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## A Review Of Technical Competency Of Laboratory Accreditation Audit

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Accreditation of a laboratory means technical competency of the laboratory to carry out various tests. Accreditation process ensures technical infrastructure, competent manpower, and records systems, all of which together deliver quality output and quality test results. It is the responsibility of the accreditation body to deliver quality assessment by a knowledgeable expert.

Objectives of accreditation audit are not only to check the adequacy, compliance and effectiveness of the system, but also to guide the laboratory for further improvement. Accreditation concept is still voluntary in India, with NABL playing a key role to initiate this movement. Technical competency of an accreditation body is very essential to assess the technical competency of the laboratory.

### Developing Technical Competency

Stage I : This involves formation of a technical cell, which should have at least one leading consultant with proven experience. The Cell will draft guidelines for auditing and interpretation of standard system and technical aspect. It will also decide on selection of auditor, training, competency assessment of auditor and clarifying the clients' request.

Stage II : This entails developing or creating eligible auditors for assessment of laboratory. Accreditation body is required to develop a very clear and transparent audit system policy and procedures which shall include the following:

- a) Development of detailed guidelines on "specified requirement" auditing: The guideline should include checking quality manual, procedures, instructions, records, requirement of regulatory authority, etc.
- b) Procedure for guideline on document adequacy audit/intent audit: For instance, the auditors should assess whether the quality system element is properly addressed or not. He/she should not give their personal opinion in form of non-conformance (NC) on header, footer content and alignment of the document.
- c) Policy on selection of audit sample: Period (span of checking old document and record) and area of audit sample or the scope of audit should be delineated.
- d) Guidelines for assessing effectiveness of quality system.
- e) Guidelines for effective audit and assessing auditors' efficiency by the accreditation body.

Stage III : This involves training of auditors. The requirements are a) A person should be trained on quality system standard and as well as technical standard requirement by the accreditation body.

b) Lead assessor shall be trained in such a way that he/she can handle overall

technical assessment independently in pre-audit and leading assessment audit.

Stage IV: This is about selection of the auditors. The process involves assessing the background and experience in similar kind of laboratory set-up. For example, a commercial laboratory auditor should have a background in working in commercial laboratory.

Stage V: This entails selection of the auditor in pre-audit. When a laboratory is applying for biochemistry, the lead assessor should be from biochemistry only. If the laboratory is applying for most of the discipline, then MD pathology and experience in multi discipline will be suitable.

Stage VI: This is about competency assessment of the auditors, which is very essential and can be accomplished in the following way:

- a) Asking them to solve various case studies on technical and accreditation requirement.
- b) Review of their technical competency through various technical assessment programme. For instance, a histopathologist should also participate in similar kind of Proficiency Testing (PT) programme applicable for a commercial laboratory. A histopathologist assessor should have successful grading in "X" no of PT programmes where slides are reviewed by him/her.

#### Role Of Laboratory Accreditation Consultant

Consultants of laboratory accreditation with proven experience can help the accreditation body for developing accreditation system and auditing because systems in the laboratory is developed by the consultant and one consultant represents the experience of working in many laboratories. Consultant can help by sharing his experience in developing the laboratory quality management system.

#### Present Systems In NABL

- Committee is formed for preparation of technical document, but policy and procedures on auditing is not clear and transparent.
- Auditors training are given on ISO15189 requirements, but no technical training is conducted, and training is not sufficient with respect to case-study analysis and conducting/managing pre-audit and assessment.
- Auditors selection policy is not established, and in some cases biochemist assessor is selected as lead assessor for assessment of multidisciplinary testing field.
- Most of the assessors are selected from educational and government institutions, which are not accredited or lack sufficient work experience in commercial laboratory operation.
- There are no technical cell or person available who can resolve client query or solve dispute raised from an audit.
- Competency assessments of the assessors are not conducted or technical competency of the assessors are not reviewed.

#### Case Study

Examples of some of the NCs raised by NABL assessor during audits, which however do not constitute NCs.

1) Assessor raised NC that 'Quality Manual Header Footer is to be revised'- Auditor should review the adequacy of the quality manual content as per ISO 15189 not pattern of header footer. However, it is the discretion of the laboratory to select the pattern of header and footer of the manual by satisfying the requirement of document control.

2) NC raised that 'laboratory has no cytocentrifuge', when the truth is that the laboratory has not applied for cytopathology tests on Cerebro Spinal Fluid(CSF). Cytocentrifuge is a specified requirement for cytopathology test on CSF. As it is not under the scope of accreditation, so lacking cytocentrifuge does not

constitute an NC.

3) Assesor raised NC for 'Records before August 2005 are not maintained'. This cannot be an NC as maintaining records are required from August 2005 only as per Quality manual issue date.

4) NC rose on 'Space is not sufficient', considering the high volume of work. There is no specified requirement for the space required for a particular discipline accreditation, if the present job volume did not affect their working system. Hence, this cannot be an NC.

5) NC raised on 'Equipment "X" authorisation record, personnel competency and training record is not available. In a particular case, the equipment was installed in March 2004 and laboratory started implementing quality system from August 2005. The authorisation declaration was available from laboratory director. Equipment "X" was installed one year before the date of quality system implementation, staff were trained in that time, no incompetence found during audit and hence no authorisation evidence such as training certificate and other competency assessment were required. So, this cannot be a non-conformance.

6) NC rose on-'In the SOPs, kit insert page no is not given.' This can not be an NC. A company- supplied kit insert pages can be changed from time to time and every time changing total SOPs is not feasible and this is not the specified requirement.

#### Conclusion

It is the need of the hour that the NABL reviews its accreditation process, along with technical competency of the assessor. Audit should be of quality for technical competency standardisation. Accreditation should not be reduced to mere paperwork. Besides, I feel APLAC accreditation is not relevant for assessment of clinical laboratory. APLAC is relevant in industrial sector only.

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