



**Accreditation Education Research & Scientific Service Center,
Nepal**

Assessors Guide

Document No. – AERSSC 29

Issue No.: 11

Issue Date: 31st March 2024

Amendment No.: 0

Amendment Date:



Amendment Records

S. No.	Page No.	Section No.	Issue Date	Issue No.	Revision Detail



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1. Introduction

Accreditation Education Research & Scientific Service Center, (AERSSC) provides third-party accreditation to Conformity Assessment Bodies according to international standards. AERSSC is committed to ensuring that the accreditation requirements and assessment system for CABs are in line with international norms and practices.

AERSSC assures itself of the competence of the CAB it accredits through a system of assessment in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical Laboratories- Requirements for Quality and Competence. The assessment is carried out by a team of Assessors, led by a Team Leader, empanelled by AERSSC.

The assessment is carried out systematically on all aspects of technical competence and CAB's management system. The objective evidence so collected forms the basis:

- for arriving at a judgment for recommendation of the team on grant, continuation, or renewal of accreditation,
- to specify the competence of CAB in terms of its capability to perform the activities for which it is seeking accreditation or holds accreditation

The objective of the assessment, however, is not to compile non-conformities as evidence to justify the denial of accreditation in case of a negative recommendation.

This Guide has been published to assist Assessors in conducting assessments for AERSSC. It describes the role of an Assessor in conducting the Assessment-related activities for AERSSC. The methodologies being described are basically to help an Assessor to be able to discharge his / her responsibilities effectively. Since an Assessor would be representing AERSSC during the assessment of a Conformity Assessment Bodies, (s)he should understand AERSSC and its accreditation process, its objectives, and mission as well as the assessment methodology.

This guide has been prepared based on the general practices followed by international bodies and the experience of experts in the country. This document accordingly aims to:

- a. provides guidance to the Assessors for conducting assessment of a CAB;
- b. ensures uniformity of assessment and reporting; and

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2. Assessor's Role and Responsibility

- 2.1 The objective of any on-site assessment is to obtain evidence of compliance with respect to the ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence' whichever is applicable. The AERSSC Assessor's role is to conduct an assessment of CAB to adjudge the compliance with above Standards.
- 2.2 The Assessor shall also check that the CAB meets other requirements of AERSSC including the AERSSC's Specific Criteria for the relevant field and / or discipline (wherever applicable), Policy Documents and has the competence to perform the specific test(s)/ calibration(s). The compliance of all 'shall' requirements is to be verified. The Assessor shall ensure that (s)he is using the latest documents which are available on the AERSSC website for each assessment. The Assessor shall also pay attention to the specific announcements on website pertaining to policy decisions and its transition period (if any) before proceeding with the assessment.
- 2.3 Since CAB accreditation requires formal recognition of competence to carry out specific test(s) by a CAB, an Assessor has also to consider conformities against these aspects in the assessment. Thus, an Assessor would be required to exercise his scientific & technical judgment and form his opinion regarding the extent of conformity with respect to accreditation criteria.
- 2.4 Assessors are required to maintain confidentiality on the matters/subjects related to CAB.
- 2.5 Notwithstanding the strength of the AERSSC system, the success of the accreditation scheme depends on the Assessors who conduct the assessment. Thus, the Assessors play a vital role in determining the credibility and value of the accreditation.
- 2.6 In case the assessment team members observe gross non-conformities in the documents and their implementation, the Team Leader shall consult with AERSSC to abandon the assessment process.
- 2.7 The Technical Assessor should clearly understand the areas/activities to be assessed by him. He must review the Laboratory's documented system to verify compliance with the requirements of ISO/IEC 17025/ ISO 15189, related AERSSC Specific Criteria and other policies/ guidelines of AERSSC. (S)he should assess to verify that the documented SOPs, test methods, records are indeed implemented & effective, and record observations. (S)he should also complete AERSSC 26 'Assessment Forms and Checklist – ISO 15189:2012', AERSSC 27 'Assessment forms and Checklist – ISO 15189:2022' or AERSSC 28 'Assessment forms and Checklist – ISO/IEC 17025:2017' related to the requirements of respective clauses and using forms available in these documents for recording his/her observations. The Technical Assessor must review and endorse the Measurement Uncertainty / % CV calculations for each test/ parameter witnessed. In case a Technical Expert is a member of the team, the Technical

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Assessor has to provide information to the Technical Expert regarding AERSSC forms and policies and guide him during the assessment. NC identified by the Technical Expert will, however, be raised by the Team Leader.

- 2.8 The role of the Technical Expert is the same as that of the Technical Assessor, except that he will seek guidance from the Technical Assessor in filling the relevant forms, checklist etc. A technical expert is not allowed to raise any NC. In case NC is identified during an assessment by TE, it has to be raised by the Team Leader.
- 2.9 The Observer (Potential Assessor) will be assigned to accompany the Team Leader and Technical Assessor(s) as per the schedule provided. (S)he shall be guided by the Team Leader and the Technical Assessor(s).
- 2.10 An Assessor must ensure that (s)he is well versed with:
- Assessment principles including risk-based assessment principles, practices, and techniques,
 - General management system principles and tools,
 - Applicable standard (ISO/IEC 17025 ‘General Requirements for the Competence of Testing Laboratories’ or ISO 15189 ‘Medical Laboratories – Requirements for Quality and Competence’),
 - Other relevant Specific criteria documents, and
 - AERSSC policy documents before the visit to Conformity Assessment Bodies (CABs).
- 2.11 Considering improvement as a continuous process, the assessor is required to enhance the following knowledge and skills on an ongoing basis:
- Understanding the knowledge of practices and processes of the Conformity Assessment Body business environment,
 - Communication skills,
 - Note-taking and report-writing skills,
 - Opening and closing meeting skills,
 - Interviewing skills,
 - Assessment Management Skills



3. Assessor Assignment Procedure

- 3.1 Whenever required, AERSSC shall constitute the assessment team and inform the CAB about the proposed assessment team. CABs have the right to object to the appointment of a particular Team Leader/ Technical Assessor, and in such cases, AERSSC may offer an alternative to the extent possible, if the reasons given by the CAB are acceptable to AERSSC.
- 3.2 Assessors are chosen to the extent possible from the empanelled list of Assessors maintained by AERSSC based on individual's technical expertise vis-à-vis a CAB's requested scope of accreditation. The number of Assessors in the team shall depend on the range and volume of scope involved. For multi-disciplinary CAB, Assessors shall be selected in such a manner so as to cover each discipline and its range/ scope of operation.
- 3.3 Team leader/ Technical Assessor(s) are informed after the CAB has agreed to the members of the Assessment Team.

4. Procedure for Assessment of CAB

- 4.1 AERSSC appoints a Team Leader and sends CAB's Management System Document / Quality Manual and application(s) to the Team Leader.
- 4.2 The Team Leader shall examine the Management System Document / Quality Manual and application(s) and shall submit the Document Review / Quality Manual Adequacy Report to AERSSC within 10 days.
- 4.3 Once the CAB satisfactorily addresses the inadequacies of the Document Review / Quality Manual Adequacy; AERSSC appoints Team Leader and plans the pre-assessment (if opted by the CAB) in consultation with the Team Leader and CAB.
- 4.4 The Appointed Team Leader has to undertake a Pre-Assessment visit to CAB to assess the Management System and the quantum of work, and take the following actions:
- 4.4.1 The Team Leader has to check the readiness of the CAB for final assessment.
 - 4.4.2 The Team Leader shall share a copy of the report to the CAB covering areas of inadequacies and actions to be taken by the CAB as mentioned in the forms given in AERSSC 36 'Pre-assessment Forms and Checklist' and submit the report to AERSSC.
 - 4.4.3 The Team Leader has to provide comments on the corrective actions based on root cause analysis taken by the CAB on NCs raised (if any) at the earliest.
 - 4.4.4 In case there is no inadequacy or CAB has satisfactorily closed the NCs, the Team Leader has to recommend for final assessment.
- 4.5 AERSSC takes acceptance of the CAB on the members of the assessment team and dates of assessment. A CAB can object to any member(s) of the assessment team with valid justification. After the dates and assessment team members are accepted by the CAB, communication is sent to the assessment team.



- 4.6 AERSSC provides a copy of the application, Management System Document / Quality Manual and previous assessment summary (wherever applicable) to each Assessor.
- 4.7 The Assessor may also seek any further information like test procedures etc. from the CAB, to better prepare for their assigned areas of responsibility.
- 4.8 The assessment team has to verify the continued compliance of corrective actions taken by the CAB against NC related to violation of AERSSC 37 'Agreement between AERSSC and CAB' & AERSSC 17 'Policy for Use of Accreditation Symbol', if raised during the previous assessment and report to AERSSC.
- 4.9 To the extent possible, the assessment shall be completed in one phase, even for multi-disciplinary CABs. There shall be only one Team Leader for the entire assessment. For large and multi-disciplinary CABs, it may not be possible to conduct the assessment in one phase and may be completed in two or more phases (Split Assessment).

5. Pre-Assessment

5.1 Objective

5.1.1 The objective of a Pre-Assessment visit carried out by AERSSC is:

- i. to have a better understanding of the documentation;
- ii. to familiarize with the facilities, sites/location, and circumstances and to have better knowledge of operations;
- iii. to make the methodology to be adopted for the assessment;
- iv. to check the preparedness of the CAB to undergo assessment;
- v. to review the scope of accreditation and to ascertain the requirement of the number of assessors/experts and the duration of the assessment. The Team Leader must take into consideration the traveling distance and time required for visits to different sites and also for witnessing site activities.

5.2 Visit

During the Pre-Assessment visit made by the Team Leader, the following actions should be carried out in every case:

- i. explaining the purpose of the assessment, the tasks of Assessors and making clear to the CAB the methodology to be adopted,
- ii. explaining the obligations on the part of the CAB to confirm by demonstration that the management of the CAB understands the procedures,
- iii. reviewing the management system documents including the availability of standard operating procedures to cover the tests/measurements that it is carrying out, Internal Audit & Management Review reports,
- iv. reviewing the scope of the accreditation,
- v. reviewing the traceability of equipment and reference standards,
- vi. Proficiency testing,
- vii. giving an overview of the accreditation process,

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- viii. Informing CAB about non-conformances, if any, and the number of days by which the corrective actions are to be submitted to AERSSC and share a copy of the report with the CAB.

6. On-Site Assessment

- 6.1 Before the assessment, the Assessment Team shall interact and plan the assessment program. This shall include the distribution of work amongst the Assessors. The format of the assessment plan to be finalized is given at F15(b/c/d) of the relevant checklist. The time schedules in the assessment plan shall be realistic so that each activity can be completed as scheduled. The team Leader shall ensure proper time management of the team members during the assessment.
- 6.2 Opening Meeting
- 6.2.1 To begin with the Team Leader and the team shall have an opening meeting with CAB representatives where the team and the CAB personnel will introduce each other and clarify their roles and responsibilities.
- 6.2.2 The Assessment team should get acquainted with the CAB, the departments/ sections and their location(s).
- 6.2.3 The Team Leader should make it clear in his opening remarks that the object of the assessment is to assess the work of CAB according to ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189: 'Medical laboratories - Requirements for Quality and Competence'.
- 6.2.4 The Team Leader shall ensure that (s)he explains the purpose of the assessment, accreditation criteria, assessment schedule/ plan, scope for the assessment, accreditation process, reporting etc. and what is expected from the CAB during the assessment.
- 6.2.5 The Team Leader shall confirm the changes/updates on scope, the person proposed by CAB to review, report, and authorize the results and express opinion and interpretation (wherever applicable), equipment etc.
- 6.2.6 The Team Leader shall present the assessment plan F15 (b/c/d)] to CAB representatives. The CAB is to be requested to assign a coordinator to accompany each Assessor.
- 6.2.7 The Team Leader shall assure the CAB that all findings will be treated in strict confidence.
- 6.2.8 The Team Leader shall inform the CAB that the team members shall not be approached by the CAB for closure of NCs during the assessment and the response to the closure of NCs has to be sent by CAB after conducting root cause analysis.
- 6.2.9 The Team Leader shall obtain the signatures/ endorsement of all participants of the opening meeting in F08 'Attendance Sheet' of the relevant checklist.

Note: The assessment team should spend considerable time for the opening meeting specially to explain the objectives and scope of the assessment.



6.3 On-site Assessment Procedure

- 6.3.1 The Assessment Team shall proceed to various sections of the CAB as planned earlier.
- 6.3.2 Assessors must be objective and should not convey the impression of having superior knowledge and judgment.
- 6.3.3 Assessor(s) should thoroughly examine the technical competence of the CAB in terms of manpower, qualification, experience, up to date knowledge, equipment and other related elements. Assessor(s) shall also verify the confidentiality by CAB personnel including those on contract / outsourced.
- 6.3.4 While interviewing the CAB personnel, the assessors should create a comfortable environment to gather all information needed to accurately evaluate the competence of the CAB.
- 6.3.5 The technical competence of the CAB personnel could be verified by examining their qualification, experience, training relevant to the job/ responsibilities assigned and observations during the activities related to the scope of accreditation.
- 6.3.6 The Assessor shall interview the person proposed by the CAB for personnel who are responsible for reporting, reviewing, and authorizing the results of the CAB and for opinion and interpretation on the following criteria:
 - i. Knowledge of relevant CAB accreditation standards,
 - ii. Technical knowledge of the relevant scope
 - i. Qualification and experience
 - ii. Position in overall staff structure.
 - iii. Familiarity with the calibration or test and awareness of any limitations of these procedures.
 - iv. Knowledge of the procedures for recording, reporting and checking results.
 - v. Awareness of the need for periodic re-calibration of equipment, where applicable.
 - vi. Awareness of the requirements and conditions for AERSSC accreditation.
- 6.3.7 Test methods used by the CAB should be in accordance with those prescribed by National / International organizations. Other methods could be accepted, provided they are properly documented, controlled and appropriately validated.
- 6.3.8 Assessors should ascertain that the measuring capability of the instrument/ equipment used by the CAB is commensurate to the ranges in which it claims to operate its system. This shall be an element in determining the scope of accreditation of CAB.
- 6.3.9 During the assessment of calibration laboratories, the Assessor shall review the capability of the laboratories to make measurements within the uncertainty claimed for each parameter for which accreditation is being sought.
- 6.3.10 During the assessment, if the team finds that work is being sub-contracted, they should inquire into the circumstances and if the practice appears to contravene ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence whichever is applicable, this should be recorded and included in the Assessment Report.
- 6.3.11 For site facilities the assessors shall do a thorough examination of the operation of the management system at the site, normally where testing/calibration for a customer is performed. The assessors shall also assess the testing/calibration competency of the



- on-site staff, with particular emphasis on those tests/calibrations that can only be carried out at site. The same is to be done in case of temporary/ mobile facilities.
- 6.3.12 If the CAB is functioning in shifts; the assessor shall ensure the competence of staff working in shift operations and report the details.
- 6.3.13 Although the assessment must be thorough, the Assessors should avoid giving the impression that they are trying to score points or trap the CAB staff in order to find reasons for rejecting its application. Assessors need to show a positive attitude during the process of assessment. The object of assessment is to ascertain by observations of the activities whether the work of the CAB is being carried out in accordance with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence' whichever is applicable and any other requirements specified by AERSSC.
- 6.3.14 Favourable and adverse notes must be based on objective evidence and be recorded and verified before leaving the area under assessment. To secure agreement on the facts, and to avoid subsequent disputes, Assessors shall record detailed non-conformities as they occur. Each non-conformity shall be acknowledged/countersigned by the accompanying CAB representative or the section in charge.
- 6.3.15 At the time of assessment of the CAB, Assessors will discuss with the CAB staff whether the CAB is participating in any National / International Proficiency Testing, Interlaboratory Comparison Program, their performance and the action taken by the CAB based on root cause analysis, if the performance was unsatisfactory.
- 6.3.16 Checklists provided should be verified and completed during the course of the assessment of the CAB. Checklist(s) are like aid memoirs to Assessors so that all aspects of the CAB management system and technical criteria are taken care of.
- 6.3.17 The assessor shall, during the assessment of the site/mobile/temporary facility of the CAB, verify the effectiveness of the management system and related documents using the audit techniques and shall raise the relevant non-conformity. The Assessor shall use record the findings.
- 6.3.18 Since it is not possible to assess every procedure in operation, Assessors should use his/ her own judgment to select the test/calibration activity for their demonstration. The selection of the test/calibration activity would have to be such that it can help assess the CAB's competence, in terms of equipment and capabilities of experts with equal emphasis on on-site activity / subcontracted activity for such CABs. In doing so, the Assessors shall select items of work in progress, witness measurement and verify documents and record calibrations/tests. The emphasis shall be given to covering critical and important tests/parameters of all the applied/accredited groups/sub-discipline/subcategory in each discipline/ category based on risk analysis.
- 6.3.19 The Assessors are required to witness the conduct of some replicate tests, where applicable, using old samples whose reported results are available to study repeatability and reproducibility of measurements etc. whichever is applicable.
- 6.3.20 In some cases, Assessors may trace back results from previously issued certificates or reports to the original entries in the CAB's registers/ notebooks/ worksheets. Aspects,



that require evidence from some other area of CAB before they can be settled, may be perused for further investigation.

- 6.3.21 Using the checklist, the Assessors shall conduct the assessment and raise non-conformity as may be relevant to record the findings.
 - 6.3.22 At the end of each assessment day, the Team Leader shall consolidate their findings.
 - 6.3.23 The Team Leader shall brief the CAB about the non-conformity(s) noticed by the team. The above would facilitate CAB to take corrective actions on the non-conformity observed.
 - 6.3.24 A formal meeting for de-briefing of each day's findings may not be necessary for small CABs (one with limited scope and resources), where the findings have been conveyed during the day's proceedings.
 - 6.3.25 The Team Leader and Assessors shall individually complete "Assessor's summary of Non-Conformity" which shall be acknowledged / countersigned by the accompanying CAB representative. After the Assessors have completed their individual assessment, a preliminary meeting of Assessment Team is held to summarize their conclusions.
- 6.4 **Compilation of Report**
- 6.4.1 Each Assessor shall prepare his/ her recommendation on the scope to be recommended for accreditation. This has to be based on his/ her observations and verifications during the assessment.
 - 6.4.2 The Team Leader shall consolidate the findings based on the individual Assessor's report(s) including F09b.
 - 6.4.3 The Team Leader shall, in his final report, give the reasons for limiting or partially recommending the scope of accreditation, for test(s) / calibration(s) against those applied. The Team Leader/ Technical assessor must endorse / sign the documents related to scope of Testing or Calibration with the comment 'recommended.'
- 6.5 **Closing Meeting**
- 6.5.1 The Team Leader shall summarize the findings of the Assessment Team and present it to the CAB representative. The Team Leader shall invite each Assessor to summarize his/ her findings.
 - 6.5.2 During the closing meeting, the management representative present shall be asked to suggest a date for completion of corrective action with root cause analysis of all non-conformity and to acknowledge /sign F10b. A copy of this form along with F09b and F31 is to be shared with the representative of the CAB.
 - 6.5.3 The closing meeting is to end with thanksgiving for the cooperation and assistance given by CAB.
- 6.6 **Post Assessment**
- 6.6.1 Team Leader shall send the assessment report along with recommendation to AERSSC at the earliest and in confidence by speed post or by courier service mail or through portal.



6.6.2 Assessor shall provide comments and recommendations for closure of NC(s) raised once CAB have submitted satisfactory corrective actions including root cause analysis with documentary evidence.

6.6.3 In cases when assessor is not able to close the NC, then the assessor should give his/her opinion.

7. Guide to formulate Recommendations

7.1 Where no non-conformities are found, the Team Leader shall recommend accreditation of the CAB.

7.2 The Team Leader shall take into account the nature of non-conformities found during the assessment.

7.3 When non-conformities are found, the recommendation shall be such that accreditation is recommended subject to the satisfactory closure of all non-conformities.

7.4 When in any specific area of testing, competence is not established, but overall, there are no major system failures, the Team Leader may recommend accreditation for all areas except for the non-complying area.

7.5 The CAB management shall be asked to specify the period required to complete the corrective action for non-conformities in line with AERSSC norms.

7.6 Where the number and seriousness of non-conformities found is such that the whole of the CAB's management system and organization is demonstrably inadequate, the Team Leader's recommendations shall be such that accreditation is not recommended. In such cases, the CAB may write to AERSSC about the dissatisfaction / disagreement.

8. Procedure for conducting Closing Meeting

8.1 The purpose of the closing meeting is to enable the team to present the CAB management with a summary of the findings of the assessment and to inform the management about the recommendations that the team will make to AERSSC. Thereafter the decision will be communicated to the CAB by AERSSC.

8.2 The concluding report [F10b] shall be based on the summary report including [F09b] prepared by Assessment Team.

8.3 Closing meeting shall be chaired by the Team Leader in presence of CAB senior management. The Team Leader has to:

- Thank the CAB for its assistance and co-operation. (S)he shall also refer to individuals as may be appropriate.
- Explain the significance of the non-conformities.

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- Ask for questions to be deferred until the findings have been presented, although points of clarification should not be refused.
- Invite each Assessor to summarize his or her findings based on the report, but it should not be discussed in detail. (S)he should present his / her findings as individual Assessor.
- Invite the CAB to specify the date by which any required corrective actions will be implemented. It should be in line with AERSSC norms.
- Provide the CAB with an opportunity to discuss the assessment and answer any questions.
- Apprise CAB with the requirements of AERSSC 37 and AERSSC 17.
- During the closing meeting, the Assessment Team should not enter into debating the validity of their conclusions or recommendations. If these are questioned, the Assessor may, however, enumerate individual non-conformities, which justify the recommendations in question and point out the combined effect of the observations of the assessment. If the CAB is still unwilling to accept the recommendations, the Team Leader should advise them to take up the matter with AERSSC.
- Team Leader shall obtain acknowledgement / signature of those who attend the closing meeting in F08.
- Team Leader shall inform the CAB about the provision of complaint and appeal as per AERSSC 32.

9. Scope of Accreditation

- 9.1 It is AERSSC's policy to define the scope of a CAB's accreditation in line with ISO/IEC 17011. CABs are, therefore, asked to specify in detail the scope for which accreditation is sought in the desired format given in application forms (e.g. AERSSC 33 and AERSSC 34).
- 9.2 Assessor(s) should ensure by discussing with CAB for capability and competence of the CAB to determine and define its scope of accreditation.
- 9.3 Every effort has to be made to reach agreement with the CAB on the content of their scope before the assessment. This is important, not only to avoid possible misunderstandings, but also to help the Assessors to operate effectively, concentrating their attention in those areas of activity appropriate to the scope of Accreditation.
- 9.4 In some cases, as the assessment proceeds, it may become clear that the CAB is not really in a position to achieve accreditation in certain areas within the originally applied scope. In such cases, the Team Leader may be able to recommend accreditation for a suitably reduced or redefined scope and it should reflect in F31.
- 9.5 The applied scope of accreditation by the CAB may be used for this purpose. It should ensure for the elements of accreditation as detailed in F31 are covered. The recommended scope of accreditation shall clearly specify the parameters for which the CAB is performing site activities.

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- 9.6 When CAB refers to handbook type publications like IP, BP, NCCLS, USP, ASTM, AOAC etc. in its scope of accreditation, the assessor(s) shall ensure that relevant clause/ chapter/ page number of the procedure is mentioned.
- 9.7 The Assessors shall diligently verify the status of all test /calibration methods and their revision status while recommending the scope of accreditation. In case of withdrawn test methods, the same shall be clearly mentioned in the recommended scope of accreditation.

10. Procedure for Handling the Management System Document / Quality Manual and other Documents after Assessment

- 10.1 For reasons of ensuring confidentiality of documents of the CAB, the following rule is to be observed:
- 10.1.1 On completion of the assessment visit, Assessors shall return the Management System Document/ Quality Manual, Application and other documents to the CAB wherever applicable.

11. On-Site Surveillance and Re-Assessment

- 11.1 Accreditation is granted for a period of three years. Surveillance of accredited CAB is to be completed on yearly basis.
- 11.2 Surveillance is to ensure that accredited CAB continues to comply with ISO/IEC 17025 'General Requirements for the Competence of Testing and Calibration Laboratories' or ISO 15189 'Medical laboratories - Requirements for Quality and Competence or ISO/IEC
- 11.3 The on-site surveillance or re-assessment team shall be headed by a Team Leader.
- 11.4 The on-site surveillance visit takes place within 12 months of the grant or renewal of accreditation and cover all aspects of the CAB accreditation, such that the entire scope is covered including those of site activities.
- 11.5 AERSSC provides on-site surveillance / re-assessment audit team a copy of relevant parts of the previous assessment report as a background information.
- 11.6 Assessors are required to concentrate particularly on areas where there is reason to believe standards have not been maintained, where non-conformities were observed during previous visits, or where there have been changes in staff. However, all elements of CAB accreditation standard are to be assessed.
- 11.7 Management System Document / Quality Manual will be made available to members of the assessment team by AERSSC prior to the assessment.
- 11.8 If during an on-site surveillance or re-assessment visit, it is found that there have been significant changes, e.g. staff, equipment or the range of services available, these matters shall

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be recorded. Assessors shall check that the changes are not such as to diminish the CABs capabilities, particularly as described in the scope of accreditation and that they have already been fully notified to AERSSC.

- 11.9 At the time of on-site surveillance/ re-assessment, Assessors are required to find out whether the CABs have participated in accredited Proficiency Testing program and Interlaboratory Comparison, wherever applicable, as specified in their 3-year PT participation plan. Also, whether they have taken the necessary corrective action based on root cause analysis in those situations, where their performance was not found to be satisfactory.