Guidelines for Establishment of Accreditation of Health Laboratories

World Health Organization

Regional Office for South-East Asia
New Delhi

Guidelines

on

Establishment of Accreditation
of Health Laboratories

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Contents

Preface

Laboratory accreditation is recognized as an efficient tool for putting in place a quality system for achieving continuous improvement in laboratory services in a sustainable fashion. The laboratory accreditation system is important for the acceptance of test results nationally and internationally: accreditation is immensely beneficial in supporting an achievable and efficient health-care system. All medical services need reliable laboratory support for taking proper action, making decisions and formulating policies.

In many countries of South-East Asia (SEA) Region, laboratory accreditation, especially in the areas of medicine and health, is not as yet available or implemented. This document is intended to provide guidelines on the facilities and personnel needed, and examples of how to initiate establishment of an accreditation process in a system. Making a beginning with national standards and achieving an internationally acceptable accreditation system should be the goal.

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1

Accreditation and quality system

Accreditation of health laboratories is the process by which an independent and authorized agency accredits the quality system and competence of a laboratory on the basis of certain pre-defined standards. Accreditation 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.

The accreditation process requires:

- identification of an authoritative body
- adoption of standards, and
- institution of a mechanism of assessment of laboratories to certify their compliance with standards.

The benefits of accreditation are listed in the table below.

Benefits of a quality system/accreditation

- Facilitates the implementation and maintenance of an effective quality system
- Gives confidence to users in availing the services
- Gives confidence to the laboratory for the results generated
- Provides national/international recognition of technical competence
- Helps in defending laboratories while dealing with legal disputes pertaining to laboratory results
- Reduces the operating costs of the laboratories by getting results right the first time and every time
- Helps private sector laboratories to attract more business
- Helps in national and international acceptance of results
- Meets purchase or regulatory specifications
- Increases competitiveness and market share.

Establishment of an accreditation programme requires a national consensus on various issues, which are grouped under the following categories:

- Identification of standards that will be used in the country
- Establishment of an accreditation body with adequate resources, infrastructure and personnel
- Characterization of the concepts of the accreditation body
- Areas that will be covered by this scheme
- Identification of stakeholders: the government, private sector, regulatory agency, laboratory professionals and users
- Identification of customers and delineation of the relationship with them
- Setting up a process of accreditation and publicizing it widely.

In setting up an accreditation system in any country, it may not always be necessary initially for it to conform to an international standard. A step-wise approach is suggested, depending on the available resources. National standards conforming to the most important key elements of the international standards may be used in the early phase. The emphasis, however, should be on strengthening the quality system in laboratories and promoting quality improvement on a continual basis.

1.1 Quality system

A well-defined quality system is a must for ensuring quality. It is a part of overall quality management which aims at ensuring the consistency, reproducibility, traceability and reliability of the products or services.

A quality system is defined as the organizational structure and resources needed to implement quality requirements. The International Organization for Standardization (ISO) defines a quality system as the organizational structure, responsibilities, procedures and resources needed for implementing quality management.

A quality system has the following five key elements:

- Organizational management and structure
- Quality standards

- Documentation
- Training
- Assessment

Organizational management and structure

The overall responsibility for the design, implementation, maintenance and improvement in the quality system rests with the laboratory management. Quality is the responsibility of all staff members of the organization.

Quality standards

Quality standards are an integral part of the quality system. These aim at ensuring safety and consistency. They need to be followed to meet regulatory requirements as well as to monitor functioning of the laboratory.

Documentation

A document is a record of any information or instructions including policy statements, quality manuals, procedures, specifications, calibration tables, reports, job description, documents of external origin such as regulations, standards and examination procedures, etc. Documents may be stored either as hard copy or electronically.

Training

The quality system is only as good as the staff who actually works with it. No matter how good the quality system is on paper, if theory cannot be translated into practice, quality cannot be achieved. Training must also include an understanding of why quality is important. Training should be competency-based and must be followed by post-training support.

Assessment

The laboratory management shall develop and implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement within the system, the laboratory management shall take appropriate steps to address them. Error management shall be vigorously implemented.

Assessment of quality through audits (internal or external) and participation in external quality assessment schemes (EQAS) are other tools, the results of which should guide the management in further improving quality.

- Accreditation is a tool that recognizes the existence of a quality system in a laboratory.

- An accreditation system should be built on the strong foundation of a quality system.

- Countries that 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 (IQC), audit, validation, internal quality assessment and participation in EQAS are strengthened.

1.2 Status of accreditation in countries of South-East Asia Region[1]

Quality systems in and accreditation of laboratories in countries of the SEA Region are in varying phases of development. While India, Indonesia and Thailand have established accreditation systems, other countries are still in the planning phase. In Sri Lanka, a 10-year plan for granting accreditation has been developed by the Ministry of Science and Technology using ISO 15189.

India

The National Accreditation Board for Testing and Calibration Laboratories (NABL) was established by the Government of India in 1994 for accreditation testing, calibration and clinical laboratories. Initially, it followed the ISO Guide 58 and ISO 17025, and gradually moved to adopt ISO standards for clinical laboratories. NABL is a full member of the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and International

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[1] Based upon presentations made in the Intercountry Meeting on Establishment of Quality Systems and Accreditation in Health Laboratories held in Thailand from 9-13 October 2006 (SEA-HLM-393, WHO Regional Office for South-East Asia, New Delhi) 2006.

Laboratory Accreditation Cooperation (ILAC). Accreditation is offered on a voluntary basis. Till 2006, 74 medical laboratories have been accredited and 21 certificates have been issued for conforming to ISO 15189.

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

Indonesia

The National Accreditation Committee (KAN) is the accreditating agency in Indonesia. Till 2006, four laboratories in Jakarta, Surabaya, Bandung and Palembang had been accreditated. The Center for Health Laboratory develops national standards for health laboratories on Microbiology, Clinical Chemistry, Pathology and Immunology, and imparts technical training for laboratory staff of hospitals and public health units.

Thailand

The Bureau of Laboratory Quality and Standards (BLQS) is the designated authority in Thailand for providing accreditation according to ISO/International Electrotechnical Commission (IEC) 17025 for laboratories that test health products, and according to ISO 15189 for medical laboratories. The BLQS is a member of the APLAC and ILAC.

The BLQS has entered into a mutual recognition agreement (MRA) with other government organizations such as the Food and Drug Administration (FDA), Ministry of Public Health and National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture, to make use of the services of BLQS-accredited laboratories in evaluating the competence of laboratories. It provides accreditation to both government and private laboratories without discrimination.

A prerequisite for granting accreditation to an applicant laboratory in Thailand is satisfactory performance in at least one proficiency testing activity. The accreditation process normally followed by the accreditation body is the international standard ISO 17011. On-site assessment is an essential step, which is by the appointed assessment team. Non-conformity with ISO 15189, and the general and specific criteria of the BLQS are identified by the assessment team during the on-site assessment or surveillance visit. A summary of the assessment findings and details of any

non-conformity are recorded in the assessment report. This report is given to the assessed organization before the assessment team leaves. For new accreditation and extension of scope, a summary report is submitted to the Technical Subcommittee, which specifically considers each field of tests in detail and then submits their findings to the Laboratory Accreditation Committee which makes an accreditation decision.

Thailand has accelerated the accreditation system by implementing a project on national and international standards for medical laboratories throughout the country. The approach of this project is documented in the WHO publication *Quality standards in health laboratories, implementation in Thailand: a novel approach*, World Health Organization Regional Office for South-East Asia, 2005 (SEA-HLM-386).

1.3   International accreditation agencies

International Laboratory Accreditation Cooperation (ILAC)

The ILAC is the apex international authority on laboratory accreditation, with a membership consisting of accreditation bodies and affiliated organizations throughout the world. The ILAC arrangement builds upon existing or developing regional arrangements established around the world. The accreditation bodies participating in these regional arrangements are responsible for maintaining the necessary confidence in their respective areas.

Asia Pacific Laboratory Accreditation Cooperation (APLAC)

The APLAC groups accreditation bodies responsible for accrediting calibration, testing and inspection facilities in the Asia Pacific region. APLAC's principal objectives are to foster the development of competent laboratories and inspection bodies in participant countries, to harmonize accreditation practices within the region and with other regions, and to facilitate mutual recognition of accredited tests, measurements and inspection results through the APLAC multilateral MRA.

Mutual recognition arrangement

Till 2006, 55 laboratory accreditation bodies of the ILAC had signed the multi-lateral MRA (ILAC Arrangement) to promote acceptance of accredited test and calibration data. This facilitates the acceptance of testing and calibration results between countries when the results can be demonstrated

to come from accredited laboratories, and helps to reduce technical barriers to trade. Through the ILAC Arrangement, the foundation for realizing the ideal of having products "tested once and accepted everywhere" has been established.

Both the ILAC and APLAC have been established for the purpose of reducing duplication or replication of activities in laboratories and the final outcome would be to facilitate trading in the global market.

In the global trade system, the buyer would like to buy goods with the specified quality if it has been tested by an accreditated laboratory. In the globalization system, many buyers and sellers have not even seen each other and the accreditation system is a means for laboratories to accept the competency of other accredited laboratories and finally, acceptance of test reports.

In the APLAC, it has been agreed to have a separate MRA for medical laboratories. This is probably due to the fact that medical laboratories use a different international standard, ISO 15189, which is specially formulated for medical laboratories only, while all other types of laboratories – both calibration and testing – use ISO/IEC 17025.

2

Guiding principles for the establishment of accreditation

Broadly, there are three essential principles for establishing accreditation:

- Setting up an accreditation body
- Formulation or adoption of standards
- Implementation mechanism

2.1　Setting up an accreditation body

An international standard (ISO 17011) can be used as a guideline for setting up an accreditation body. The ISO17011 is published by the ISO and is entitled *General requirements for accreditation bodies accrediting conformity assessment bodies*. The full standard must be obtained legally from the ISO. This standard needs to be followed by accreditation bodies to get recognition from regional and international bodies.

The standard is composed of eight clauses; these are

(1) Scope
(2) Normative references
(3) Terms and conditions
(4) Accreditation body
(5) Management
(6) Human resources
(7) Accreditation process, and
(8) Responsibility of the accreditation body to the conformity assessment body.

The requirements of clauses 4–8 need to be followed by the accreditation body to conform to this standard.

A summary of these five clauses is given below.

Clause 4: Accreditation body

Clause 4 elaborates that the accreditation body shall have legal responsibility to ensure that its functions will be sustained and duplication of work avoided. However, there is no restriction that only a government entity can be the accreditation body; any private sector entity also can perform this function. In some countries, most of the accreditation bodies belong to the private sector and this may create competition in the accreditation services. The best situation would be for a country to have only one accreditation body to serve this activity to avoid confusion and duplication of work. This will also help in providing consistency in the accreditation system and lead to efficient utilization of resources.

This clause also describes the structure of the accreditation body in order to establish confidence in its accreditation. The structure is similar to any organization that has implemented a quality system such as a clear policy, manuals and procedures for all important activities, and a well-defined structure that describes the responsibilities of important personnel. It also emphasizes the process of accreditation and the competency of the personnel involved.

Impartiality is described in detail in this clause to show how this is to be implemented. The implementation of policy and procedures where no single party dominates in any process, especially decision-making for accreditation, is the main tool to show impartiality, and emphasize that all laboratories shall be treated in a non-discriminatory manner. Consultancy services linked with the accreditation activity are prohibited for any accreditation body to avoid compromising the confidentiality and decision-making process for accreditation.

Clause 5: Management

This clause explains how the accreditation body should have a transparent management system to ensure proper services. Control of documents with good record-keeping at all stages is a key factor for traceability. The standard also describes the procedure for taking corrective and preventive actions, carrying out internal audits and management reviews, and responding to customer complaints.

Clause 6: Human resources

Human resource is the most important criterion that highlights the competency of the accreditation body The personnel involved are not only

employees of the accreditation body but also others such as technical assessors, lead assessors, decision-making committees, technical committees, and personnel involved in deciding the requirements and laying down criteria Systematic monitoring of all functioning personnel must be implemented to ensure consistency of work. It is also important to keep all the necessary records of all personnel working for the accreditation body.

Clause 7: Accreditation process

The accreditation process is described in detail in this standard. It explains the main process for accreditation which comprises application for accreditation, review of resources, subcontracting of assessment, preparation for assessment, review of documents and records, on-site analysis of assessment findings and the assessment report, decision-making and granting of accreditation, appeal, reassessment and surveillance, extending accreditation, suspending, withdrawing accreditation, records on laboratories, proficiency testing and other comparisons of laboratories. These clearly show that for each step, some principles and concepts need to be followed.

Clause 8: Responsibility of the accreditation body to the conformity assessment body

This clause explains the responsibility of the accreditation body to the laboratories before, during and after the accreditation, as well as the obligations of both parties.

2.2 Key elements of the accreditation body

The important the accreditation body as described in ISO 17011 are summarized below:

Non-discrimination in services

The accreditation body shall operate its services in the same manner for all kinds of customers irrespective of the owners of the laboratories, whether they are private or government organizations, related or unrelated bodies, big or small organizations. This may sound simple but the accreditation body must demonstrate this in subjective ways and not merely by declaring policy. For example, all requirements must be made transparent and an application should not be refused without valid reasons.

Conflict of interest

Conflict of interest of the accreditation body and related bodies needs to be addressed, especially if the accreditation body is a part of one big organization of the government. The accreditation process should be totally free from interference by the top management as this can adversely affect the credibility of the programme.

Conflict of interest can be minimized or eliminated by designing an appropriate accreditation system. For example, the accreditation committee should include all types of stakeholders (users, other accreditation bodies if any, regulatory bodies, NGOs, competitors in the business, other government organizations, etc.) to make decisions for accreditation. Accessible complaint and appeal mechanisms are good ways to find out if there are any conflicts of interest.

Allowing laboratories the chance to accept or reject personnel involved in the accreditation process is also important for avoiding conflicts of interest. However, the accreditation body shall take action only if the laboratories can give valid reasons and not merely express subjective feelings or personal reasons for not accepting a particular person.

The top management shall not have any power over the accreditation process, including the decision-making process. The accreditation committee shall take full responsibility for the decision to offer or refuse accreditation. Apart from reducing conflicts of interest, this process will help the accreditation body to avoid all influence from outsiders, which may happen in any country.

Traceability

In all types of quality systems, traceability of all actions and documents is a must. As an accreditation body, the process of establishing a quality system must be implemented in such a way that it is readily accessible for verification by any party. The question of who, when, where, why and how shall be recorded in all processes. This also supports the transparency criterion for the accreditation body.

Evidence-based operations

All actions must follow laid-down procedures and the necessary forms must be filled up to ensure the consistency of actions as well as record-keeping

Confidentiality

Laboratories shall be assessed in a continuous fashion with regard to all aspects of standards and requirements. All the findings and evidence during the accreditation process must be treated as confidential information. However, the laboratories themselves may allow access to any of their records if they wish to. In some instances, prior permission may be required from the laboratories by the accreditation body to reveal the findings of the report to a particular party.

Integrity

The accreditation body must maintain its integrity, especially in technical areas. This will build trust in the customers. This must be created through the openness of the process, traceability and, most importantly, is the right attitude for accreditation personnel. It is also recommended that there should be flexibility in facilitating the accreditation work, which should be done on the basis of sound and valid reasons.

Transparency

The accreditation process should be done in accordance with the principles of good governance. In other words, every step should be transparent so as to allow monitoring and evaluation. This will induce trust in the accreditation body, thus making it sustainable. It will also improve the quality system in laboratories.

2.3 Standards

Countries can adapt existing international standards or formulate their own.

International standards

Some of the internationally accepted standards and their evolution in the past two decades are described below.

ISO/IEC Guide 25

In 1989, an international standard for laboratories, ISO/IEC Guide 25 *General requirements for the competence of calibration and testing laboratories* was published and used as a guidance document for many organizations throughout the world.

The standard described the general requirements of a quality system and the technical competency of all the aspects that a laboratory needs to ensure reliable and accurate reports. Most of it is described in a non-explicit manner. This was the main hurdle to the implementation of this standard, especially for health and medical laboratories, as the interpretation of each clause differed from one to the other and was difficult to put into practice.

ISO/IEC17025

In 1999, ISO/IEC Guide 25 was replaced by ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*. This standard was intended to overcome the weak points of ISO/IEC Guide 25. This new standard had more details in each clause as compared with the old one and also had more content to suit laboratory practices. In 2005, this standard was reviewed again to use the same wording as ISO 9001:2000 which is the standard for quality systems in general production and services.

It is internationally accepted practice for laboratories to obtain accreditation to ISO/IEC 17025, and not ISO 9001 certification. Obtaining ISO 9001 certification for laboratories does not demonstrate technical competence to undertake scientific tests or measurements and issue reports that can be relied on. On the other hand, care has been taken to incorporate all the elements of ISO 9001:2000 relevant to the scope of testing and calibration services covered by the laboratory's management system.

ISO 15189

The specific standard for medical laboratories (ISO 15189) was published in 2003. This standard was published to address the unique nature of medical laboratories compared with other types of laboratories, especially the pre-analytic and post- analytic parts of the quality system, as these two parts play a vital role in generating the results of tests. Moreover, the concept of "patient care" has also been emphasized in this new standard.

The ISO 15189:2003 is widely used by all accreditation bodies throughout the world and accepted as the international standard for medical laboratories. However, any standard needs to be reviewed periodically. The new version of ISO 15189:2007 has been recently published and will be implemented by all accreditation bodies in two years period.

Current use of international standards

Till 2006, two International standards, ISO/IEC 17025:2005 and ISO 15189:2003, were used as tools for laboratory accreditation by accreditation bodies. The first edition of ISO/IEC 17025:1999 replaced ISO/IEC Guide 25 and EN 45001. It contained all the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results. ISO 9001:1994 and ISO 9002:1994 are related to only the part about a management system in the first edition. It does not, however, cover the part that relates to technical competence. These standards have been superseded by ISO 9001:2000 in the second edition of ISO/IEC 17025:2005.

ISO/IEC 17025:2005, clause 1.6 states: "If testing and calibration laboratories comply with the requirements of this international standard, they will operate a quality management system for their testing and calibration activities that also meets the principles of ISO 9001." But ISO/IEC 17025:2005 also says that demonstrated conformity to ISO/IEC 17025 does not imply conformity of the quality management system within which the laboratory operates to all the requirements of ISO 9001:2000.

The first edition of ISO 15189:2003 specifies requirements for quality and competence particular to medical laboratories. It is based upon ISO/IEC 17025:1999 and ISO 9001. It is intended for use throughout the currently recognized disciplines of medical laboratory services; those working in other services and disciplines could also find it usual and appropriate. The second edition of this international standard is aimed at more closely aligning with a second edition of ISO/IEC 17025:2005 and ISO 9001:2001.

Composition of standards

ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories – focuses on the following two elements:

- Management requirements (Clause 4)
- Technical requirements (Clause 5)

Management requirements

These specify 15 key elements for sound management. These are:

- Organization
- Management system
- Document control
- Review of requests
- Tender and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Services to customer
- Complaints
- Control of non-conforming testing and/or calibration work
- Corrective action
- Preventive action
- Control of records
- Internal audits
- Management reviews.

Technical requirements

The technical requirements specify 10 key elements. These are

- General
- Personnel
- Accommodation and environmental conditions
- Test and calibration methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of test and calibration results, and
- Reporting of results.

According to both management and technical requirements, the laboratory shall develop its own structure for documentation. A typical structure of a quality management system documents hierarchy, a quality manual, management procedures, testing procedures or work instructions and supporting documents such as worksheets or forms or log books.

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

The laboratory shall appoint a (team of) Technical Manager who has overall responsibility for the technical operations and provision of resources needed to ensure the required quality of laboratory procedures, and a Quality Manager who has the responsibility and authority to oversee compliance with the requirements of the quality management system. The Quality Manager shall report directly to the top management. In addition, a Document Control Officer should be identified who shall control all the documents developed.

Medical laboratories may use the ISO 15190 as a guideline for preparing a written laboratory safety procedure, training staff on techniques of safety precaution, e.g. not to drink or eat in the laboratory, wear gloves, a mask and gown when working with infectious material. The laboratory shall perform testing in a biosafety cabinet class 2 or fume hood, where necessary.

National standards as a step to international standards

Development of a national standard as a starting standard for any country, especially a developing country, is one of the logical ways of implementing and initiating an accreditation programme. The standard may differ from one country to another depending on the state of development of the quality system in health laboratories. The national standard must be aligned with the international standard, e.g. in the case of medical laboratories, the aim of accreditation to ISO 15189 shall be the final target.

Although the international standard focuses on a process of continuous development, the main concepts and core content will not change dramatically.

Approach adopted by Thailand

Thailand has successfully initiated its accreditation process by starting with national standards and gradually moving to international standards. In Thailand, the national standard covered approximately 75% of the international standard ISO 15189. Thailand also provided enough training to all medical laboratories to implement the national standards. The country could therefore accelerate the implementation of national and international standards within a short time.

The content of the standard is composed of 10 elements; these are:

- Organization and management
- Personnel
- Laboratory instruments and equipment
- Procurement and external services
- Process control; document control
- Control of non-conformity
- Internal audit
- Continual quality improvement
- Client management

A summary of each chapter is given below:

Organization and management

Organization

The organization or part of the organization of medical laboratories shall be legally identifiable. All services of medical laboratories shall meet the relevant requirements of this standard. The medical laboratory management shall be responsible for the design, implementation, maintenance and improvement of the quality management system. This shall include the following: designated quality manager/technical manager with specified responsibility and authority for the management of laboratories according to the quality manual. All personnel shall be encouraged to foster close working relationships. The posts of deputy quality manager/technical manager or other important positions shall have well-defined responsibilities. Continual training shall be designed for all personnel. Client

data protection shall be developed. A quality index for quality monitoring shall be specified.

Quality management

Quality policies, procedures and manuals shall be documented and communicated to all relevant personnel. The management shall ensure that the documents are understood and implemented.

Quality management shall include standard of services, and procedures to be followed by personnel regarding the quality policy as well as document control. Medical laboratories shall perform IQC and participate in interlaboratory comparison/proficiency testing (PT)/EQA schemes. Equipment/ instrument maintenance and calibration plans shall be implemented.

Management review

At least once a year, the quality manager or relevant person shall review the internal audit report, surveillance report, quality index results, laboratory service evaluation reports, and the complaint record for management planning. The quality management review report shall be documented.

Personnel

Policy

A policy and plan for employing sufficient staff shall be implemented. Personnel qualifications shall be specified in relation to the job description. Policy and planning for improvement of personnel on a continual basis shall be implemented. Person(s) who can have access to confidential laboratory data stored on computers shall be defined. Annual check-up and vaccination of laboratory personnel shall be supported.

Head of laboratory

The head of the laboratory shall have a professional medical technologist's license or clinical pathology license with adequate work experience. He/she will be responsible for work related to instructing, managing, advising and training in the laboratory.

Personnel quality improvement

All laboratory personnel shall undergo training through educational programmes on a continual basis. Work performance evaluation shall be regularly monitored for designing the training plan. Non-licensed personnel shall work under the supervision of licensed staff. The curriculum vitae and training records of all laboratory personnel shall be documented.

Laboratory instruments and equipment

These include equipment, instruments, reference materials, reagents and test kits.

Working status of the equipment

The laboratory shall have all the equipment required to provide services. Procedures for transferring equipment shall be implemented. Maintenance and calibration plans shall be implemented. Knowledge and proper use of equipment by all personnel shall be ensured. The laboratory management shall establish a programme to regularly monitor and demonstrate proper calibration and functioning of all equipment. The equipment shall be operated only by authorized personnel.

Equipment identification and working status

Each item of equipment shall be uniquely labelled, marked or identified. Whenever the equipment is found to be defective, it shall be taken out of service, clearly labelled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet the specified acceptance criteria.

Validation and verification

The laboratory shall follow a procedure to ensure that quality manuals or related documents have been corrected as and when the need arises. A procedure for protection against unauthorized amendments shall be implemented.

Equipment data records

Equipment data records shall include the serial number, model, name of the manufacturer, name of the distributor, date and place of installation, and maintenance data.

Operation of computer and auto-analyser

Laboratory data for each item of equipment shall be thoroughly reviewed before it is operated. The operation failure protection system shall be implemented. All records shall be documented.

Procurement and external services

Procurement

The laboratory shall define and document its policy and procedures for selection and use of purchased external services. There shall be an inventory control system for supplies. Appropriate quality records of external services, supplies and purchased products shall be established. The laboratory shall evaluate suppliers of critical reagents, supplies and services that affect the quality of examination, and maintain records of these evaluations and a list of approved suppliers.

External services

The laboratory shall define and document procedures for the selection of referral laboratories and advisory committee matters. A list of referral laboratories and advisory committee matters shall be documented. The laboratory shall establish procedures to ensure that the reports received from external laboratories are correct. A copy shall be maintained for an appropriate period of time.

Process control

Laboratory space

The laboratory shall have enough working space and appropriate conditions to ensure quality of services. The laboratory shall separate the contaminated area from the sterile area and only authorized persons will be allowed entry into the laboratory room. The laboratory shall monitor, control and document all environments that may affect the quality of its services. The laboratory shall designate an appropriate room for collection of specimens. The laboratory shall have a clear procedure for waste management and environment protection.

Quality assurance

The laboratory shall undertake IQC to monitor the quality system and record all factors affecting the quality of services. The laboratory shall calibrate testing procedures by using reference materials, or compare the test results between laboratories. The laboratory shall participate in an EQAS/PT. If no EQAS is available, the laboratory shall establish a procedure for comparing the test results between laboratories. If the laboratory performs the test using more than one instrument, it shall have a procedure for comparing and confirming the results generated by each instrument.

Pre-analytical process

The laboratory shall develop a specimen collection manual. The manual shall be reviewed by the laboratory supervisor. The laboratory shall establish a procedure for handling specimens without a request form and a procedure for specimen management (acceptance or rejection of specimens).

Analytical process

The laboratory shall use only the standard or validated method for specimen testing. The head of the laboratory shall annually review the method and reference value. The procedure for all test methods shall be documented and maintained. The laboratory management shall define the duration of each test method and inform clients.

Post-analytical process

The laboratory shall designate a person to approve of the results. The tested specimen shall be kept for an appropriate period of time as per the policy. Only authorized person(s) shall discard the unused specimen and the specimen management procedure shall be documented.

Reporting

The reporting procedure shall be clearly established including reporting by telephone, reporting via a computer network and reporting critical results. The design of the report form shall have an appropriate format that includes the name and/or symbol of the laboratory, name or code of the patient, tests requested, specimen receiving date, reporting date, test results, names

of persons who have reported and approved of the results, etc. All reports are legal documents. The laboratory shall maintain a copy of the report for an appropriate period of time.

Altering the test results

The laboratory shall not use an eraser or correcting fluid to correct wrong results. A pen shall be used to cross out incorrect results and the new results shall be entered and signed by the concerned person, indicating the date of correction.

Document control

Quality document and document control

The laboratory shall define the level, type and details of the document in the header. The document shall be reviewed and approved by the authorized person. A list of all documents shall be maintained. Obsolete or cancelled documents shall be labelled and removed from the working area.

Quality and technical record

The laboratory shall define the procedures for proper record-keeping and documentation, sequences and timing of specimens and duly designate a responsible person for this task.

Control of non-conformity

The laboratory shall define the criteria and procedure for control of non-conformance. Root cause analysis shall be undertaken for prevention planning.

Internal audit

A plan for internal audit shall be established and documented. The laboratory management shall ensure that the plan is maintained and recorded.

Continuous quality improvement

The procedure for corrective and preventive action shall be documented and maintained. The laboratory shall design the process for reviewing client

feedback, analysing errors, and reporting to laboratory personnel and top management. A plan for quality system review shall be established and maintained.

Client management

The responsibilities of various personnel shall be related to their job. The procedure for client feedback management shall be established.

In countries where a quality system in health laboratories is not widely appreciated and implemented, the national standard containing lesser requirements may be more appropriate so that implementation is more rapid especially during the starting period.

3

Implementation of accreditation

Implementation of accreditation at the national level requires a step-wise approach and national commitment. The following steps are suggested:

- Development of national policy
- Establishment of accreditation body
- Formulation and dissemination of national standards
- Development of process of accreditation and its dissemination
- Forging linkages with national and international partners.

3.1   Development of national policy

A national policy articulates the commitment of national authorities to implement accreditation of health laboratories. The policy should be drafted by an organization/institute that has experience in and/or mandate for promoting quality, in discussions with all stakeholders, viz. regulatory agencies, environmentalists, disease surveillance programme managers, hospital administrators and international agencies.

The policy should address all broad issues of accreditation. Once approved by the national authorities, this policy shall be made known to all parties, especially laboratories, medical schools and professional bodies. This will create awareness and emphasize the importance and benefits of accreditation to both the laboratories and users.

3.2   Establishment of accreditation body

The accreditation body may be established as an independent set-up or a part of an existing big organization can be designated to start with. Its independence needs to be ensured.

An accreditation body may opt to have international recognition. The accreditation body must fully implement ISO17011 and take all the pathways for recognition by international agencies such as the APLAC and ILAC.

The accreditation body should have a defined structure with adequate resources to operate efficiently. Dedicated staff with aptitude, experience and knowledge of current concepts and the intricacies of accreditation is critical for the success of implementation.

3.3   Formulation and dissemination of standards

The accreditation body has to decide on the use of either international standards or national standards as accreditation criteria.

For a developing country, the national standard is a good start for initiating the process of laboratory accreditation. This will motivate and encourage laboratories to achieve accreditation. The national standard should be in line with and act as a step to international standards such as ISO 15189 for medical laboratories in order to eventually achieve the international standard.

The most important part of formulating national standards is to get the whole-hearted agreement of all stakeholders such as laboratories, medical or related schools, and professional and regulatory bodies. The process of involvement should start at the inception of formulation of standards. Formation of a multi-stakeholder committee may be one way of doing this. This process may appear tedious and inefficient but it is critical to get the cooperation of all stakeholders for the success of accreditation.

Once finalized, the standards must be widely disseminated. The standards should form the basis of training at various levels of laboratories. It is also advisable to allow adequate time between dissemination of standards and initiation of accreditation so that the laboratories can make the required preparations.

It is worth mentioning again that accreditation of laboratories against a national standard could be the first step towards reaching international standards. However, the accreditation body should encourage those laboratories which are ready to go for international standards. Facilities should be provided for high-performance laboratories.

Selection of areas for accreditation

It is advisable to start the accreditation programme in the area/s that the country considers a problem area or a priority. This will support the success

of the accreditation system. For example, if malaria or HIV is the priority of work in the country, accreditation of the diagnosis of these two diseases will get the attention and interest of laboratories. Policy announcement is another way of implementing the accreditation system in certain areas.

3.4   Development of process of accreditation

Development of the process of accreditation should be entrusted to a small core group comprising experts who have a background in health or medical laboratories and are interested in the quality system. They must have adequate experience in implementing the quality system in the laboratories. The core group may not necessarily be a big one.

The expected functions of this core group are summarized as follows:

- Draft requirements and conditions for the accreditation of medical and public health laboratories.
- Formulate and prepare a quality manual for the accreditation body
- Document procedures related to the accreditation process.
- Prepare the necessary forms and worksheets including application forms.
- Advocate the standard and requirements to all the laboratories.
- Identify technical and system assessors.
- Collaborate with other stakeholders.

Draft requirements and conditions

Requirements are aimed at informing laboratories about how to get accreditation. The contents of this requirement normally consist of the accreditation body policy and scope of accreditation, definitions (to avoid confusion), qualifications of the laboratory applicants, general requirements and quality requirements.

The accreditation process is also spelt out to allow laboratories to understand the process that they have to go through for primary accreditation as well as for surveillance, scope of the accreditation and conditions for secondary accreditation. The conditions for suspension and withdrawal of accreditation should also be described in this document.

At the same time, laboratories should know how to appeal if they think they have not received fair treatment from the accreditation body. In this case, the appeal committee must contain members who do not have any power in the accreditation body and accreditation committee. The composition of all the committees should represent a balance of all the parties for laboratories while maintaining impartiality. This essential document shall be published and should be accessible to any laboratory in a non-discriminatory manner.

For laboratories to apply for accreditation, apart from the requirements and conditions, the accreditation body shall also prepare an application form to collect all the necessary information about the laboratories and their readiness for accreditation.

After everything has been prepared, committees should be set up for different functions. Some of these are:

- Accreditation committee
- Technical committees
- Appeal committee

The most important one is the accreditation committee which should include all relevant parties. Technical committees in different disciplines are also needed to review the technical matters of each applicant before sending these to the accreditation committee. The appeal committee may be set up after the accreditation process starts. Setting up a consulting committee to assist the accreditation body in all aspects is desirable.

The number and types of committees depend on the needs and infrastructure of each country.

Quality manual of the accreditation body

The accreditation body shall establish its own quality manual to suit the need of a particular country; however, the composition can be composed using ISO 17011 as a guidance document (Annex 1).

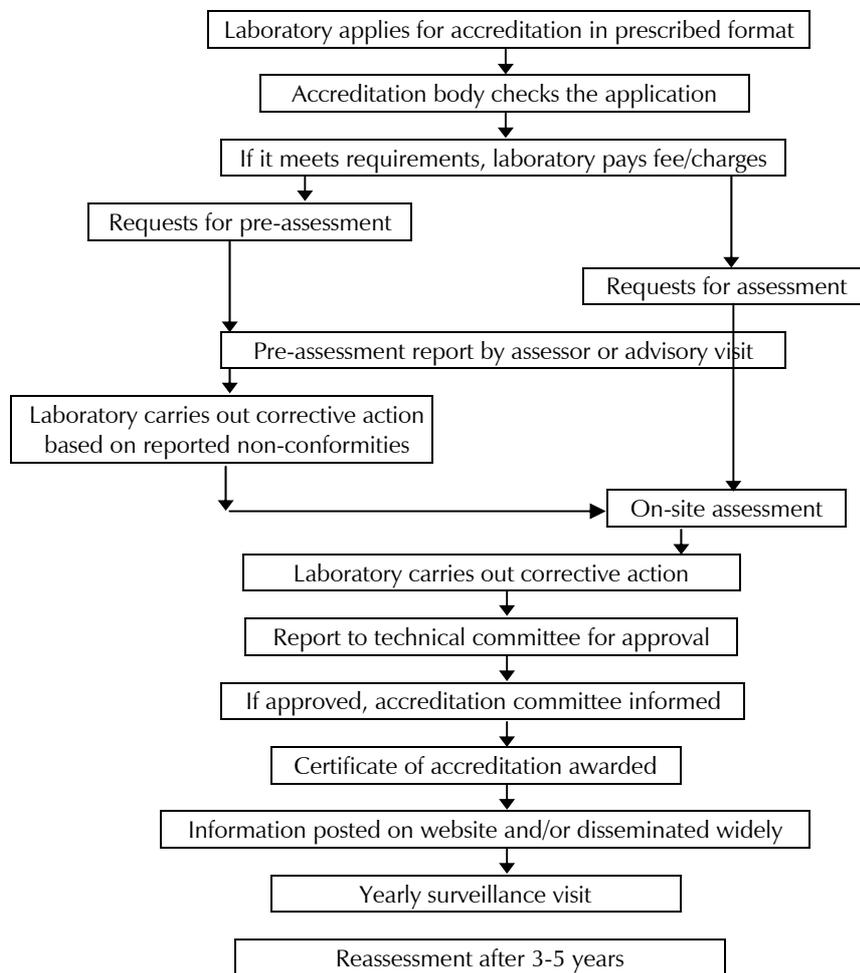## Documentation of the accreditation procedure

The first document to be developed is the accreditation procedure. This should describe the whole process of accreditation. It can be written in the form of a flow chart as shown below. In each procedure, there will be many related procedures and worksheets to go with these. The objective of the worksheets is to uniformly list all the activities that are undertaken.

A possible framework for the accreditation process is depicted in the flow chart below. Keeping the broad framework in place, countries can adopt a feasible and sustainable time-frame for the various steps. The laboratory fees for accreditation could be as per the prevalent local practices.

Forms and worksheets

Consistency must be achieved in all the activities of a quality system. In order to achieve these procedures, worksheets and forms are efficient tools. All these forms should be designed to meet the needs of the procedures and the purpose of data collection.

```
┌─────────────────────────────────────────────────┐
│ Laboratory applies for accreditation in prescribed format │
└─────────────────────────────────────────────────┘
                        │
          ┌───────────────────────────────────┐
          │ Accreditation body checks the application │
          └───────────────────────────────────┘
                        │
      ┌───────────────────────────────────────────┐
      │ If it meets requirements, laboratory pays fee/charges │
      └───────────────────────────────────────────┘
                │                           │
  ┌──────────────────────────┐              │
  │ Requests for pre-assessment │            │
  └──────────────────────────┘              │
                │              ┌──────────────────────────┐
                │              │ Requests for assessment   │
                │              └──────────────────────────┘
                │                          │
      ┌──────────────────────────────────────────┐
      │ Pre-assessment report by assessor or advisory visit │
      └──────────────────────────────────────────┘
                │                          │
┌────────────────────────────────┐        │
│ Laboratory carries out corrective action │       │
│ based on reported non-conformities │     │
└────────────────────────────────┘        │
                │              ┌──────────────────────────┐
                └─────────────►│ On-site assessment        │
                               └──────────────────────────┘
                                          │
            ┌──────────────────────────────────────┐
            │ Laboratory carries out corrective action │
            └──────────────────────────────────────┘
                                          │
            ┌──────────────────────────────────────┐
            │ Report to technical committee for approval │
            └──────────────────────────────────────┘
                                          │
            ┌──────────────────────────────────────┐
            │ If approved, accreditation committee informed │
            └──────────────────────────────────────┘
                                          │
            ┌──────────────────────────────────────┐
            │ Certificate of accreditation awarded    │
            └──────────────────────────────────────┘
                                          │
          ┌──────────────────────────────────────────┐
          │ Information posted on website and/or disseminated widely │
          └──────────────────────────────────────────┘
                                          │
            ┌──────────────────────────────────────┐
            │ Yearly surveillance visit               │
            └──────────────────────────────────────┘
                                          │
            ┌──────────────────────────────────────┐
            │ Reassessment after 3-5 years            │
            └──────────────────────────────────────┘
```

Advocacy for standards and requirements

The accreditation body can function and be useful to all parties only when it is approached by laboratories wanting to be accredited. Therefore, as a part of advocacy, the accreditation body informs its potential customers about the standards and requirements used for accreditation. This process should be done in tandem with setting up of the accreditation body.

Apart from letting laboratories know about the accreditation body, preparation of the laboratories in implementing the national standards and quality system is an important component. This can be done by the accreditation body itself and the best way is to get some partner(s) from medical schools and professional organizations through networking. An example of how to implement a quality system in laboratories can be found in the publication *Quality standards in health laboratories, implementation in Thailand: a novel approach*, New Delhi, WHO SEARO, 2005.

Assessors

Types of assessors

In the accreditation system, assessors play a key role in measuring the quality system and the competency of laboratories. Normally, there are two groups of assessors.

- System assessors
- Technical assessors

System assessors may also act as lead assessors. These groups of assessors normally know the quality system and standards. It is preferable for them to have a technical background in laboratories but this is not essential. In any assessment, there will be only one system or lead assessor.

The second group of assessors is the technical assessors. In general, technical assessors are not in the accreditation body but are experts working in each field of the laboratory. This is to ensure that technical assessors always keep up-to-date with technology and know-how. The principle for selecting technical assessors for each of the applicant laboratories in the specific scopes shall be based on the experience and familiarity of the assessors in the particular field. The procedure and forms for the selection and monitoring of assessors should be well defined.

Training of assessors

In order to establish an accreditation system, intensive training of assessors of both types (system and technical assessors) must be provided. There are several ways of enabling assessors to perform the assessment satisfactorily, apart from formal training in standards, requirements and assessment techniques. Observing on-site assessment initially with experienced assessors after a formal training has proven to be very effective. The next step is to allow them do the assessment under the guidance of experienced assessors. Persons who are familiar with internal audit would have a good start in becoming assessors.

3.5   Collaboration with other stakeholders

An accreditation process requires close collaboration of the accreditation body with several other agencies which may be its customers, or institutions that can advocate for the use of its standards and promote accreditation. Some examples of stakeholders that may play a key role in accreditation are:

- Medical and health laboratories
- Other accreditation bodies
- Professional organizations
- Regulatory bodies
- Medical schools
- Related government/nongovernmental organizations.

Medical and health laboratories

As the target customers, laboratories play a key role in the success of accreditation programmes in a country. In any accreditation programme, if there are no customers, the programme will not be able to sustain itself. Even if the programme is made compulsory and enforced by policy-makers, it will neither be sustainable nor achieve the ultimate goal of continuous improvement.

The value and importance of accreditation should be communicated to all potential participating laboratories, especially from the point of view of benefits to them and their personnel. Laboratories should be given the opportunity to comment on the contents of the standard prior to starting

the programme. Training is necessary for understanding and implementing the standard. Networking of laboratories and other professional organizations should be achieved to spread mass awareness. All these activities should run parallel to the preparation of the accreditation process.

Other accreditation bodies

Some countries may have a few accreditation bodies. Cooperation with these existing bodies will not only save scarce resources but will also help in accelerating the process.

Professional organizations

In the area of health and medical laboratories, influential professional organizations exist in practically all the countries. These organizations can play a very important complementary role in the development of a quality system for laboratory services. It may be of great use to take these bodies into confidence and involve them, starting with standard formation, training and public relations, as they can persuade their members who are the potential targets for improvement and accreditation.

Regulatory bodies

Some regulatory bodies may control the functions of target laboratories in their respective areas. It is advisable to incorporate their requirements in the accreditation criteria to avoid duplication of work. It will lessen the burden on laboratories as they will not require assessment by several organizations and will prevent wastage of the limited resources of the country. Some examples of regulatory bodies are the hospital accreditation body, national registration body, social security body, health insurance organizations, Food and Drug Administration, etc.

Medical schools

In many countries, the role of medical schools includes not only training of personnel in this area but also setting norms and practices for medical laboratories. Apart from laboratory professionals, persons graduating from medical schools include physicians who are the customers of medical laboratories. If they get involved from the beginning of the accreditation process, they will offer valuable human resources for the accreditation system as well as in preparing for implementation of the standard or requirement for laboratories.

Related government/nongovernmental organizations

Many organizations/departments in the Ministry of Health are the direct customers of medical and health laboratories such as the communicable diseases control organization, epidemic control organization, health promotion, etc. Though it is not necessary to involve them from the beginning for approval of the standards, their comments should be given due consideration.

Cited above are some examples of stakeholders, which in no way constitute a complete or exhaustive list. Each country should enlist possible partners and stakeholders at the start of the accreditation programme and attempt to solicit their views and comments at all stages of development of the accreditation system. It is important to keep in mind that they are partners in achieving the same goal and not competitors.

3.6   Factors to be considered in implementation

Before a country decides to start an accreditation system for medical and health laboratories, several key factors need to be considered. Usually, due to limitation of resources, especially in the health area, priority is given to disease control and treatment rather than to diagnosis in laboratories. Therefore, with the limitation of resources and low priority for budgeting, networking of existing facilities for setting up an accreditation system is a feasible approach that should be considered.

Country context

Despite some similarities, the structure of the health services system in each country is different. Some countries in the Region are relatively small compared with others and the infrastructure of the health-care system is not set up in a systematic manner. It is not advisable to set up an international accreditation system for medical laboratories in such countries. However, if the country needs to set up a laboratory accreditation system according to international standards for other purposes (such as for trade), the accreditation of medical laboratories will benefit collaterally.

Laboratory accreditation is a voluntary process. However, the voluntary approach is rather slow and a lot of persuasion is needed to motivate laboratories, particularly those in the public sector. In some developed countries accreditation of medical laboratories is mandatory for obtaining

financial support from the government. There are pros and cons for any approach and countries must select the approach that suits their situation.

Geographical factors also need to be considered while designing the system, such as whether it will operate in a centralized or networking mode. The advantage of a centralized mode is that it is easier to control the conformity of the process and ensure non-discrimination, which are crucial properties of an accreditation body.

Availability of accreditation body

In some countries there may be well-established accreditation bodies providing services in other areas of expertise. It is recommended to have a cooperation programme for medical and health laboratories with such existing accreditation bodies. In certain situations, the international standard for medical laboratories, ISO 15189 is beyond the achievement capacity of small laboratories in rural areas. A national standard and national accreditation programme should be an alternative for improvement of these laboratories, which will finally attempt to achieve international standards. The joint efforts of existing accreditation bodies and the Ministry of Health will be the most beneficial solution for all parties and countries in such situations.

If an accreditation body does not exist in any field, the use any existing organization which has related functions should be considered. Establishing a new organization needs a lot of resources in the form of personnel, accommodation and budget. Another possibility for starting an accreditation programme is to begin with registration of laboratories and have some criteria to assess the quality system and competency of laboratories. It must be ensured that such criteria shall conform to international standards or a part of international standard and that eventually an international standard will be adopted. In all these, critical criteria such as IQC and EQA or interlaboratory comparison must be the first step in implementing the quality system.

Readiness of laboratories

The most important stakeholders of the accreditation programme are the laboratories. Hence, the state of development of a quality system in laboratories is very crucial. One should not attempt to set up an accreditation programme of a certain standard when laboratories are not aware of the standard. Laboratories must be educated and sensitized before

launching the programme. In some situations, consulting and coaching are the tools for implementing the standard in society. Stakeholders such as professional associations and medical schools can play an important role in the development and implementation of the standard. The approach for implementation of the standard should be through networking in order to achieve a mass impact.

Participation in External Quality Assessment Scheme (EQAS)

Apart from accreditation, participation in EQAS is another important tool for implementing good laboratory practices. For medical laboratories it is mandatory to participate in EQAS prior to accreditation. Therefore, the accreditation body must identify an acceptable EQAS programme for laboratories to participate in. If such a programme is not available in the country, a commercial or international programme from outside the country must be listed, though such programmes are usually expensive. Apart from EQAS, strengthening IQC is an equal or more important step for ensuring the quality of results released by the laboratories.

Beginning with leader and model laboratories

In any society, there are always some leader organizations and this is also true for laboratories. There will be some leaders that other laboratories will follow. It would be good strategy to convince these organizations (laboratories) to join the accreditation programme initially. This will stimulate other laboratories to consider getting accredited.

Regulators and other requirements

In any government organization, there will be some overlapping responsibilities while catering to the requirements of different customers. For example, the Food and Drug Administration needs laboratories to serve them in surveillance activities. They may need to do their own assessment. At the same time, the environmental agency may use the same laboratory for testing of water and may require the laboratory to conform to their standards and do the assessment as well. This will be a waste of resources and create problems for the laboratory. It is advisable to cooperate in fulfilling all the requirements of regulators or users in the accreditation criteria to avoid duplication of work from the beginning.

Normally, international standards will cover all the requirements of many organizations. However, there are some specific requirements of the

organization which may be added to the international standard. The key factors that can affect the process of accreditation and thus must be addressed in the beginning are summed up in the table below.

Factors to be considered before initiating accreditation

- Choose the accreditation standard based on the structure of the health-care system.

- Make a beginning with national standards, which can eventually be scaled up to international standards.

- Prioritize areas for accreditation.

- Cooperate with the specific requirements of regulators.

- Make use of already established accreditation bodies.

- Assess the readiness of laboratories for accreditation.

- Begin by strengthening EQAS.

3.7 Critical factors determining success

Participation of all stakeholders

It is essential to involve all stakeholders from the beginning, starting from policy formulation. This will make the accreditation system sustainable and result in good quality laboratories in the country. Partners also can take part in the development and implementation of standards for laboratories and this will have a major impact on the development of a quality system and competency in laboratories.

Clear understanding of the accreditation process

Clear and tangible objectives should be spelt out for everyone to know and understand that laboratory accreditation is a system for developing laboratories to have a good quality system and maintain up-to-date competency. This will help provide an efficient health-care system, thus saving the scarce resources of laboratories. Accreditation will provide a sustainable and good quality system for laboratories, as they will be assessed periodically. Accreditation is not a one-time activity but is a continuous process of improvement. Therefore, getting accreditation does not mean that a laboratory is perfect; it means that it is at an acceptable level

according to the standard and requirement. The next assessment will aim for laboratories to improve performance. Accreditation should be taken as a positive tool for laboratory improvement.

Leader laboratories

Accreditation of selected "leader" laboratories in the initial phase may act as a catalyst for other laboratories to aim for accreditation.

Reward system

The names of accredited laboratories are published for wider dissemination. ISO 17011 clause 8 states the need for an accreditation body to publish the accreditation laboratories' names and scope of accreditation. This will highlight the difference between accredited and non-accredited laboratories. Special logos shall be permitted to be used only by accredited laboratories within their approved scope. By promotion of accredited laboratories, the users will be the outside force for non-accredited ones to get accredited. This may be one of the ways by which laboratories can be encouraged to initiate the process of accreditation. Other means as locally applicable can also be considered.

Maintaining confidentiality

It is important to maintain the confidentiality of participating laboratories by ensuring anonymity and a non-derogatory approach. It is of paramount importance for participating laboratories to be apprised of the benefits of accreditation and have their fears and doubts addressed.

Maintaining impartiality

The accreditation board should develop a high degree of credibility, integrity, transparency, easy accessibility and, above all, impartiality for all types of participating laboratories – be they small or large, public or private.

Creating an enabling environment

The accreditation body should attempt to sensitize laboratories about the need for and benefits of accreditation. It should facilitate and create an enabling process for laboratories that might be in different stages of development to attempt obtaining accreditation in a step-wise fashion.

The critical factors determining the success of accreditation are summarized in the box below.

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Factors determining the success of accreditation

- Involve all stakeholders at all stages.

- Everyone should understand the objectives of accreditation.

- Try to involve leader laboratories in the beginning.

- Reward the accredited laboratories by way of publishing their names and permitting the use of special logos.

- Maintain confidentiality, anonymity and a non-derogatory approach towards all participating laboratories.

- The accreditation body should have a high level of credibility, integrity, transparency and impartiality.

- The accreditation body should create an enabling environment

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Further reading

Documents published by International Standards Organization:

(1)   ISO 9000:2000. Quality management systems – fundamentals and vocabulary

(2)   ISO 9001:2000. Quality management systems – requirements

(3)   ISO 9004:2000. Quality management systems – guidelines for performance improvements

(4)   ISO/IEC 17011:2004. Conformity assessment – general requirements for accreditation bodies accrediting conformity assessment bodies

(5)   ISO/IEC 17025:2005. General requirements for the competence of testing and calibration laboratories

(6)   ISO 15189:2003. Medical laboratories – particular requirements for quality and competence

(7)   ISO/IEC Guide 2. Standardization and related activities – general vocabulary

(8)   ISO/IEC Guide 43-1. Proficiency testing by interlaboratory comparison – Part 1: development and operation of proficiency testing schemes

Documents published by WHO:

(1)   Quality standards in health laboratories, implementation in Thailand: a novel approach. New Delhi, World Health Organization Regional Office for South-East Asia, 2005 (SEA-HLM-386).

(2)   KumariS and BhatiaR, Quality Assurance in Bacteriology and Immunology, (WHO Regional Office for South-East Asia, 2nd Ed., 2004)

Abbreviations and acronyms

ILAC	International Laboratory Accreditation Cooperation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
WHO/SEAR	World Health Organization South-East Asia Region
MRA	Mutual recognition arrangement
ISO	International Organization for Standards
SOP	Standard operating procedures
EA	European Cooperation for Accreditation
FDA	Food and Drug Administration
HIV	Human immunodeficiency virus
ISO/IEC	International Organization for Standards/International Electrotechnical Commission
BLQS	Bureau of Laboratory Quality Standards
DMSc	Department of Medical Sciences
NATA	National Association of Testing Authorities
NABL	National Accreditation Board for Testing and Calibration Laboratories
KAN	Komite Akreditasi Nasional
NAC	National Accreditation Council
TLAS	Thai Laboratory Accreditation Scheme
PT	Proficiency Testing
EQAS	External Quality Assessment Scheme
QM	Quality Management
AB	Accreditation Body

Annex 1

Example of content of quality manual of Accreditation Body

Quality Policy for health laboratory accreditation

Chapter 1   Introduction

       1.1   Background

       1.2   Organization

       1.3   Objective

       1.4   Scope

       1.5   Conflict of interest

       1.6   Subcontract

       1.7   Documentation

Chapter 2   Organization management and authority

       2.1   Organization and authority

       2.2   Roles and responsibility of personnel

       2.3   Delegation of authority

Chapter 3   Quality system

       3.1   Objective

       3.2   Conflict of interest, confidentiality and information security

       3.3   Quality manual

       3.4   Internal audit

       3.5   Quality system review

       3.6   Complaint handling

       3.7   Appeal handling

       3.8   Corrective action and preventive action

Chapter 4   Personnel

       4.1   Objective

       4.2   Job description

       4.3   Training and training records

       4.4   Personal evaluation