratories in the Centres for Prevention of Epidemics. The other stream of laboratories are those attached to hospitals and in universities.

	Type of Laboratories	
	Anti-epidemic	University/Hospital
Central	1	6
Provincial	12	36
Country	213	213

I. Stream of laboratories in the prevention of epidemics

- Laboratory in the Centre for Prevention of Epidemics – One central laboratory
- Laboratories in Provincial Centres of Prevention of Epidemics - 22 District level
- Laboratories in County Centres of Prevention of Epidemics - 230 Peripheral level

II. Stream of University Hospitals

- University/Hospital at CentralPyongyang University

III. Regional Hospitals - 5

IV. Provincial hospitals at district level - 36

V. County hospitals at Peripheral level - 213

Quality assurance in the laboratories is non-existent. There are no private laboratories.

Through its emergency action programme, WHO has been endeavouring for the past several years in improving the health laboratories and has provided several consultants to advise on strengthening of laboratories. Considerable amount of equipment and reagents were supplied to the stream of laboratories in the prevention of epidemics.

A WHO consultant visited DPR Korea in March 2000 and had held a workshop for initiation of QA programmes in the country. On another visit in July 2001, QA was still not in operation largely due to paucity of resources. A re-orientation course for key trainers was carried out to sensitize the nationals.

Since all the laboratories are under the administrative control of the ministry of health, it is expected that further steps for enunciation and implementation of national policy of quality assurance and accreditation of laboratories will be taken up as top priority.

4.4 India

In India, there is no national policy for EQAS as yet, but a programme of networking of laboratories for surveillance of communicable diseases has been drawn up with the help of WHO and has been submitted to Government of India. It includes provision of QA as an ongoing activity involving all laboratories in India. Accreditation of laboratories on voluntary demand has been started, but these are mainly private laboratories. It is hoped that the national policy for QA, when initiated and implemented, will encompass accreditation of all the laboratories in the network.

On behalf of the Indian Association of Medical Microbiologists, the Department of Microbiology of Christian Medical College and Hospitals, Vellore, Tamil Nadu has been organizing an external quality assessment scheme (EQAS) in microbiology for laboratories in India. The participation is voluntary. A total of 52 laboratories are participating in this EQAS, some of which belong to the private sector.

On behalf of the Indian Association of Pathologists and Microbiologists, the Department of Pathology, Banaras Hindu University, Varanasi started EQAS in clinical pathology and biochemistry in 1990 and EQAS for microscopy in clinical microbiology was started in 1998.

4.5 Indonesia

The Directorate for Health Laboratories (Direktorat Laboratorium Kesehatan – Dit Lab Kes) is the supreme controlling authority in Indonesia. It controls the public health laboratories in the 26 provinces of Indonesia and is responsible for their functioning and carrying out activities for public health in the respective provinces. In coordination with the appropriate directorates in the Ministry of Health, it also controls the pathology laboratories in the Ministry of Health, Government hospitals, and peripheral health laboratories. With this mandate, it has been carrying out external quality assessment in various disciplines of laboratory medicine.

WHO has been closely associated with this activity since its inception. In 1989 a workshop was held in Yogyakarta for the initiation of EQAS in clinical microbiology. Under the WHO/UNDP project, another workshop was held in 1992 in EQAS for laboratory medicine, clinical chemistry and clinical microbiology.

The Yogyakarta BLK has been participating in IEQAS in clinical microbiology conducted by Belgium for the past 12 years. Since 1989 EQAS is also being carried out there.

The microscopy subscheme for acid-fast bacilli was started in 1994, along with microscopy for malaria and faecal parasites. The EQAS for clinical microbiology now covers 80 laboratories, while 1 750 laboratories for AFB, 1 500 for malaria and 1 500 for faecal ova are covered for microscopy.

NEQAS for immunology and serology is being conducted by BLK Surabaya since 1991 in which 160 laboratories are participating. It covers four parameters viz., VDRL, Widal, HBsAg, anti HIV. Networking has been started and in 2000 the

responsibility of EQAS in AFB microscopy has been given to provincial laboratories.

Considering the EQAS in clinical microbiology, the performance of most laboratories is variable for isolation and identification of cultures, but is consistently good for antibiotic sensitivity testing.

WHO consultant conducted an orientation course for key trainers for expansion of QA network in Indonesia in November 2000. He also submitted an action plan for expansion of the quality assurance network. Directorate of Health Laboratories is the national authority that deals with health laboratories. Central laboratory for EQAS is located in BLK Yogyakarta. Indonesia has 26 provincial laboratories (Class A 5 and Class B 21), and 329 District Laboratories (Class B,C,D Hospitals).

4.6 Maldives

There are twenty three (23) health laboratories in the Maldives. Of these, fourteen are situated in the island of Male' and nine outside. Of the fourteen laboratories in Male', there are three large laboratories, namely, the Indira Gandhi Memorial Hospital (IGMH) laboratory, which is the main laboratory in the country concerned with patient care, the Public Health Laboratory (PHL), dealing with food, water and sanitation aspects and the "ADK" laboratory, a large private laboratory. Additionally, there are three medium-sized and eight small laboratories.

The hospitals and laboratories of the public sector are administered by the Ministry of Health. The Indira Gandhi Memorial Hospital, the thalassemia centre and the regional hospitals are directly administered by the Ministry of Health, while the public

health laboratory is administered by the Public Health Department. The private sector laboratories are independent organizations.

Outside Male', the laboratory service consists of five regional laboratories and four smaller laboratories (atoll hospital laboratories). All laboratories apart from IGMH and the public health laboratory are manned by medical laboratory technicians (MLT).

Apart from the staff of IGMH and PHL, the laboratory staff in the other establishments have very little knowledge of the concept of quality assurance. The ADK hospital laboratory, the private medical laboratory is well equipped and the staff is aware of the concept of quality assurance.

There is no clear national laboratory policy, or quality assurance policy in place at present and no system of laboratory accreditation exists. There is also no state control over eight laboratories in the private sector. At district level there are 11 laboratories and in addition, regional hospitals have their own laboratory support services.

Regional hospitals

- (1) Addu regional hospital laboratory
- (2) Kulhudhuffushi regional hospital laboratory
- (3) Ugoogaaru regional hospital laboratory
- (4) Mulee regional hospital laboratory
- (5) Thnadhoo regional hospital laboratory
- (6) Eydhafulah atoll hospital laboratory
- (7) Fuahmulah atoll hospital laboratory
- (8) Naifaru atoll hospital laboratory
- (9) Laamu atoll hospital laboratory

4.7 Myanmar

Administratively, the country is divided into 17 states and divisions with 52 districts, 324 townships (rural and urban). The population of the country is 50 million with more than 75 % population residing in the rural areas.

The laboratory services provide the essential backbone support for the prevention, control and treatment of diseases and other related health care programmes being carried out in Myanmar in the context of the National Health Plan.

In general, laboratory facilities in Myanmar are graded into three types A, B and C with the National Health Laboratory as the Central Reference Laboratory. Type A laboratories serve the states and division level, Type B at the district level and type C at the township level.

There are 38 type A laboratories attached to teaching hospitals, general hospitals, and specialist hospitals, 33 type B laboratories attached to district hospitals and 281 township hospitals that are served by type C laboratories.

Type A laboratories are generally headed by consultant pathologists who look after microbiology, clinical chemistry, haematology, and blood banking. They serve hospitals with a bed strength of 200 and above.

Type B laboratories are headed by medical technologists. They carry out services in clinical chemistry, haematology, microbiology and blood banking. The hospitals served by type B laboratories have a bed strength of 100-150.

Type C laboratories carry out the tests classified under essential clinical chemistry, essential haematology, public health

microbiology and blood banking. The number of hospital beds served by these laboratories are generally 16 to 50.

In general, type A laboratories carry out 200-500 tests per day, type B laboratories, 50 to 200 test and type C laboratories 10-50 tests per day.

Level	Type of Labs
Central level	NHL Yangon
State level	38 (Grade A)
District level labs	33
Peripheral – Township	281

International training on quality assurance has been carried out from time to time in Myanmar. A WHO/DANIDA National Training Course on Quality Control in Clinical Microbiology was held from 6-17 January 1986 with 24 participants, microbiologists, pathologists and medical technologists from all over Myanmar.

A national workshop on introduction of Quality Standards and Appropriate Technology for Primary Health Care Laboratory Services, was held from 15-17 November 1990. WHO STC, 20 participants – laboratory personnel from peripheral, district and central labs and authorities from community health and communicable diseases control work participated.

A three day national workshop on the Introduction and Establishment of External Quality Assurance Network was conducted in Yangon from 13-15, November 1992. A workshop on Development of Laboratory Efficiency and Quality Assurance

Scheme was held from 11-13 May, 1998, and a training course for Key Trainers in Quality Assurance from 11-13 September 2000.

NEQAS in microbiology is conducted by NHL. It started in 1986 with 15 type A laboratories participating. In 1993, it was reorganized to include parasitology and mycology. Since 1996, there are 22 participating laboratories.

4.8 Nepal

Nepal has a network of 185 health laboratories in the Government sector that are scattered in various geographical regions of the country.

At the central level - the National Public Health Laboratory (NPHL) is located at the Department of Health Services premises, Teku, Kathmandu. There are six central level hospital (250-350 beds) laboratories in Kathmandu, the Bir Hospital, the Kanti Children Hospital in Patan, the maternity hospital, the National Tuberculosis Centre in Thimi and the Ayurvedic Hospital. There is one regional hospital (200 beds) laboratory in the Western Region in Pokhara and one sub-regional hospital laboratory in the central region in Birgunj. In addition, there are nine zonal, 64 district, 132 PHC and 24 health post laboratories.

Recently Guidelines on SOP in clinical chemistry, haematology, microbiology and blood banking have been printed. A quality assurance programme is being conducted by the National Public Health Laboratory (NPHL) with the help of the International Nepal Fellowship (INF). An external quality assessment scheme for various parameters is also in operation in which 54 laboratories participate.

Type of Laboratory	Number
Central Laboratory – National Public Health Laboratory (NPHL)	1
Central level hospital laboratories	6
Regional laboratories	2
District level	73 (9 zonal, 64 district)
Peripheral level	156
Private laboratories	Not available

4.9 Sri Lanka

There are three levels of curative care institutions administered by the Ministry of Health:

- (1) The central dispensaries, maternity homes, rural hospitals, peripheral units and district hospitals are primary health care institutions.
- (2) The base hospitals (n=33) and provincial hospitals (n=05) are secondary care institutions.
- (3) The teaching (n=15) and special hospitals (5) are tertiary care institutions.

Type of Laboratory	Number
Central lab: MRI Colombo	1
Central Level: Teaching and special hospitals	20

District laboratories	38
Peripheral laboratories	523

A WHO STC visited in 1997 and conducted a workshop on quality assurance in microbiology.

Medical Research Institute, Colombo, Sri Lanka (MRI) initiated a national external quality assessment scheme (NEQAS) in 1997 in bacteriology for laboratories in government institutions and universities. Fourteen laboratories agreed to participate during 1997 and 18 in 1998. Three cycles of NEQAS were completed in 1997. In each cycle, two bacterial isolates were sent for identification and determination of antimicrobial susceptibility testing (AST). Now 30 government hospital laboratories participate in NEQAS.

The Central Laboratory STD/HIV runs NEQAS in VDRL serology since 1998 in which 19 laboratories participate. It has started a reverse proficiency testing in STD microscopy since June 2000 in which 12 STD laboratories send all their reported positive smears and 5% of the negatives to the Central Laboratory for cross checking.

4.10 Thailand

The Bureau of Laboratory Quality Standards - BLQS

As one of the bodies of the Department of Medical Sciences (DMSc), the Bureau of Laboratory Quality Standards (BLQS) is responsible for laboratory quality assurance in a range of medical science areas aiming to control the quality of test results, to promote the implementation of reference laboratories and to

develop the operation quality of consumer protection and clinical laboratories.

***Accreditation of laboratories according to ISO/IEC 17025
International Standards***

This programme is offered with different purposes. One is to entitle the accredited laboratories to operate laboratory services for health product registration at Thai-FDA, they can also undertake services to FDA in product assessment for consumer protection surveillance. The BLQS also accredits clinical laboratories of the private sector and those who are responsible for health check of people working abroad. Examples are diagnostic laboratories and food, drug, cosmetics, condom and clinical laboratories.

EQAS

This service is provided to laboratories of both public and private sectors throughout the country, especially those of clinical laboratories covering the areas of clinical chemistry, clinical microscopy, clinical microbiology, haematology, clinical immunology, and blood banking. Altogether, there are now 600 health stations joining this programme, which is 20 years old.

There are three levels of hospitals:

- (1) 12 regional – Many provinces come together
- (2) 73 provincial – for each province

- (3) Community – for each community
- (4) Health centre - > 15 000. Medical doctor may not be there
- (5) 141 private laboratories: also take part in NEQAS.

The regional hospital serves as a referral centre, and provides training and advice for staff in smaller hospitals. All laboratories/hospitals have to be registered.

Since participation in EQAS is free, there seems to be no constraint to participation. The registration fee for laboratories has also been kept minimal to encourage all laboratories to participate, since participation in EQAS is voluntary.

There exists a fairly advanced quality assurance system in practice in medical laboratories in Thailand – much more than is in existence in the other countries.

5. INFRASTRUCTURE AS RELATED TO DIFFERENT LEVELS OF LABORATORIES

The details of infrastructure available at different levels of laboratories are provided in Table 1. Broadly, the human resource, equipment, quality control measures, documentation, technical expertise and infrastructure available in the central laboratories and medical colleges laboratories conform to international requirements, rules and regulations. Infrastructure is weak at the peripheral laboratories. Adequate human resource is available only in some peripheral laboratories and their continuous training and upgradation of skills are rarely undertaken. These laboratories document most of their activities and results, but are deficient in internal quality control, availability and maintenance of equipment as well as quality reagents, kits, antisera and other chemicals.

6. PROGRESS MADE DURING 1996-2001

WHO has been endeavouring to promote the practice of quality assurance in the countries of the Region since the 1980s. Consultations provided and workshops conducted from time to time did sensitize some countries in the practice of quality assurance with emphasis on IQC and the need for starting EQAS programmes.

Table 1
Status of IQC parameters-
STATUS OF QUALITY ASSURANCE ACTIVITIES IN SEAR COUNTRIES

Parameter for quality assurance of diagnostic labs	Bhutan	Bangladesh	DPR Korea	Indonesia	India
1 Status of IQC parameters					
Central level					
Adequacy of staff					
Professional	Yes	Yes	Yes	Yes	Yes
Supportive	Yes	Yes	Yes	Yes	Yes
Training of staff	Yes	Yes	Yes	Yes	Yes
Availability and use of SOP	Yes/WHO	Yes/WHO	Yes /WHO	Yes/Own	Yes/WHO
Equipment maintenance	Yes	Yes	Yes	Yes	Yes
Documentation	Good	Good	Good	Good	Good
Internal quality assessment	Yes	Yes	No	Yes	Yes
Internal audits	Rarely	Rarely	No	Yes	Rarely
Medical College labs/Regional/Provincial					
Adequacy of staff					
Professional	Yes	Yes	Yes	Yes	Yes
Supportive	Yes	Yes	Yes	Yes	Yes
Training of staff	Yes	Yes	Yes	Yes	Yes
Availability and use of SOP	Yes/WHO	Yes/WHO	Yes/WHO	Yes /Own	Yes /WHO
Equipment maintenance	Yes	Yes	Yes	Yes	Yes
Documentation	Good	Good	Good	Good	Good
Internal quality assessment	Yes	Yes	No	Yes	Yes
Internal audits	Rarely	Rarely	No	Yes	Rarely
District level					
Adequacy of staff					
Professional	Yes	Yes	Yes	Yes	Yes
Supportive	Yes	Yes	Yes	Yes	Yes
Training of staff	Yes	Yes	Yes	Yes	Yes
Availability and use of SOP	No	Yes/WHO	No	Yes/Own	Yes /WHO
Equipment maintenance	Yes	Yes	Rarely	Yes	Yes
Documentation	Good	Good	Good	Good	Good
Internal quality assessment	No	No	No	Yes	Yes
Internal audits	Rarely	Rarely	No	Rarely	Rarely
Peripheral level					

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Adequacy of staff	No	No	No	No	Yes
Professional	Yes	Yes	Yes	Yes	Yes
Supportive	Rare	Rare	Rarely	Yes	Yes
Training of staff	No	No	No	Yes /Own	Yes /WHO
Availability and use of SOP	Rarely	Rarely	Rarely	Yes	Yes
Equipment maintenance	Good	Good	Good	Good	Good
Documentation	No	Rarely	No	No	Yes
Internal Quality assessment	Rarely	Rarely	No	Rarely	Rarely
Internal audits					

QA was started on a small scale in countries like Myanmar, Indonesia, Nepal and Sri Lanka in early 1990s. Only Thailand has had a fairly advanced quality assurance system in practice for the last twenty years.

Since 1996, some countries have started EQAS in microbiology. In India, the largest country in the Region, it started as a voluntary participation programme in 1997 and the participation is increasing slowly.

At the behest of Indian Association of Medical Microbiologists, the Christian Medical College, Vellore started EQAS in clinical microbiology. To begin with, 22 laboratories signed up but by 2001, the number has risen to 52. It may be mentioned that participation is mainly voluntary and a few private laboratories are also participating.

Another EQAS provider, the Department of Pathology, BHU, Varanasi, started EQAS for microscopy in clinical microbiology in 1998. This scheme is also purely voluntary.

A programme of networking of laboratories for surveillance of communicable diseases drawn up with the help of WHO has been submitted to the Government of India. It includes provision of QA as an ongoing activity involving all laboratories in India.

Accreditation of clinical laboratories has been started by the Department of Biotechnology, Government of India in 1999. This is largely voluntary and mostly private laboratories are coming forward for accreditation. In the last two years, 22 private laboratories have been accredited. It is hoped that the national policy for QA, when initiated and implemented, will encompass accreditation of all the laboratories in the network.

In Indonesia, though the EQAS in clinical microbiology is continuing since 1989, it was being provided by one provincial laboratory – BLK Yogyakarta. It was decided to increase the ambit of the QA programme by networking, so that all laboratories in the country could be involved in the practice of QA on an ongoing basis. A consultant visited Indonesia in 1999 and prepared a plan for expansion of QA in clinical microbiology as a network, which is now being implemented.

In Myanmar, NEQAS in microbiology is conducted by NHL since 1986 and since 1996, the number of participating laboratories has increased.

In Nepal, Quality Assurance Programme has been started since 1996 and is conducted by the National Public Health Laboratory (NPHL) as shown in Table 2

Table 2
Organization of EQAS
STATUS OF QUALITY ASSURANCE ACTIVITIES IN SEAR COUNTRIES

	Parameter for quality assurance of diagnostic labs	Bhutan	Bangladesh	DPR Korea	Indonesia	India	Maldives	Myanmar	Nepal	Sri Lanka	Thailand
1	National policy and guidelines for quality assurance of diagnostic labs	No	No	Yes	Yes	In Planning CMC	No	In planning-	No	No	Yes
2	Organizing Unit NEQAS Analytes	NRL- TGH AFB Microscopy	-No	No	BLK Yogyakarta	CMC Vellore Voluntary	No	NHL Yangon Clinical microbiol	NPHL Clinical microbiol	MRI Clinical microbiol	BLQS/DMS c
3	Number of participating units	?	No	No	+	52	No	15 in 1980 22 in 1996	54-	14 in 1997 30 in 2001	N.A.
4	Feedback mechanism	-?	No	No	By post	By post	No	Post-	Post-	Post	Post
5	Networking of EQAS	No	No-	No	In planning	No	No-	No-	-No	No	No
6	Participation in IEQAS	Not since 1999	No	No-	Yes Belgium	Yes Belgium	No	No	No	Yes since 1988	Yes Australia
	Accreditation	-	-	-	-	-					
	National policy	No	No	No	Yes	Yes	No	No	No	No	Yes
	Process	-	-	-	DIT LabKes	NABL	-	-	-	-	BLQS

In Sri Lanka, MRI initiated a national external quality assessment scheme (NEQAS) in 1997 in bacteriology for laboratories in government institutions and universities. Fourteen laboratories agreed to participate during 1997 and 18 in 1998. Now 30 government hospital laboratories participate.

For specific programmes

(a) STD/HIV Central Laboratory runs NEQAS in VDRL serology since 1998 in which 19 laboratories participate and, (b) Central Laboratory STD/HIV has started a reverse proficiency testing in STD microscopy since June 2000 in which 12 STD laboratories send all their reported positive smears and 5% of the negatives to the central laboratory for cross checking.

It will be seen that Bangladesh, Bhutan, DPR Korea and Maldives need to start EQAS in clinical microbiology. Other countries such as India, Myanmar, Nepal and Sri Lanka should adopt networking of all their laboratories for EQAS purposes to involve all the laboratories in their countries.

7. CONSTRAINTS IN ENSURING STANDARDS IN HEALTH LABORATORIES

Several constraints were identified in ensuring quality standards in health laboratories. These include:

- (1) Lack of national health policy on laboratory services;
- (2) Absence of mandatory national quality assurance programme;
- (3) Inadequate funding;

- (4) Shortage of qualified laboratory staff in most countries of the Region;
- (5) Deficient education and training of staff in QA in all its aspects;
- (6) Absence of continuing medical education (CME) programmes for QA in most countries;
- (7) Irregular supply of equipment and materials (media, chemicals, reagents, antisera and disposables);
- (8) No set norms in health laboratory establishments;
- (9) Low priority to laboratory services in hospital set-up;
- (10) Limited laboratory space for microbiology and inadequate numbers of technicians in most laboratories;
- (11) Non-availability of authenticated standard operating procedure manuals in clinical microbiology and biosafety;
- (12) NEQAS in clinical microbiology not started in many countries. IQC not being followed;
- (13) Failure of laboratories to keep pace with clinical specialization;
- (14) Mutual distrust between clinician and pathologist;
- (15) Absence of regular discussions and meetings between laboratory officials and clinician/public health physicians;
- (16) Lack of modern equipment for improving conduct of quality assurance;
- (17) Unsatisfactory maintenance of equipment;
- (18) Erratic supply of electricity and water in most countries;

- (19) Non-availability of quality reagents and kits, and
- (20) Absence of networking between laboratories for referral of samples, training, support and supervisory visits.

8. ACTION PLAN FOR STRENGTHENING OF QUALITY ASSURANCE

Strengthening of quality assurance in health laboratories in SEAR countries will require improvements in internal quality control measures along with a mechanism for assessment of quality. The former is a continuous process whereas the latter, being a tool to assess the former requires regular, but periodic, participation.

8.1 Internal quality controls

Every laboratory must strive to ensure implementation of internal quality control measures. Achieving quality should be the objective and responsibility of all the staff members of the laboratory, irrespective of their status in the hierarchy. Top management must play the role of catalyst, supervisor and motivator in ensuring quality of the results of the laboratory and strive for continuous quality improvement. A review of the current status should be made, deficiencies identified and appropriate steps initiated through an action plan to put a reliable and sustainable quality system in place in the laboratory.

The internal quality control measures encompass all aspects of health laboratories and can be grouped under various important key elements, each being composed of many sub elements:

Management

- Policy and commitment for quality

- Planning
- Allocation of appropriate resources
- Provision of suitable infrastructure, material, manpower
- Networking between laboratories
- Biosafety
- Errors management
- Participation in EQAS, accreditation

Standards

- National
- International

Training

- Induction training
- In-service training to upgrade the skills in specific areas

Documentation

- Quality Manual
- SOP
- Worksheets
- Records

Monitoring, evaluation

- Use of statistical process tools
- Internal assessment
- Internal audit

8.2 Assessment of quality

The retrospective and periodic assessment of quality can be undertaken by an independent external agency or internally by the designated staff on behalf of the laboratory management. Quality can be thus assessed by an on-site inspection by trained professionals (viz. auditors) or by processing of the material sent by a designated institution. Accordingly, assessment of quality can be man-driven (audit: internal or external) or material driven (quality assessment: internal or external).

The main objective of external quality assessment (EQA) which is done in planned and a schematic way is to establish inter-laboratory comparability. This will influence the reliability of future testing. In contrast, the main objective of internal quality control is to ensure day-to-day consistency. Hence, both internal quality control (IQC) and quality assessment are complementary in ensuring the reliability of procedures, their results and finally the quality of the product.

External Quality Assessment Scheme

The assessment of quality in a schematic way through an external agency using material of known but undisclosed results is called external quality assessment scheme (EQAS). This is considered a powerful tool that challenges the internal quality control measures being adopted by the laboratory. EQAS is a tool by which the entire testing process, including the quality of results generated by a particular laboratory is assessed.

External quality assessment scheme compares the performance of different testing sites and challenges other components of the quality assurance system (internal quality control). This assessment is achieved through processing of

specimens of undisclosed but known contents. It measures the accuracy of the results.

Objectives of external quality assessment scheme

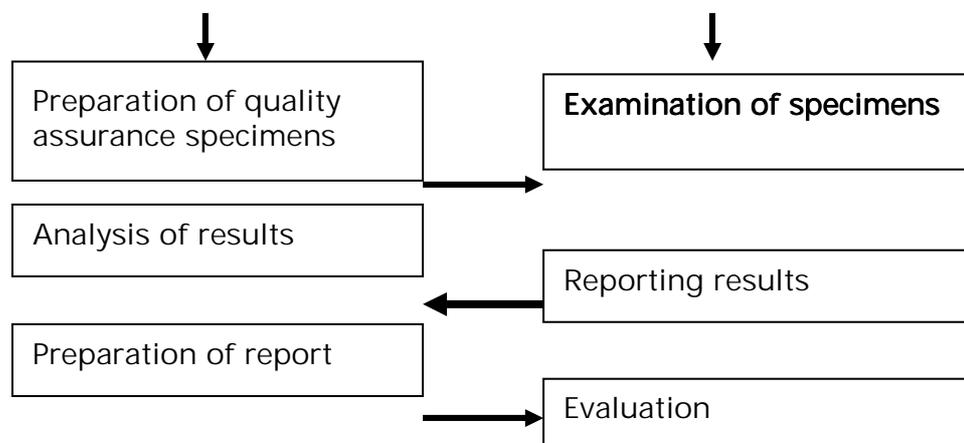
EQAS are organized to achieve the following objectives:

- (1) Monitoring laboratory performance and evaluation of quality control measures;
- (2) Establishing inter-laboratory comparability;
- (3) Influencing reliability of future testing;
- (4) Ensuring credibility of laboratory;
- (5) Stimulating performance improvements;
- (6) Promoting high standards of good laboratory practices;
- (7) Encouraging use of standard reagents/methodology and trained personnel;
- (8) Identifying common errors;
- (9) Providing mechanisms to remedy identified deficiencies;
- (10) Facilitating information exchange;
- (11) Supporting accreditation, and
- (12) Educating through exercises, reports and meetings.

Process of EQAS

EQAS requires a well-equipped, experienced laboratory at the intermediate or central level to act as the organizing laboratory and a fairly reasonable number of laboratories as the participating laboratories. The process of EQAS with important functions of organizing and participating laboratories has been shown in Fig





The external assessment of laboratories is beneficial in the following ways:

- (1) Helps laboratories in comparing their results with other laboratories;
- (2) Acts as an educational stimulus to laboratory staff;
- (3) Participation provides credibility to the laboratory;
- (4) Helps the health administrators and regulatory agencies to have an insight into the status of quality across the country, identifying the problems and devising methodology to overcome these.

The above-mentioned features should be incorporated by Member Countries in their plan of action for improving the quality of laboratories in SEAR countries.

Annex 1

STATUS OF QUALITY ASSURANCE ACTIVITIES IN SEAR COUNTRIES

	Parameter for quality assurance of diagnostic laboratories	BHU	BAN	DPR K	INO	IND	MAV	MMR	NEP	SRL	THA
1.	National policy and guidelines for quality assurance of diagnostic laboratories	-	-	-	-	-	-	-	-	-	+
2.	National policy on accreditation of diagnostic laboratories	-	-	-	-	+	-	-	-	-	+
3.	National regulatory authority assuring quality of diagnostic laboratories	-	-	+	+	+	-	-	-	-	+
4.	Networking of diagnostic laboratories	-	-	-	+	-	-	-	-	-	+
5.	National Regulatory Laboratory for diagnostic kits	-	-	-	-	-	-	-	-	-	+
6.	Availability of SOPs for IQC &	-	-	-	+@	+@	-	+@	-	-	+

	EQAS										
7.	Networking of laboratories for quality assurance	-	-	-	-	-	-	-	-	-	+
8.	Organization of NEQAS	-	-	-	+	+*	-	+	-	+*	+

* Mainly on voluntary basis by NEQAS providers and participating labs.

@ Available only in central laboratories

Annex 2

Number of Laboratories in public sector

STATUS OF QUALITY ASSURANCE ACTIVITIES IN SEAR COUNTRIES

	Parameter for quality assurance of diagnostic laboratories	BHU	BAN	DPRK	IND	INO	MAV	MMR	NEP	SRL	THA
1.	Number of laboratories in public sector										
	Central level	1	1	1	1	1	2	1	1	1	1
	Medical college laboratories/ Regional/ Provincial	13	2		180+ 31	26	9	38	6+2	20	12
	District level	64	28	12+ 36	535	329	11	33	73	38	73
	Peripheral level	490	145	213 + 213	CHC 2500 PHC 1900 0						
2.	Number of laboratories in private sector	2000	Nil	Nil	N.A	N.A			N.A	N.A	N.A

Laboratories in metropolitan cities	400					8	4		
Laboratories in Districts	N.A						N.A		
Laboratories in villages	N.A						N.A		

NA – Not Available

