Accreditation of conformity assessment bodies in the field of environmental testing in India

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Abstract: The assessment of conformity assessment bodies (CABs) in the field of environmental testing is conducted as per ISO/IEC 17,025:2017 by the accreditation bodies (AB). All the environmental testing CABs are required to face the assessment for getting accreditation as per the applied scope of accreditation for the testing of air, water and soils samples. The CABs may undertake the testing of various samples as per the facility available within the CAB. The testing of environmental parameters can be segregated into three discipline, namely biological testing, chemical testing and mechanical testing. The techniques of assessment for the applicant CABs and accredited CABs can be divided into two categories, off site assessment and onsite assessment. The types of assessment adopted by the accreditation bodies (AB) can be different at different stage based on the requirement of the economic environment of the country. In this paper, the various types of assessment techniques along with the national accreditation processes in India are discussed.

Keywords: Accreditation; Conformity assessment; Conformity assessment body; Remote assessment

1. Introduction

Assessments are an integral part of accreditation as per ISO/IEC 17,025:2017, and without assessment, the accreditation process cannot be completed. Any environmental testing CAB either applicant or accredited has to face the assessments to maintain the accredited status. Assessment can be divided into two categories, namely, onsite and offsite. In offsite assessment, the documents are reviewed without visiting the premises of the CAB and recommendations are given accordingly. On the other hand, onsite assessment is conducted at the premises of the CAB and most of the time; test witnessing is the part of the onsite assessment. There are various types of assessments mentioned in the standard, and most of the assessment techniques are followed by the accreditation bodies for giving accreditation to the environmental testing CABs in the country. However, the nomenclature of the type of the assessment is not exactly matching with the related standard, but the process is totally followed on the basis of the standard (Fig. 1).

Due to globalization and regularization, various environmental parameters are required to be tested and the importance of accreditation is increasing day by day. The CABs in the field of environmental testing are increasing every year. Due to the global acceptance of results produced by accredited CABs, every CAB wants to be accredited by the accreditation body. There are three main components, i.e., accreditation, accreditation body and conformity assessment body, are required to establish the competence of the CAB. These terms and other relevant terms are defined below [1]:

Accreditation Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Accreditation body Authoritative body that performs accreditation.

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Conformity assessment body (CAB) Body that performs conformity assessment activities that can be the object of accreditation. In India accreditation is a voluntary program. Any CAB can apply for accreditation in the field of testing to the accreditation body which undertake accreditation of environmental CABs as per ISO/IEC 17,025. The list of accreditation bodies is given in Table 1.

The approximate time taken for the accreditation of applicant CABs by the accreditation body in India is ranging normally from 3 to 6 months. As accreditation is a two-way process, therefore the time of accreditation is depending upon the promptness of applicant CABs as well as on accreditation body. The CABs can be divided into two categories, applicant and accredited CABs. Applicant CABs are the CABs that apply for the first time for accreditation, and accredited CABs are those CABs which are already accredited. The applicant CABs may apply to the accreditation body. In case, the applicant CAB wants to apply in NABL for fresh accreditation, then the applicant CAB needs to apply on the portal of NABL. The link for the new application is available on the website of NABL. The applicant CAB needs to provide all the required information on the portal and need to upload the required documents related to the legal identity, GST number, organization structure, etc. The accreditation is given for a fixed time period based on the compliance of ISO/IEC 17,025:2017 standard [2].

Proficiency testing Evaluation of participant’s performance against pre-established criteria by means of inter-lab comparison.

Inter-lab comparison Organization, performance, and evaluation of measurements or test on the same or similar items by two or more CABs in accordance with predetermined conditions.

Certified reference materials (CRM) Reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a reference material certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability [3].

Non-conformity Nonconformity is a failure to meet one or more of the existing requirements of the standards (Table 2).

2. Methodology

There are various types of assessment techniques given in the ISO/IEC 17,011:2017-Conformity Assessment-Requirements for accreditation bodies accrediting conformance assessment bodies [4], remote assessment, witnessing, document review, file review, measurement audits, review of performances in proficiency testing and other inter-lab comparisons, validation audits, unannounced visits and Interviewing. There are certain techniques that are used in parts, and some are used in totality. The assessment techniques used for accreditation can be discussed for applicant CABs and accredited CABs. Generally, accreditation processes in environmental CABs are carried out in the following steps/flow diagram.

There is a two-way communication between the accreditation body and the CAB. The accreditation may ask for any type of additional information which is required for the assessment. Similarly, CAB may get information about any kind of clarification related to the accreditation process.

2.1. Applicant CAB

When any CAB applies for accreditation for the first time, it will be considered an applicant CAB. The assessment techniques applied for the applicant CAB are started when the CAB sends its application to NABL. At the very first stage, there is a review of documents.
2.1.1. Scrutiny of application

The scrutiny of the application consists of the completeness of the application filed for accreditation by the applicant CAB. There is certain information required in the application, and this information is provided by the CAB, and completeness is reviewed by NABL. The document review of the applicant CAB includes name and address, legal identity, personnel, qualification of personnel, training, proficiency testing (PT)/Inter-lab Comparison (ILC) participation, information about reference standards/Certified reference materials (CRMs), calibration status/validity, details of Internal audit, management review meeting and management document/Quality manual, etc., of the CAB.

If there is any gap found during the document review, CAB is informed and 30 days’ time is given to the CAB to address the gap.

If everything is found in order during the scrutiny of application, the next stage of the assessment will be done. This type of technique can be considered file review.

2.1.2. Review of document

Review of documents is done by the empanelled assessor of NABL, the assessor who will conduct the review of documents must be Lead Assessor (LA). There are various types of assessors empanelled by NABL, and these categories are Lead Assessor (LA), Technical Assessor (TA) and Technical Expert (TE). The person who qualified for assessor training as per ISO/IEC 17,025:2017 is empanelled as TA and after completing a certain number of assessments, a TA is promoted to LA.

The document review is done by the LA by avoiding any type of conflict of interest. The conflict of interest means there is no association or affiliation of the CAB and the LA in any manner.

During the document review, the LA thoroughly checks the completeness of the application, and the main focus is on the management document/quality manual. The main purpose of the adequacy of the quality manual is to see whether the CAB has mentioned its policy and objectives along with the requirements of ISO/IEC 17,025:2017. Also, there are certain requirements that are needed by the quality manual. These are organization structure and the block diagram of the CAB.

If all the clauses of ISO/IEC 17,025:2017 are properly addressed, quality policy and objectives are well defined in the quality manual. In case, there is any inadequacy, it will also be reported to the NABL. The NABL representative will inform to the CAB, and a specific time limit will be given to the CAB to address these inadequacies. The action taken by the CAB will be sent to the LA, and once LA
accepts the corrective action taken by the CAB, then the next stage of assessment will proceed.

2.1.3. Pre-assessment

The pre-assessment is optional, and it depends upon the CAB whether they opt for pre-assessment or directly go for the final assessment. Pre-assessment is onsite activity, preferably a LA visits the CAB premises for one day, and the purpose of this visit is to check the preparedness of the CAB to face the assessment. Also, during this visit, LA comes to know the operations, policy, accommodation, and environmental conditions of the CAB, scope of accreditation and number of employees available with the CAB, calibration status of reference instruments and validity of CRM, PT/ILC participation in the applied scope of Accreditation. By getting familiar with the above, the LA is able to decide the number of TAs required for the final assessment of the CAB, the number of man-days required to perform the final assessment of the CAB. If any specific arrangement is required for site witnessing, it may also be communicated to the CAB during the pre-assessment visit so that CAB can prepare well during the final assessment visit.

If any non-conformity (NC) is found during the pre-assessment visit, it will be informed to the CAB.
and 30 days’ time will be given to the CAB for taking the corrective action to close the particular non-conformity. The corrective action will be communicated to the LA, and it will review the corrective action and close the NC. After the closure of the NC, CAB is ready to face the final assessment.

2.1.4. Final-assessment

On the basis of recommendation of pre-assessment (if conducted) or scope applied by the CAB, the team will be constituted on the basis of the scope applied by the CAB and the expertise of the TA and LA. The assessment team will be headed by LA or LA and TA along with TA. Time duration of the final assessment will be preferably of two days, and in some special cases, it may be extended for more than two days as per the applied scope of accreditation. The formation of the team will depend upon the scope of accreditation applied by the CAB. For example, a CAB has applied for water testing (Chemical and biological), soil testing (Chemical and Biological), and air monitoring.

The scope of the CAB applied is water, air, and soil, and the team required for conducting the assessment will be as follows:

- LA or LA and TA-overall head.
- TA-water (Chemical)-Environmental Testing.
- TA-water (Biological)-Environmental Testing.
- TA-soil (chemical)-Environmental Testing.
- TA-Soil (Mechanical)-Environmental testing.
- TA-soil(biological)-Environmental Testing.
- TA-air monitoring-Environmental Testing.

In this way, for the final assessment, seven assessors are required to conduct the assessment of the CAB.

The scope of the environmental CABs can be further distributed into the following sub-groups:

The number of assessors will be decided upon the number of sub-groups applied by the CAB. Most of the time, it has been noticed that for different disciplines and different groups, there will be different TAs. Sometimes, there can be a different TA for the different sub-groups. In this way, there are number of TAs who conduct the assessment for the CAB. The greater number of TAs enhances the cost of conducting the assessment. Also, there are some times similar groups and if the CAB is found competent in one sub-group, then same TA may be asked to see the demonstration of similar sub-groups to cut down the cost of the assessment. The sampling of the demonstration needs to be re-organized in such a way that if the CAB is competent in one group, then the CAB may be given accreditation for a similar group based on the availability of traceability and reference standards.

During the final assessment, the applied groups and subgroups may be witnessed for critical parameters along with management system requirements. The system requirements will be taken care of by the LA or LA & TA, and technical demonstration will be taken care of by the respective TA. The results of PT/ILC participation will be reviewed by the respective TA and LA. A collective report on the recommendation will be prepared by the LA, and it will be given to the CAB along with the number of NCs raised (if any). Specific time limits will be given to the CAB to close the NCs. All NCs corrective action will be sent to the respective assessor, and the assessor will comment on the corrective action. When NC is closed by the assessment team, the assessment is reviewed by the accreditation committee.

2.1.5. Accreditation committee

A committee of subject matter experts along with chairmen review the report of the CAB for a final decision on granting the accreditation to the CAB. All the members are independent and do not have any conflict of interest. Independent means the committee members have never part of the organization and have not provided the consultancy in any form. Committee members will be selected on the basis of their technical expertise, and they are the senior assessors having long experience in the field of testing and preferably participated in a reasonable number of assessments.

The committee will review the test witness during the onsite assessment and the scope recommended by the assessment team. PT/ILC results will also be reviewed, and NCs raised during the assessment along with corrective action taken by the CAB will also be reviewed by the committee.

Once the committee is satisfied, the decision on granting the accreditation is taken and accordingly information is given to the CAB.

On the other hand, if the committee is not satisfied, they may ask for clarification for a particular thing. The same will be communicated to the CAB with a specified time limit to respond to the clarification.

Sometimes, decisions cannot be taken only on the basis of clarification; in that situation, a supplementary audit may be recommended, and on the basis of the outcome of supplementary audit, decision on accreditation will be taken by placing the report again in the committee.

2.1.6. Supplementary audit

When it is not possible to take a decision on accreditation in the particular group, then a supplementary audit may be sought by the accreditation committee. For example, a
CAB has applied for water testing (Chemical and Biological), soil testing (Chemical and Biological), and air monitoring. When the report was reviewed by the accreditation committee, it was found that an oven was not working which was used in soil testing. NC was raised and also closed by the assessment team, but accreditation committee feels that after repair and calibration of the oven, the competency of the test related to the oven needs to be established. In that case, supplementary audit for soil was sought. In this case, a technical assessor can be deputed for supplementary audit. The outcome of the supplementary audit will be reviewed by the accreditation committee again, and a final recommendation on the accreditation will be given accordingly.

2.1.7. Desktop surveillance

Every CAB is given accreditation for two years, staring from issue date valid till the next two years, and from the 10th to 12th month from the issue date of the certificate, the CAB required to submit the documents for desktop surveillance to the accreditation body for a continuation of the accreditation. The documents required for conforming to the requirements of desktop surveillance are the status of non-conformities raised during the last onsite assessment whether it is final assessment or re-assessment regarding the implementation of the effectiveness of corrective action, a summary of internal audit and management review meeting, any complaint received by the CAB and their resolution, details of PT/ILC participation and initiation by the CAB and result of participated PT/ILC, details of the reference standard, CRM and other equipment maintained by the CAB, details of training provided to the personnel of the CAB, any major change in the legal identity, ownership, top management, key CAB personnel, policies resources, premises of the CAB, major test equipment and authorized signatories, etc.

The information provided by the CAB will be reviewed by the accreditation committee, and accreditation will be continued if the accreditation committee is satisfied with the information provided by the CAB. However, if a committee is not satisfied with the information provided by the CAB, a supplementary audit may be sought by the accreditation committee.

2.2. Accredited CAB

The CAB which is accredited first time for two years and successfully completed the desktop surveillance and got the continuation for complete cycle of 2 years needs to apply for renewal of accreditation before six months of expiry to maintain the continuity of the accreditation. After completion of the first cycle, CAB will be considered as an accredited CAB and the process of assessments will be as follows.

There will be scrutiny of application in the same way as done earlier for the applicant CAB, but a review of documents and pre-assessment is not required in the case of an accredited CAB. After scrutiny of an application, direct re-assessment will be conducted for renewal of accreditation.

2.2.1. Re-assessment

This activity is an onsite activity and the team again formed on the basis of the scope of accreditation applied by the CAB. The CAB may enhance its scope of accreditation, and a team of assessments will be assigned as per the existing and enhanced scope (New addition of scope).

The only difference between the final assessment and re-assessment is that the assessment team may do the sampling, they can exclude some parameters from the witness on the basis of previous witnesses and also some of the parameters which are not critical may also be excluded from the witness. The assessment should be preferable in such a way that no repetition from the previous assessment team to avoid any conflict of interest. The time duration will be two days, and enhanced scope shall be witnessed by considering the critical parameters.

The report of the assessment will be reviewed by the accreditation committee.

2.2.2. PT/ILC participation

The scope of accreditation is not given only on the basis of the technical demonstration but after successful participation in PT/ILC [5] to support the applied scope.

2.2.3. Unannounced visit

To check and maintain the quality of the CAB, unannounced audits are also conducted by NABL. The unannounced audits are performed by the lead and technical assessors, and the CAB comes to know about the unannounced audits only in the morning and the assessor reached the premises of the CAB in the morning hours. The unannounced audits are conducted on a sampling basis, or sometimes some information come from some stakeholder, client of the CAB, and sometimes a specific sector. The report is again reviewed by the accreditation committee.

2.2.4. Other assessments

There is another type of assessment like remote assessment, measurement audits that are very rarely used by the accreditation bodies. Remote assessment is conducted when physically it is not possible and as per ISO/IEC
17,011:2017, it can be defined as “Assessment of the physical location or virtual site of a conformity assessment body using electronic means.” A virtual site is an online environment allowing persons to execute processes, e.g., in a cloud environment. As the visit of assessment site due to some calamity or due to some other problem in that situation, video conferencing can be used for remote assessment. Due to the tough situation of COVID-19 in most cases, it was not possible to go onsite for assessment. In that case, remote assessment is the most powerful tool to assess the CAB. The remote assessment can be conducted on google meet or any other platform. In the remote assessment, the CAB provides a link of the meeting to all the assessors. In case, there is more than one assessor, the link of the meeting can be separate. For example, there are two assessors for the assessment of CAB, and the scope of the CAB is water under chemical and biological. There are two assessors, one is for biological and another is for chemical. The CAB needs to send a separate link for conducting the assessment of the CAB. The requirements for the remote assessment are good quality of internet connection, laptop or mobile phones, etc. The remote assessment has many advantages in comparison with physical assessment. The remote assessment is cost-effective, time-saving and accreditation bodies can have better control in the case of any dispute between the CAB and assessment team. The representative of the accreditation body can join the assessment at any time and can see the quality of the assessment. The boarding, lodgings, and travel costs of the assessment team are saved in the remote assessment. The disadvantage during the remote assessment can be poor connectivity of the internet, and sometimes, it is very difficult to see the demonstration of the technical competence of the CAB due to the complexity of the testing procedure.

Measurement audits are conducted by the accreditation body to check the capability of the CAB. In this type of assessment, the known value artifact is given to the CAB and the value observed by the CAB is compared with the already known value.

3. Recommendations

There can be multiskilled TA who can cover the biological, chemical, and mechanical scope of the environmental testing CABs in the country. Also, the TA should be developed in such a way that one TA can cover most of the sub-group applied by the environmental CAB. The accreditation body needs to focus on the development of the multiskilled TAs from the various government and private organizations. There are many organizations where multiskilled assessors can be developed for the assessments of the environmental CAB to cut down the assessment cost. A sampling of the assessment should be done in such a way that it represents similar subgroups to avoid the repetition of the witness during the onsite assessment.

The online assessment should be continued even after the COVID-19 pandemic, for the cost-saving, and there can be a mixed assessment, i.e., onsite and online assessment to make the assessment more effective and cost economic.

4. Conclusion

There are two types of CABs categorized in the field of environmental testing CABs, namely applicant and accredited CABs. Applicant CABs are those which apply for first time for accreditation. On the other hand, accredited CABs are CABs that apply for the renewal of accreditation. There is a specific accreditation cycle of two years, and after every two years, CAB needs to face the assessment for the renewal of accreditation.

There are three disciplines namely, biological, chemical, and mechanical in the environmental testing CABs and four groups, namely, environmental pollution, atmospheric pollution, water and soil and rock. There are fifteen subgroups in biological, nineteen in chemical, and three in the mechanical discipline.

The cost of the onsite assessment is very huge to cover all the disciplines by the different TA.

It is evident that there are two types of assessment techniques used by the accreditation body, namely, onsite and offsite. Both the techniques are essential for the accreditation of the CAB whether the CAB is accredited by an applicant. Scrutiny of application, review of document, Accreditation Committee, Desktop Surveillance can be categorized under offsite assessments techniques. On the other hand, Pre-assessment, Final-assessment, Supplementary audit, Re-assessment, and Unannounced visit can be categorized under onsite assessment techniques. Also, assessment techniques adopted by the accreditation body depend upon the requirement of the operating environment of the country. The multiskilled assessors need to be developed by the accreditation body.

A sampling of the witness during the assessment is to be redefined so that it may represent similar subgroups.

The remote assessment is a very useful technique, and it has been observed that during the COVID-19, more than 5000 assessments were conducted during the pandemic for all types of CABs. Also, there were many CABs in the field of environmental testing which were accredited during the pandemic by using remote assessment techniques. For cost-cutting and better control over the assessment process of the CAB, the accreditation bodies may continue remote
assessment after the pandemic. The accreditation body may continue remote assessment with physical assessment. The mixed type of assessment, remote and onsite may be done by the accreditation bodies. The remote assessment techniques will be the future of conformity assessments. The mixed type of assessment, physical and remote assessment can be the tool of cost-cutting and time saving for the accreditation process.

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