

Review Article

Medical Laboratory Accreditation - A benchmark for performance

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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.

Recognition of Competence:

Accreditation provides proof that a laboratory complies with best practice. It also offers authoritative assurance of the technical competence of a laboratory to undertake specified analysis or measurements according to validated methods¹. Accreditation: provides an opportunity for external perspectives on, the laboratory's practice, can prevent the unnecessary duplication of information gathering on performance, encourages the sharing of best practice, stimulates innovation, reduces risk and provides international recognition.

It also provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and select reliable testing, measurement and calibration services able to meet their needs. To maintain this recognition, laboratories are re-evaluated periodically by the accreditation body to ensure their continued compliance with requirements, and to check that their standard of operation is being maintained².

ISO 15189 Medical Laboratory Accreditation

Medical laboratories can seek accreditation to International organization for standardization (ISO) 15189 Medical laboratories - Particular requirements for quality and competence, an internationally recognized standard that contains the requirements necessary for diagnostic laboratories to demonstrate their competence to deliver reliable services. 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 preanalytic 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. The new version of ISO 15189:2007 has been recently published and will be implemented by all accreditation bodies in two years period. The standard, which has been developed with strong involvement from the medical, scientific and clinical community, is for the use of medical laboratories in developing their management systems and maintaining their own competence; and for accreditation bodies to confirm or recognize the competence of these laboratories through accreditation³. Medical Laboratories can still choose between two accreditation standards -ISO17025 and ISO15189, though ISO17025 is more intended towards testing and calibration.

Guidelines on Establishment of Accreditation of Health Laboratories

Organization and management:

The medical laboratory management shall be legally identifiable and provide services designated to meet the needs of patients and clinical personnel responsible for patient care. Laboratory shall be responsible for the design, implementation, maintenance and improvement of the quality management system (QMS). Laboratories should have policies which ensure appropriate management support,

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training and supervision of staff appropriate to their experience and level of responsibility. This shall include the designated quality manager/technical manager to oversee compliance with the requirements of the QMS. Technical Manager who has overall responsibility for the technical operations and provision of resources needed to ensure the required quality of laboratory procedures. 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^{4,5}.

Quality management system (QMS):

Quality policies, processes, programmes procedures and instructions shall be documented, understood, implemented and communicated to all relevant personnel. Quality management shall include standard of services, and procedures to be followed by personnel regarding the quality policy for example, procedure for receipt or rejection of samples, policy for providing advisory services to clinical staff, use of referral laboratory etc, as well as document control^{4,5}.

Quality Manual:

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^{4,5}.

Document control:

Quality documents shall be controlled in accordance with a defined and documented procedure. The laboratory shall define the level, type and details of the document- title, edition/revision date/revision number, number of pages, authority for issue, source identification. etc in the header. The document shall be reviewed and approved by the authorized person. A list of all valid version of documents shall be maintained. Obsolete or cancelled documents shall be labeled and removed from the working area and there should be rules for amendments of documents by hand and in computerized system^{4,5}.

Review of contracts:

Contract reviews should be conducted in a practical and efficient manner. There will be a procedure for evaluating and selecting referral laboratory- It will cover all the works done by the referral laboratory- perform specific analysis or more extensive investigations, advisory services regarding choice of methods needed, research and development. Contract reviews shall be recorded. Referral laboratories are assigned to Deviations of

contracts shall be informed to the patients and shall be resolved before any work commences^{4,5}.

Examination by referral laboratories:

The laboratories shall have an effective documented procedure for evaluating and selecting referral laboratories and consultants who are to provide second opinion. Arrangements shall be reviewed periodically to ensure that requirements of pre and post examination procedures are adequately defined and documented, referral laboratory is able to meet the requirements, there is no conflict of interest, selection of appropriate examination procedure and responsibility for the interpretation of results. The laboratory shall maintain a registrar of all approved referral laboratories and subcontractors and samples referred to another laboratory^{4,6}.

External services and supplies:

The laboratory management shall define and document its policy and procedures for selection and use of purchased external services, equipments and consumable supplies that affect the quality of its service. Purchased items shall consistently meet the laboratory's quality requirements. These will be used after verification as complying with standard specifications (PT, IQC, RM, etc)^{4,6}.

Advisory services:

Appropriate laboratory professional staff shall provide advice on choice of examinations and use of the services including repeat frequency and required type of sample, and interpretation of the examination of required. There should be regular documented meetings of professional staff with the clinical staff regarding use of the laboratory services. Professional staffs may participate in clinical rounds, enabling advices on effectiveness. Laboratory's contribution on patient care shall be monitored⁴.

Resolution of complaints:

The laboratory shall have a policy and procedures for the resolution of complaints or other feedback received from clinicians, patients or other parties. Records for complaints and of investigations and corrective actions taken by the laboratory shall be maintained⁴.

Identification and control of non-conformities (NC):

Nonconforming activities occurs in different areas including clinician complaints, quality control indicators, instruments calibrations, checking of consumable materials, staff comments, reporting checking, laboratory management review, internal and external audits, etc. The laboratory shall define the criteria and procedure for control of nonconformance- ensuring that personal responsible for problem resolution are designated, medical significance of the NC examinations, root cause

analysis, corrective action, recall of work, responsibility of resumption of work, release and review of the results^{3,4,7}.

Corrective actions (CA):

Procedures of corrective action shall include an investigative process to determine the underlying causes of the problem. When needed it can lead to preventive actions. CA shall be appropriate to the magnitude of problem and corresponding with possible risks^{3,4}.

Preventive actions (PA):

For identifying the improvement needed and potential sources of NCs preventive actions are required. There shall be a procedure for PA for initiation of action, implementation of action plan, surveillance follow up to see if actions work as intended, control measures and recording. For this, important tools used are review of procedures, methods instructions, data analysis^{3,4}.

Continual improvement:

All procedures shall be systematically reviewed by the laboratory management at regular intervals to identify any potential sources of NC or other opportunities for improvement in the QMS or technical practices. Action plans for improvement shall be developed, documented and implemented as appropriate. Tools for this will be quality policy and objectives, analysis of data from internal and external controls, CA and PAs, audit results and management reviews^{3,4}.

Quality indicators:

These are established measured information that indicates the performance of a process, determine quality of services, potential quality concerns to determine how well an organization meets needs and operational and performance expectations. Commonly used indicators are PT testing/ performance testing, quality controls, competence of testing personnel, turnaround times, patient identification and its accuracy^{3,4}.

Quality and technical records:

The laboratory shall establish and implement procedures for identification, collection, indexing, access, storage, maintenance and safe disposal of quality and technical records. All record shall be legible and stored such that they are readily retrieval, stored in appropriate medium, and shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access^{3,4}.

Quality and technical records: request forms, examination results and reports, instrument print outs, maintenance records, examination procedures, laboratory workbooks, accession

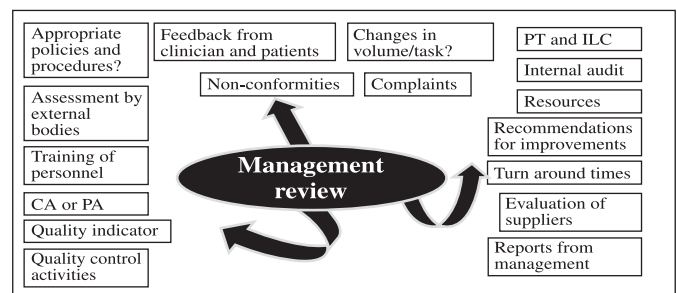
records, QC records, Complaints, incidents/accident records and actions taken, Records of internal and external audits, EQA/ILC (Staff training and competency records).

Internal audit (IA):

Systemic and documented process to evaluate whether the QMS and the practical implementations of it in the laboratory complies with the requirements for the system. The laboratory shall have a procedure ensuring structure, timetable, carry out, auditor qualifications and training, reporting requirements, follow up activities. IA are performed on regular basis according to cover and dates, all elements of the QMS or at least annually performed^{3,4}.

Management review (MR):

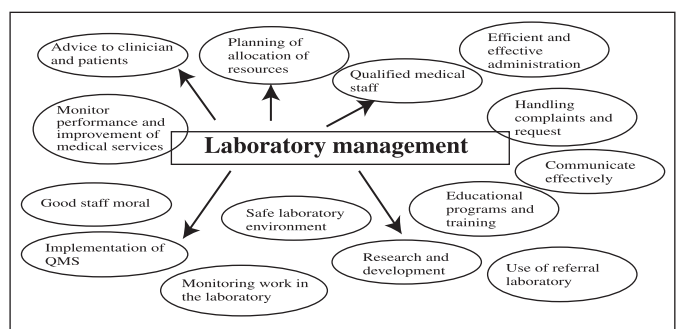
MR is the regular, systematic evaluation by top management of the suitability, adequacy, effectiveness and efficiency of the QMS with respect to the quality policy and quality objectives. At least once a year, the quality manager or relevant person shall review the internal audit report, surveillance report, quality index results, laboratory service evaluation reports, and the complaint record for management planning. The quality management review report shall be documented^{3,4}.



Technical requirements:

Personnel:

Medical laboratories shall be directed by a person/s having executive responsibility and the competence to assume responsibility for the services provided.



All laboratory personnel shall undergo training through educational programmes on pre-analytic activities, sample collection, examination and post analytic activities on a continual basis. Work performance evaluation shall be regularly monitored for designing the training plan. The curriculum vitae and training records of all laboratory personnel shall be documented⁴.

Accommodations and environmental conditions:

The laboratory shall have enough working space and appropriate conditions to ensure quality of services. The laboratory shall monitor, control and document all environmental conditions (temperature, humidity, noise level, electrical supplies, etc that may affect the quality of its services. The laboratory shall designate an appropriate room for collection of specimens and enough storage spaces for samples, reference materials, culture media, chemicals and reagents, documents, etc. The laboratory shall have a clear procedure for waste management and environment protection⁴.

Laboratory equipment:

These include equipment, instruments, reference materials, reagents and test kits. 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 data records shall include the serial number, model, name of the manufacturer, instruction and his contact, name of the distributor, date and place of installation, current location, condition when received and maintenance data, damage/malfunction/modification/ repair data, predicted replacement date etc⁴.

Pre-examination procedures:

a) Sample collection may be carried out by nursing staff, technologist and/or medical doctors, but the responsibility for proper collection lies with the laboratory. The lab is also expected to have frequent communication and liaison with sample collection personnel to ensure that instructions are understood and followed. All samples received shall be registered and requirements shall be reviewed by authorized personnel. Requisition shall include: Patient identification, gender, date of birth, Name of ordering physician and Clinician's address, Type of primary sample and site, Date and time of collection, Examinations requested, Pertinent clinical information, Sampling should be documented.

b) Sample collection manual : Include description of location

and opening times of the laboratory, services offered by the laboratory, sample collection, transportation (time, temperature, safety) and storage of samples, Sample acceptance and rejection criteria, safe disposal of materials and instruments, examination repertoire, availability of clinical advice and interpretation. Updated information for patients (explanation of clinical procedure, instructions for preparation of procedure) shall be available.

Examination procedure:

- (a) Methods and procedures shall be:
- (b) Recognized when possible
- (c) Appropriate and understandable
- (d) Detailed enough
- (e) Validated and updated
- (f) Available to personnel
- (g) Key information on workbench is essential
- (h) Deviation is acceptable only if they are documented
- (i) Technically justified, authorized and accepted
- (j) Laboratory should have an updated list of accredited and non accredited tests
- (k) Biological reference intervals shall be periodically reviewed.

Management responsibility is to ensure the contents of the examination procedure, review methods. Standard methods (ISO, consensus methods, Instrument/kit based, working procedures) or even non standard methods (in house developed, validated, publications) and latest valid version can be used to get result with traceability, reproducibility, measurement uncertainty.

Assuring quality of examination procedure:

Shall be established by calibration or by equivalent methods.

- (a) Calibration to SI units
- (b) CRM (Certified reference material) and RM (Reference material))
- (c) Standard solution
- (d) Proficiency testing (PT) prior to accreditation, annually or within a re-accreditation period (4-5 years)
- (e) ILC (Inter Laboratory comparison)- two laboratories swapping samples or analyzing the same objects and parameter.
- (f) IQC (Internal quality control) of all the procedure (records of data, source, storage requirements of IQC material, traceability to SI unit) including examination process, stability of method, frequency of testing and average number of sample tested.
- (g) All IQC, PT and ILC results shall be recorded and evaluated regularly. But these may vary with technical

areas, availability and volume of test/ calibrations.

- (h) Determination of MU (measurement uncertainty): main components causing MU to be identified and weighted for all examinations. Top down model (internal reproducibility data together with data of accuracy), results from previous experiments and validation data, data from standard methods are used.

Post Examination procedure:

Review of examination results before reporting and evaluation of conformity with clinical information has to be performed by authorized personnel. of interpretive comments is an essential role of the laboratory service. Retain samples according to described procedures. And disposal of examined samples in a safe and environmentally sensitive manner is mandatory.

Reporting:

Reports of results should be legible, reported (in writing, electronically or e-mail), transmitted within time limit agreed, clear and unambiguous, stored for a defined period. The design of the report form shall have an appropriate format that includes identification of the medical laboratory, unique identification and location of the patient, clear identification of the test requested, name and address of the requester, unique identification of the destination of the report, date and time of primary sample collection and time of receipt by the laboratory, date and time of release of report, primary sample type and results of the examination and interpretation, identification of the person authorized to release the report with signature. Other comments required if applicable are: quality and adequacy of the sample, results from referral laboratories, detection limits, MU⁴.

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 standard³.

How do laboratories become accredited?

Laboratory accreditation is generally provided by one recognized accreditation body within a country. In some developing economies without established accreditation bodies, laboratories may have to seek accreditation from an established accreditation system in another country. There are local accreditations bodies like: Bangladesh accreditation Board (BAB), the Institute for Accreditation of Bosnia and Herzegovina (BATA), Norwegian Accreditation (NA),

COFRAC, etc. Regional Accreditation bodies are European Cooperation for accreditation (EA), APLAC (Asia Pacific Laboratory for accreditation), PAC (Pacific Asia Laboratory for accreditation). 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 there are International accreditation bodies are ILAC (International Laboratory Accreditation Cooperation), IAF (International accreditation Forum).

Laboratories can have either all or part of their testing and calibration activities accredited. The accreditation process involves a thorough evaluation of all the elements of a laboratory that contribute to the production of accurate and reliable test data. The evaluation process can take one to several days, and involves the use of specialist technical assessors who evaluate the specific types of testing or measurement being performed. The assessment criteria are based on the international standards ISO/IEC 17025 or ISO 15189, which are used for evaluating laboratories throughout the world. Laboratory accreditation bodies use this standard specifically to assess factors relevant to a laboratory's ability to produce precise, accurate test^{1,2}.

Assessors

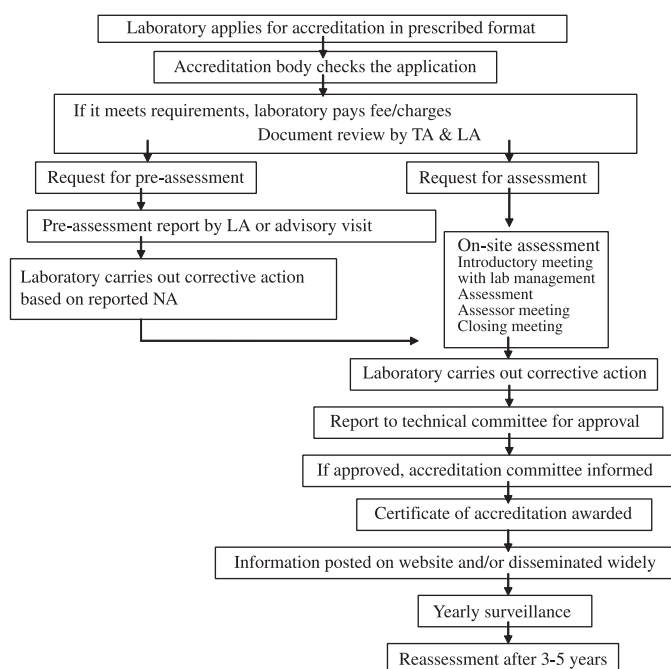
Lead Assessor (LA):

In general accreditation body (AB) personnel. He is responsible for the whole assessment, planning and reporting, lead the introductory meeting, assessor meeting, closing meeting, assessor team and make decisions. He represents the assessment team with laboratory management and assess the whole management system.

Technical Assessor (TA):

In general they are contracted specialists, trained and authorized by AB. Conduct the assessment according to instructions given by the LA and descriptions in accreditation procedure of the AB and assist LA in assessing parts.

AB gives all assessors a common understanding of the requirements in the accreditation standard using technical assessors with strong technical competence, assessor training courses, harmonization meetings, guiding documents and guidance during assessment⁴.



Implementation of accreditation:

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 agencies⁹. The policy should address all broad issues of accreditation.

Establishment of accreditation body

The accreditation body must fully implement ISO17011 and take all the pathways for recognition by international agencies such as the APLAC and ILA.

Key elements of the accreditation body: Non discrimination in the services, Conflict of interest clearly addressed, Traceability, Evidencebased operation, Confidentiality, Integrity, Transparency.

Formulation and dissemination of standards

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 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. 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 advisable to start the accreditation programme in the area/s that the country considers a problem area or a priority.

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. The expected functions of this core group are summarized as follows: Draft requirements and conditions for the accreditation of medical 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.

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. 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. Training is necessary for understanding and implementing the standard. Networking of laboratories and other professional organizations should be achieved to spread mass awareness. Apart from accreditation, participation in EQAS is another important tool for implementing good laboratory practices. It would be good strategy to convince the leader organizations (laboratories) to join the accreditation programme initially. This will stimulate other laboratories to consider getting accredited. All these activities should run parallel to the preparation of the accreditation process.

Apart from laboratory professionals if physicians who are the customers of medical laboratories. 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. Accreditation is not a one-time activity but is a continuous process of improvement. Accreditation should be taken as a positive tool for laboratory improvement.

References:

1. International Laboratory Accreditation Cooperation (ILAC). Why Use An Accredited Laboratory? [Brochure] Washington DC: ILAC; 2009
2. International Laboratory Accreditation Cooperation (ILAC). The advantages of Being An Accredited Laboratory. [Brochure] Washington DC: ILAC; 2009
3. World Health Organization. (WHO) Guidelines for Establishment of Accreditation in Health Laboratories. New Delhi, World Health Organization Regional Office for South-East Asia, 2005 (SEA-HLM-394)
4. The International Organization for Standardization. ISO 15189:2007(E). Medical Laboratories- Particular requirements for quality and competence. Switzerland: ISO 2007; 2007
5. The International Organization for Standardization. ISO/TR 10013. Guidelines for quality management system documentation. Switzerland: ISO 2001; 2001
6. International Laboratory Accreditation Cooperation (ILAC). ILAC-G13:08/2007. Guidelines for the requirements for the competence of Providers of Proficiency Testing Schemes. Washington DC: ILAC; 2007
7. Asia Pacific Laboratory Accreditation Cooperation, (APLAC) APLAC PT 002 Issue no.6,03/08 APLAC. Testing Interlaboratory Comparisons. Australia: APLAC; 2007
8. International Laboratory Accreditation Cooperation (ILAC).ILAC-G11:07/2006.Guidelines on Assessor Qualification and competence of Assessors and Technical Experts. Washington DC: ILAC; 2006
9. International Laboratory Accreditation Cooperation (ILAC). Why become an Accredited Laboratory? [Brochure] Washington DC: ILAC; 2009