EXPRESS Healthcare Management
India's First Newspaper For The Healthcare Business

Issue dtd. November 2005

Are Indian clinical laboratories prepared to accept the present accreditation system?

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The concept of quality concept in clinical laboratories is undergoing rapid changes. Quality control programme participation is not ensuring the consistency of test results and reports delivered to the patient. Laboratories are now establishing quality system in the 'laboratory report lifecycle', which covers pre-analytical, analytical and post-analytical phase.

Accreditation speaks about formal recognition of technical competency of laboratory testing. Quality system of laboratory is developed based on the 4 Ms and A (Man, Machine, Materials, Method of testing & Accommodation condition). Accreditation system is now practiced in every countries. Quality system standard ISO/IEC 17025 is now mostly followed for developing quality system in a clinical laboratory and this will be revised to ISO/IEC 1589.

Depending on the countries, laboratory tests performed in the pre-clinical phase follow several GLP (good laboratory practice) standards. In the European Union, the GLP directives are based on OECD guideline and FDA controls the US GLP.

The Accreditation Body uses the word the technical competence for granting accreditation to lab but appropriate medical competence is also required while granting accreditation. Many countries have prepared specific guideline proposal, few examples are given below:

- Germany: Accreditation of medical/ medical diagnostic Laboratory, (Eurochem/D-22G-AML)
- Netherlands: CCKL guide of practice.
- UK: CPA manual for lab accreditation.

In India, NABL as accreditation authority, publishes a book "Specific Guidelines for Accreditation of Clinical Laboratories (112) and Nuclear Medicine Laboratories (112A)". The two books published by NABL "Specific Guidelines for Accreditation of Clinical Laboratories (112)" and "Nuclear Medicine Laboratories (112A)" cannot be considered as specified requirements for laboratories. Their appointed assessor decides the technical requirements.

Accreditation scheme is available in our country based on the compliance and implementation of ISO/ IEC 17025 standard. Laboratories are forced to develop four level quality systems. Four level documentation becomes a bulky system. This spoon-feeding documented system is designed with the help of the consultants to add an USP in their certificates.

In India, accreditation for clinical laboratories is started by NABL who are newborn players in the clinical field and they are experienced in industrial testing. They are not backed by any professional medical organisation. The body, whose active involvement is required, is Indian Council of Medical Research (ICMR), which can develop the accreditation system considering the geographical size and role in the society. Indian clinical laboratories are not yet prepared for accepting the accreditation system offered by NABL. Clinical labs are now required to meet the following from the accreditation body:

- All the requirements should be available as standard and should be self-explanatory.
- Less documentation effort.
- Implementation procedure should be simple checklist type.
- Record requirement to be clearly defined.
- Auditors should not tell anything beyond the standard.
- All accreditation requirements shall be clearly explained by the expert of accreditation body. It should not be under the discretion of the appointed assessor.
- Accreditation process will be transparent, so there will be no doubt about the requirement of accreditation.

Now we will review the accreditation system from the experience of the consultants working for it, accredited laboratory and feedback received from the members of professional bodies like Indian Association of Pathologists and Microbiologists (IAPM):

Effect of the accreditation process among the clinical labs:

1. Quality Manual:

- Labs are not prepared to spend on improving quality of testing.
- Assessors create trouble for changing manual as per his liking.

This documentation exercise is not required in the beginning of accreditation system.

A common policy manual should be prepared by the accreditation body.

2. Quality System Procedure:

- In the absence of effective guidelines for sample handling or control of pre-analytical, analytical and post analytical error, labs face trouble.

Health regulatory authority or accreditation body has to prescribe the standards for maintaining sample handling and quality control procedure.

3. Standard Test Operating Procedure:

- Confidence is developed among consultants, technicians and lab management.
- Due to the absence of common standard practices, SOP standardisation depends on the auditor's acceptance. Documentation becomes a burden for the lab.

Common standard test practices should be developed by regulatory authority or shall be prescribed by the accreditation Body.

4. Records

- Labs are too burdened with records to satisfy the audit requirements.

Accreditation body should give records maintenance requirement guideline/checklist. Records maintenance requirement guideline / checklist should be given by accreditation body.

5. Quality control (Interlab/external)

- Inter-laboratory test expenses are not worthy as non-compliance test results are not identified in case of different test results.
- There are no health regulatory authorities for exercising quality control activities.
- They receive different opinions and prescriptions from the auditors on quality control activities.

- Labs feel the frequency of QC practices by using external control or participation in external program for biochemistry, hematology and clinical pathology, as prescribed, are not commercially viable. Accreditation procedure and its maintenance are expensive.

Regulatory authority or accreditation body should conduct external quality assurance or proficiency testing program. Guideline for small labs for PT or EQA should be fixed. Cost-effective EQA or PT program to be introduced.

- Inter-laboratory comparison with accredited labs to be organised by accreditation body.
- Guiding laboratories to taking corrective action should be looked after by the regulatory authority or accreditation body.

6. Internal audit

- It is a time-consuming exercise.
- Audit documentation creates a burden for the labs.

Simple checklist type audit is preferable and checklist should be supplied by accreditation body.

7. Overall cost/expenses for Audit:

- A laboratory testing covering all common disciplines (Bio-chemistry, Clinical Pathology, Hematology, Histopathology and Microbiology) need auditors (covers pre-audit and final audit) for their Audit, but heavy amount is required for air fare, hotel expenses etc.

Number of assessors should be reduced and local assessors appointed.

4Ms & A requirement to be developed by accreditation body

MACHINE: Type is not specified by accreditation body

Calibration Requirement: Specified by accreditation body.

Remarks: Approval required from the regulatory authority about its performance and acceptability in producing test results.

METHOD: Sample handling and testing is not specified by accreditation body.

MATERIALS: Type of reagent and Consumables: Not specified by the accreditation body.

Remarks: Should be approved from regulatory authority, specification procedure for handling of reagent kit by the manufacturer and supplier to be developed.

ACCOMODATION: Not specified by accreditation body.

Remarks:

Specification to be developed, the specification prescribed by state health regulatory requires changes.

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