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## RESEARCH ARTICLE

### RESPONSIBILITIES AND QUALITIES OF AN ASSESSOR/AUDITOR AS PER ISO/IEC STANDARDS

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#### ABSTRACT

Assessor/Auditor key responsibility is assessment/ audit of testing & calibration laboratories, management system, manufacturing process, service, or documentation procedure has all the requirements for standardization and quality assurance. Assessors/auditors are responsible for the assessment/audit of the conformity assessment body. The assessors are appointed or hired by accredited body (AB) on regular basis or add assessors/auditors in panel. It is prime responsibility of an assessor/auditor, to assess/audit of any CAB, impartially, in comfort environment, free from undue pressure and fair reporting. A good assessor/auditor should be professional competent and experiences of the system. Attitude & behavior are the prime factors of quality. Knowledge of procedures of quality management in the fields testing, calibration, inspection or certification based on practical experience and/or successful participation in relevant training are the main features of a good assessor. Further assessor must be able to communicate/write to either remove non-conformity or improvement. However whenever there is any such situation assessor/auditor may guide with multiple type of leading options instead of direct solution. A direct solution may be taken as consultancy and violation of impartiality.

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## INTRODUCTION

Standard is a technical document, established by consensus that provides rules, guidelines or characteristics for activities or their results [1]. ISO/IEC-17025 has been established with the aim of bringing global standardization to testing and calibration laboratories. The objective of the ISO is to develop standards that have economic and technical impact on countries around the world [2]. This is a voluntary, third party reviewed process that ensures laboratory's quality management system is thoroughly evaluated on a regular basis to guarantee continued, technical competence and compliance with ISO/IEC-17025 [3]. International standards with a slogan "make things work", they provide specifications for products, services and systems to ensure quality, safety and efficiency [4]. The standard covers the technical activities of a laboratory as well as the management and organizational aspects to perform the technical activities in a competent way [5].

An ISO/IEC accreditation or certification certificates will show potential customers that your services values quality and that you have taken steps to ensure that your accredited or certified results are accurate and reliable [6]. This work describes the human resources organization of the General Coordination for Accreditation/Certification in conformity assessment bodies/ certification bodies, in which lead and technical assessors, both internal and external to assess the competence of calibration and testing laboratories and certification bodies as per ISO/IEC standards. A person that performs an audit of any Conformity Assessment Body (CAB) is called assessor and this activity is known as assessment, while a person which conduct audit of certification bodies is called auditor. ISO 19011:2018 defines an audit as a "systematic, independent and documented process for obtaining audit evidence (records, statements of fact or other information which are relevant and verifiable) and evaluating it objectively to determine the extent to which the audit criteria (a set of policies, procedures or requirements) are fulfilled." There are three

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main types of audits: I- Process audit: This type of audit verifies that processes are working within established limits. It evaluates an operation or method against predetermined instructions or standards to measure conformance to these standards and the effectiveness of the instructions. A process audit may: Check conformance to defined requirements such as time, accuracy, temperature, pressure, composition, responsiveness, amperage, and component mixture. Examine the resources (equipment, materials, people) applied to transform the inputs into outputs, the environment, the methods (procedures, instructions) followed, and the measures collected to determine process performance. Check the adequacy and effectiveness of the process controls established by procedures, work instructions, flowcharts, and training and process specifications. II- Product audit: This type of audit is an examination of a particular product or service, such as hardware, processed material, or software, to evaluate whether it conforms to requirements (i.e., specifications, performance standards, and customer requirements). III- System audit: An audit conducted on a management system.

It can be described as a documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the system are appropriate and effective and have been developed, documented, and implemented in accordance and in conjunction with specified requirements. A quality management system audit evaluates an existing quality management program to determine its conformance to company policies, contract commitments, and regulatory requirements. Similarly, an environmental system audit examines an environmental management system, a food safety system audit examines a food safety management system, and safety system audits examine the safety management system.

Auditing is defined as the on-site verification activity, such as inspection or examination, of a process or quality system, to ensure compliance to requirements. An audit can apply to an entire organization or might be specific to a function, process, or production step. The purpose of audit should be continual improvement to enhance the performance. To check the completely findings/system improvement. Audit should be for improvement and implementation of the system. Assessor should not tell solution to CAB during audit. Assessor is conducted and selected for assessment from AB and auditor is contacted or selected for audit of the quality management system. Purpose of an audit is to verify the compliance. Who should do assessment/ audit A Dedicated internal auditor, "Part-time" internal auditor, Auditor from sister or parent company, outsource auditing firms or combination of above may be considered for assessment/ audit. Two techniques are used in audit, Horizontal audit and Vertical Audit.

**Horizontal Audits:** Detailed examination of a specific element in the quality management system, does the quality system meet the requirement in ISO/IEC 17025 or other requirement documents. Is it provide compliance between written procedure and practice?. Follow a process from start

to end. Horizontal audit is a normal audit from start to end in other in other words it is a systematic audit.

**Vertical Audits:** A vertical audit is a check of implementation of a specific task throughout the quality management system. It may starts with a contract to a customer for that particular type of task and follow all the way to the T/C certificate looks.

**Vertical Audits Strengths:** Gives a good overview of the implementation of the management system. Evaluation of many requirement elements in ISO/IEC 17025 standard at the same time. Evaluation of the work flow. Often reveals systematic weaknesses.

**Difference between Horizontal Audit: Vertical audit:** Vertical audit is audit in depth in any one clause. Mostly audits conduct are horizontal but it is necessary to take one vertical audit (complete audit).

**Table-1. Benefits of Assessment/ Audit**

To obtain factual information for management decisions
To obtain unbiased management information
To improve communications and motivation
To assist with training
To identify areas of risk
To identify areas of opportunity
To assess performance
To assess equipment status

## MATERIALS AND METHODS

**Assessor/Auditor qualifications:** The success of the auditing program depends significantly upon the selection of the right person for the task, everyone cannot be a good auditor. A good auditor must have some important features like "Good Communication and Interpersonal Skills. Interviewing Skills: Intelligent and skill of pertinent questions and may listen attentively, be vigilant and above all a good decision maker. An assessor/ auditor should have Skills: Ability to assimilate data and determine how it relates to the audit criteria. Analyze information and report results. Training and Experience in Standards, regulations, auditing techniques, audit management skills and Ability to think inside and outside the box may lead a person to be a good auditor.

**Establishing the auditor evaluation criteria:** The criteria should be qualitative (such as having demonstrated personal behavior, knowledge or the performance of the skills, in training or in the workplace) and quantitative (such as the years of work experience and education, number of audits conducted, hours of audit training) [7].

**Selecting the appropriate auditor evaluation method:** The evaluation should be conducted using two or more of the methods selected from those given in the table No. 4. It is mandatory that assessor/auditor possess qualities including; Honesty, Integrity, Impartiality, Good listener, Not talkative, Not giving leading or extra questions (don't tell the prior information regarding own experience), Positive, Open minded and Punctual.

**Auditor's Responsibilities:** Preparing the audit plan, Communicating and clarifying audit requirements, Evaluating the system, Documenting the observations, Reporting and maintenance of reports, Verifying corrective actions, (Audit team: decide who will do what), Advice/multiple suggestion, Highlight opportunity for improvements. Assessor should use 3Cs. Clear, Concise, Complete.

Every sentence in report should be clear. To find facts during audit of the body report should be informative. Auditor shall be able to Plan and organise the work effectively, Conduct the audit in a timely manner, Prioritise and focus on matters of significance, Collect information through effective interviewing, listening, observation, reviewing documents, records with the people themselves and deputies, Verify the accuracy of collected information, Confirm the sufficiency and appropriateness of objective evidence to support audit findings and conclusions, Understand the appropriateness and consequences of using sampling techniques, Record audit activities through work documents and hold information confidential, Communicate effectively.

Auditor shall have the Personal Qualities to Point out and report all the non-conformities he can disclose, and be able to make these observations acceptable, Remain firm in his opinions, despite pressure to change the objective evidence, Loyal to the policies. Open minded, Patient, be calm and courteous, should be punctual, precise and prepared; watch your time, Interested in what he/she is doing, Persistent, be determined, decisive and direct, Professional attitude, Good auditor (knows how to listen), Honest, fair and human, Good judgements, Systematic, analytical, Good appearance, Diplomatic, disciplined, Communicative on all levels.

## RESULTS AND DISCUSSION

There are some major root causes for Quality problems in which, Lack of Organisation, Lack of Training, Lack of Discipline, Lack of Resources, Lack of Time, Lack of Top Management Support. Assessor/auditor should start the assessment/audit ask for the; Master list of the relevant documents, List of authorizations so that you can select a representative sample of people for interview and demonstration, List of equipment to check their maintenance and calibration record or any other important list. During assessment/audit make use of Checklist and write any useful information on the checklist then, follow checklist carefully to cover all relevant clauses. Use checklist for recording evidences.

**Table 2. Definition of different terms**

Terms	Definitions
Assessment	Procedure to the competence on the basis of standards or other technical regulations for a certain scope of accreditation
Audit	systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled
Assessor	Person charged by an accreditation body to do an assessment of a conformity assessment body alone or together with other assessors in a team
Auditor	person who conducts an audit
Lead Assessor	Assessor taking the total responsibility for the assessment
Technical	Assessor taking the technical aspects of an assessment into account (e.g. Test methods) in relation with the scope OR person who provides specific knowledge or expertise to the audit team
Assessor/Expert	Assessor responsible for the evaluation of the Quality Management System of the conformity assessment body

**Table 3. Auditor's skills [7]**

Systematic: always carried out according to the same plan (procedure, checklist)
Independent: independent competent personnel
Documented process for obtaining evidence and evaluating it objectively
No influence/free from the influence.
NC may write after completely investigation/digging of clause.

**Table 4. Possible evaluation methods [7]**

Evaluation method	Objectives	Examples
Review of records	To verify the background of the auditor	Analysis of records of education, training, employment, professional credentials and audit experience
Feedback	To provide information about how the performance of the auditor is perceived	Surveys, questionnaires, personal references, Testimonials, complaints, performance evaluation, peer review.
Interview	To evaluate personal behaviour and communication skills, to verify information and test knowledge and to acquire additional information	Personal interviews
Observation	To evaluate personal behaviour and the ability to apply knowledge and skills	Role playing, witnessed audits, on-the-job performance
Testing	To evaluate personal behaviour and knowledge and skills and their application	Oral and written exams, psychometric testing
Post-audit review	To provide information on the auditor performance during the audit activities, identify strengths and weaknesses	Review of the audit report, interviews with the audit team leader, the audit team and, if appropriate, feedback from the auditee.

Table 5. Principles of Auditing (7)

Integrity	The integrity of internal auditors establishes trust & so provides the basis for reliance on their judgment.
Fair Presentation	Audit findings, audit conclusions and audit reports should reflect truthfully, objective, timely, clear, complete and accurately the audit activities.
Due Professional care	Auditor should exercise due care in accordance with the importance of the task they perform and the confidence placed in them by the audit client and other interested parties.
Confidentiality	Internal auditors respect the value and ownership of the information they receive do not disclose information without appropriate authority unless there is a legal or professional obligation to do so.
Independence	Auditors should be independent of the activity being audited wherever practicable, and should in all cases act in a manner that is free from bias and conflict of interest.
Evidence-based approach	Internal auditors apply knowledge, skills & experience needed

Checklist is useful to keep track of clauses of ISO standards. It is necessary to make use of checklist before assessment/audit. If assessment schedule is more than one day then write points of report. Keep on typing parts of report to save time. Before initiate of assessment/audit it is necessary to read the previous reports and NCs for follow-up, if needed. A poor quality report is miser in using words, everything is ok or bad, no description of findings and no evidence mentioned to describe a situation. A good report is that which has all the necessary details as per standard. Report should evidence based.

Highlights both positive and negative aspects of the CAB/CB only for the improvement of CAB/CB. Report gives a pen picture of an occasion for a reader who was not there but easily understands the situation. The CAB/CB have quality control procedures for monitoring the validity of all activities in the accredited/certification scope. The resulting data are recorded in such a way that trends are detectable. Control charts are maintained for activities including XYZ, ABC, TYU. The monitoring is a planned activity where participation in proficiency-testing programmes is done on regular basis. Regular use of certified reference materials and/or internal quality control using secondary reference materials is also practiced. Furthermore triplicate testing is practiced in routine. The CRM s are available for X, Y, Z of XFD with certificates supplied by the company.

**Assessor/ auditor should read and aware from PNAC policies including:** Guidance on the use of PNAC's Logo as Accreditation Mark; G-02/02. Grading non-conformities; G-02/03. Calibration of Weighing Machines and Weights of Testing Labs; G-02/05. Calibration of Thermometers in Connection with Accreditation of Testing Labs; G-02/06. Policy on Method Validation; G-02/11. Policy on Accommodation and Environment; G-02/12. Policy for Participation in Proficiency Testing; G-02/13. Policy on Assuring the Quality of T/C Results; G-02/14. Policy on Traceability of Measurement; G-02/15. Policy on Conflict of Interest, Confidentiality, Intellectual Property and Duty Loyalty; G-05/02 (8)

## Conclusion

An assessor/auditor have responsibility to complete the assessment/ audit in time, must update the management about the importance and the criteria of the assessment in the opening meeting and then keep updated the CAB representative during the assessment. At the end assessor must take the management of the CAB in confidence about the outcomes of the assessment like observation and non-conformances. A good Assessor must have good communication skills, good convincing skills, good writing and explain skills, must be a good listener and have a good blend of suitable words while questioning the CAB personnel. Overall an assessor must a good manager, planner and situation handler. Proper knowledge and experience and additional qualities of the assessor/auditor.

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