IQAS-32

Assessors Guide

AMENDMENT SHEET

Sr. No.	Page No.	Clause No.	Date of Amendment	Reasons of amendment	Amendment details	Remark	Approved by
1.	--	--	28.10.2026	Periodic Review as per document control procedure	Detailing as part of periodic review	Replaces previous issue 00 dated 01.07.2024	R.S. Rana
2.							
3.							

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Assessor guide

1. Introduction

1.1. International quality and accreditation services (IQAS) provide third-party accreditation to Conformity Assessment Bodies {Testing Laboratories/ Calibration Laboratories/ Medical Testing Laboratories/Reference Material Producer/Proficiency testing Provider/ Inspection Bodies} according to international standards. The liberalization (of trade and industry) policy of Government of India provides greater thrust for exports. This makes it imperative for the Conformity Assessment Bodies (CABs), where the products are assessed, to be at international level of competence. IQAS is, therefore, committed to ensure that the accreditation requirements and assessment system for CABs are in line with international norms and practices.

1.2. IQAS 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 whichever is applicable or ISO 17034:2016 "general requirements for the competence of reference material producers" or ISO/IEC 17043:2023 "General requirement for the competence of proficiency testing providers" or ISO/IEC 17020:2012/26 "Requirements for bodies performing inspection". The assessment is carried out by a team of Assessors, led by a Team Leader, empaneled by IQAS.

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

i. for arriving at a judgment for recommendation of the team on grant, continuation or renewal of accreditation,

ii. to specify the competence of CAB in terms of its capability to perform the activities for which it is seeking accreditation or holds accreditation

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

1.5. This Guide has been published in order to provide assistance to IQAS Assessor in conducting assessments for IQAS. It describes the role of an Assessor in conducting the Assessment-related activities for IQAS. 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 IQAS during the assessment of a Conformity Assessment Bodies {Testing Laboratories/ Calibration Laboratories / Medical Testing Laboratories / Reference Material Producers/ Proficiency Testing Providers/ Inspection Bodies}, (s)he should understand IQAS and its accreditation process, its objectives, mission as well as the assessment methodology.

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

i. Provides guidance to the Assessors for conducting assessment of a CAB;

ii. ensures uniformity of assessment and reporting;

2. Assessor's Role and Responsibility

2.1. The objective of any on-site assessment is to obtain evidence on compliance with respect to the applicable standard. Basically, the IQAS Assessor's role is to conduct assessment of CAB to adjudge the compliance to applicable Standard(s).

2.2. The Assessor shall also check that the CAB meets other requirements of IQAS including the IQAS's Specific Criteria for the relevant field and / or discipline / or category (wherever applicable) and has competence to perform the specific activities. The compliance of all shall requirements are to be verified. The Assessor shall ensure that (s) he is using the latest documents which are available on the IQAS web-site for each assessment and also pay attention to the specific announcements on web-site 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)/ calibration(s) / PT scheme /Production of RM/CRM or Inspection 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 extent of conformity with respect to accreditation criteria.

2.4. Assessors are required to maintain complete confidentiality on matters/subjects related to CAB.

2.5. Notwithstanding the strength of the IQAS system, the success of the accreditation scheme depends on the Assessors who conduct 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 IQAS for abandoning the assessment process.

2.7. The Team Leader is also required to monitor the performance of Technical Assessor(s), Expert(s) and the Observer(s) i.e. (Potential Assessor). The Team Leader shall also recommend whether the Observer (Potential Assessor) is capable to perform the role of a Technical Assessor in future, if asked by IQAS, The Team Leader's comments / rating for each Technical Assessor and the Observer(s) (Potential Assessor) shall be enclosed with the report in IQAS-FF-13.

2.8. The Technical Assessor should clearly understand the areas / activities to be assessed by him. (S) He must review the Laboratory's documented system to verify compliance with the requirements of ISO/IEC 17025 / ISO 15189/ ISO 17034/ ISO/IEC 17043/ISO/IEC 17020, related IQAS Specific Criteria and other policies/ guidelines of IQAS. (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 Checklist related to the requirements of respective clauses and using IQAS-FF- 09/IQAS-FF-37/IQAS-FF-40/ IQAS-FF-42/ IQAS-FF-45 for witness done by him. 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 Team Leader/Technical Assessor has to provide information to the Technical Expert regarding IQAS forms and policies and guide him during the assessment. NC identified by the Technical Expert will however, be raised by the Team Leader.

2.9. The role of Technical Expert is same as that of Technical Assessor, except that he will seek guidance of Team Leader/technical assessor in filling the relevant forms, checklist etc. 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.

2.10. 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). (S) he is required to submit observer report (IQAS-FF-36) and his/ her TA / DA form shall be submitted to the Team Leader. The Observer (Potential Assessor) is not entitled for payment of any honorarium.

2.11. An Assessor must ensure that (s)he is well versed with:

i. Assessment principles including risk-based assessment principles, practices and

techniques,

ii. General management system principles and tools,

iii. Applicable standard (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 17034:2016 "General requirements for the competence of Reference Material Producers" or ISO/IEC 17043:2023 "General requirement for the competence of Proficiency Testing Providers" or ISO/IEC 17020:2012/26 "Requirements for bodies performing inspection)

iv. Other relevant Specific criteria documents, and

v. IQAS policy documents prior to the visit to Conformity Assessment Bodies (CABs).

2.12. Considering improvement as a continuous process, the assessor is required to enhance following knowledge and skills on an on-going basis:

i. Understanding the knowledge of practices and processes of the Conformity Assessment Body business environment,

ii. Communication skills,

iii. Note-taking and report-writing skills,

iv. Opening and closing meeting skills,

v. Interviewing skills,

vi. Assessment management skills

2.13. The detailed requirements of knowledge and skills are mentioned below:

Sr. No	Knowledge and Skills	Document Review	Assessment
1.	Knowledge of applicable standard	✓	✓
2.	Knowledge of relevant guidance and applicable documents	✓	✓
3.	Knowledge of IQAS policies and procedures	✓	✓
4.	Knowledge of IQAS policies and procedures	✓	✓
5.	Knowledge of general regulatory requirements	✓	✓
6.	Knowledge of assessment principles, practices, and techniques	✓	✓
7.	Knowledge of general management system principles and tools	✓	✓

8.	Note-taking and report-writing skills	✓	✓
9.	Knowledge of risk-based assessment principles	✓	—
10.	Knowledge of practices and processes of the Conformity Assessment Body (CAB) business environment	✓	—
11.	Communication skills	✓	—
12.	Interviewing skills	✓	—
13.	Opening and closing meeting skills (including providing information to the CAB about IQAS complaint and appeal mechanisms during the closing meeting)	✓	—
14.	Assessment management skills	✓	—

2.14. The supplementary documents to this guide are as follows:

I. For ISO/IEC 17025, IQAS-FF-08 'Pre-Assessment Guidelines and Forms (based on ISO/IEC 17025)' and IQAS-FF-09 'Assessment Forms and Checklist (based on ISO/IEC 17025: 2017),

II. For ISO 15189, IQAS-FF-10 'Pre-Assessment Guidelines and Forms (based on ISO 15189: 2022)' and IQAS-FF-37'Assessment Forms and Checklist (based on ISO 15189)',

III. For ISO 17034:2016, IQAS-FF-39 Preliminary-Assessment-Report-as-per-ISO-17034 and IQAS-FF-40 Assessment-report-as-per-ISO-17034.

IV. For ISO/IEC 17043:2023, IQAS-FF-41 Preliminary-Assessment-Report-as-per-ISO/IEC-17043:2023 and IQAS-FF-42 Assessment-report-as-per-ISO/IEC-17043:2023.

V. For ISO/IEC 17020:2012/26, IQAS-FF-44 Preliminary-Assessment Report as per ISO/IEC 17020:2012/26 and IQAS-FF-45 Assessment-report as per ISO/IEC 17020:2012/26

3. Assessor Assignment Procedure

3.1. Whenever required, IQAS 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, IQAS may offer an alternative to the extent possible, if the reasons given by the CAB are acceptable to IQAS.

3.2. Assessors are chosen to the extent possible from the empaneled list of Assessors maintained by IQAS 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. IQAS appoints Team Leader and send 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 Document Review / Quality Manual Adequacy Report to IQAS within 7 days along with IQAS-CL-01//IQAS-ML-03/ IQAS-CL-RMP-04/ IQAS-CL-PTP-05 / IQAS-CL-IB-06.

4.3. Once the CAB satisfactorily addresses the inadequacies of the Document Review / Quality Manual Adequacy; IQAS appoints another Team Leader and plan the pre-assessment (if opted by the CAB) in consultation with the Team Leader and CAB.

4.4. Appointed Team Leader has to undertake 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 Initial 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 IQAS-CL- 01//IQAS-ML-03 / IQAS-CL-RMP-04/ IQAS-CL-PTP-05 / IQAS-CL-IB-06. Whichever is applicable and submit the report to IQAS.

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 Initial assessment.

4.5. IQAS takes an 'acceptance' of the CAB on the nominated members of the assessment team and dates of assessment. A CAB can raise objection 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. IQAS provides a copy of the application, Management System Document / Quality Manual and previous assessment summary (wherever applicable) to each Assessor.

4.7. IQAS may at its discretion, call for a meeting of the nominated assessors and the Observer(s) (Potential Assessors) to brief them about the assessment assignment allocated to them.

4.8. The Assessor may also seek any further information like test procedures etc. from the CAB, in order to better prepare for their assigned areas of responsibility.

4.9. The assessment team has to verify the continued compliance of corrective actions taken by the CAB against NC related to violation if raised during previous assessment and report to IQAS.

4.10. 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 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). Team Leader is appointed from the group of assessors who are not conducting the assessment on the same days as the Team Leader.

4.11. Witness of testing/calibration and medical testing/ PT scheme /Production of RM/CRM or Inspection: The concerned technical assessor shall select the applied scope in such a way so that the sample witness represents the complete scope of the applied scope. The technical assessor shall choose the critical points for the witness demonstrations. Also, the range and points of witness in the calibration of fine CMC asked by the CABs should be considered for the witness. In case of very large scope of accreditation in the testing/calibration/ medical testing/ PTP /RMP or Inspection Bodies the selection points should be in such a way so that similar type of testing covered for the representation of the scope. The technical assessor should do the sampling based on his/her past experience to cover the whole scope based on the sampling.

5. Pre-Assessment

5.1. Objective:

5.1.1. The objective of a pre-assessment visit carried out by IQAS is:

I. to have a better understanding of the documentation;

II. to familiarize with the facilities, sites / location, 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 assessment. The Team Leader must take into consideration the travelling distance and time required for visit to different sites and also for witnessing site activities.

5.2. Visit:

5.2.1. 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 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,

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

6. On-Site Assessment

6.1. Before assessment, the Assessment Team shall interact and plan assessment program. This shall include the distribution of work amongst the Assessors. The format of the assessment plan to be finalized is given in relevant checklist. The time schedules in the assessment plan shall be realistic so that each activity can be completed as scheduled. Team Leader shall ensure proper time management of the team members during 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 responsibility.

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 or ISO 17034:2016 "General requirements for the competence of reference material producers" or ISO/IEC 17043:2023 "General requirement for the competence of proficiency testing providers"), whichever is applicable.

6.2.4. The Team Leader shall ensure that (s)he explains the purpose of 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, 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 IQAS-FF-09(Part I)/IQAS-FF-37(Part I)/IQAS-FF-40 (Part I)/ IQAS-FF-42 (Part I)/ IQAS-FF-45 (Part I) to CAB representatives. The CAB is to be requested to assign co-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. Team Leader shall obtain signatures/ endorsement of all participants of opening meeting in IQAS-FF-09(Part II)/IQAS-FF-37(Part II)/IQAS-FF-40 (Part II)/ IQAS-FF- 42 (Part II)/ IQAS-FF-45 (Part (II).

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. Assessor shall interview the person proposed by the CAB for opinion and interpretation of results in testing and calibration laboratories and report to IQAS on the following criteria:

i. Knowledge of relevant CAB accreditation standard,
ii. Technical knowledge of the relevant scope

6.3.7. Assessors shall interview the personnel who are responsible to report, review and authorize the results of the CAB based on the following criteria and report to IQAS for acceptance:

i. Qualification and experience as detailed in relevant IQAS specific criteria document/ application form.
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 needs for periodic re-calibration of equipment, where applicable.
vi. Awareness of the requirements and conditions for IQAS accreditation.

6.3.8. 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.

6.3.9. 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.

6.3.10. During 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.

6.3.11. During assessment, if the team finds that work is being sub-contracted, they should inquire into the circumstances and if the practice appears to contravene to 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 17034:2016 "General requirements for the competence of reference material producers" or ISO/IEC 17043:2023 "General requirement for the competence of proficiency testing providers") or ISO/IEC 17020:2012/26 "Requirements for bodies performing inspection", whichever is applicable, this should be recorded and included in the Assessment Report.

6.3.12. For site facilities the assessors shall do thorough examination of the operation of the management system at site, normally where testing / calibration/ PT scheme /Production of RM/CRM or Inspection for a customer is performed. The assessors shall also assess 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.

6.3.13. If the CAB is functioning in shifts; the assessor shall ensure the competence of staff working in shift operations and report the details.

6.3.14. 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 , or ISO 17034:2016 "General requirements for the competence of reference material producers" or ISO/IEC 17043:2023 "General requirement for the competence of proficiency testing providers") or ISO/IEC 17020:2012/26 "Requirements for bodies performing inspection", whichever is applicable and any other requirements specified by IQAS.

6.3.15. Favorable and adverse noting 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 in Part V of IQAS-FF-09/IQAS-FF-37/IQAS-FF-40/IQAS-FF-42/ IQAS-FF-45. Each non-conformity shall be acknowledged / countersigned by the accompanying CAB representative or the section in charge.

6.3.16. 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.

6.3.17. Checklists provided should be verified and completed during the course of assessment of the CAB, Checklist(s) are like aid memoir to Assessors so that all aspect of CAB management system and technical criteria are taken care of.

6.3.18. Assessor shall, during the course of assessment of the site/ mobile / temporary facility of the CAB, verify the effectiveness of management system and related documents using the audit techniques and shall raise the relevant non-conformity. The Assessor shall use IQAS-FF- 09/IQAS-FF-37/ IQAS-FF-40/ IQAS-FF-42/ IQAS-FF-45 to record the findings. This form shall be an annexure to the final report.

6.3.19. Since it is not possible to assess every procedure in operation, Assessors should use his/ her own judgment to select the calibration / test /PT Scheme / RMP and Inspection activity for their demonstration. The selection of the calibration/ test/ PT Scheme / RMP and Inspection 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 site activity / subcontracted activity for such CABs (in case of PTP and RMP). In doing so, the Assessors shall select items of work in progress, witness measurement and verify documents and record of calibrations / tests/ PT Activities / RMP Activities/ Inspections. The emphasis shall be given to cover critical and important tests / parameters of all the applied / accredited groups/sub discipline / sub category in each discipline/ category based on risk analysis.

6.3.20. 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, Calibration witness, Review of PT scheme, production of reference materials, whichever is applicable.

6.3.21. 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, which require evidence from some other area of CAB before they can be settled, may be perused for further investigation. The Assessors shall record the findings.

6.3.22. Using the checklist, the Assessors shall conduct the assessment and raise non-conformity as may be relevant record the findings. This form shall be part of the final report.

6.3.23. At the end of each assessment day, the Team Leader shall consolidate their findings.

6.3.24. 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.

6.3.25. 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.

6.3.26. The Team Leader and Technical Assessors shall individually complete "non-Conformity assessment summary" Part V of IQAS-FF-09/IQAS-FF-37, IQAS-FF-40, IQAS-FF-42, IQAS-FF-45 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.

6.3.27. CABs with its technicians and analysts handling test specimens to wear hand gloves. If otherwise, this be brought to the notice of the CAB, the CAB be sensitized to safety hazards and cross contamination. Such finding be appropriately mentioned in assessment report.

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 individual Assessor's report(s) and make an assessment summary on the behalf of team.

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 or PTP or RMP or Inspection Bodies 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 Part V of IQAS-FF-09/IQAS-FF-37/ IQAS-FF-40/ IQAS-FF-42/ IQAS-FF-45. A copy of this form along are to be shared with the representative of the CAB. For details, please refer to procedures for conducting closing meeting (Section 8).

6.5.3. The closing meeting is to end with thanks giving for the co-operation and assistance given by CAB.

6.6. Post Assessment

6.6.1. Team Leader shall send the assessment report along with recommendation to IQAS at the earliest and in confidence by speed post or by courier service mail.

6.6.2. Assessor shall provide comments and recommend 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 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 one area of testing or calibration, 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 IQAS 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 IQAS about the dissatisfaction / disagreement.

8. Procedure For Conducting Closing Meeting

8.1. The purpose of the closing meeting is to IQAS 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 IQAS. Thereafter the decision will be communicated to the CAB by IQAS.

8.2. The concluding report IQAS-FF-09/IQAS-FF-37, IQAS-FF-40, IQAS-FF-42 and IQAS-FF-45 shall be based on the summary report

8.3. Closing meeting shall be chaired by the Team Leader in presence of CAB senior management. The Team Leader has to: 8.3.1. Thank the CAB for its assistance and co-operation. (S) He shall also refer to individuals as may be appropriate.

8.4. Explain the significance of the non-conformities.

8.5. Ask for questions to be deferred until the findings have been presented, although points of clarification should not be refused.

8.6. 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.

8.7. Invite the CAB to specify the date by which any required corrective actions will be implemented. It should be in line with IQAS norms.

8.8. Provide the CAB with an opportunity to discuss the assessment and answer any questions.

8.9. Apprise CAB with the requirements of IQAS policies.

8.10. 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 IQAS.

8.11. Team Leader shall obtain acknowledgement / signature of those who attend the closing meeting in IQAS-FF-09(Part II)/ IQAS-FF-37(Part II)/IQAS-FF-40 (Part II)/ IQAS-FF-42 (Part II)/ IQAS-FF-45).

8.12. Team Leader shall inform the CAB about the complaint (IQAS-010) and appeal (IQAS-011) procedure of IQAS.

9. Scope of Accreditation

9.1. It is IQAS'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., IQAS-002/IQAS-003/IQAS-004/IQAS-036/IQAS-037/IQAS-042).

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 the assessment report.

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 assessment report. The recommended scope of accreditation shall clearly specify the parameters for which the CAB is performing site activities.

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/ PT scheme /Production of RM/CRM or Inspection 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:

10.2. 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 four years in the case of testing, calibration and medical testing, and of one year for PTP, RMP and Inspection Bodies. Surveillance of accredited CAB is undertaken on receipt of complain in the case of PTP, RMP and Inspection Bodies. In case, of testing, calibration, and medical testing accreditation cycle is of four years consisting desktop surveillance in the end of first year, onsite surveillance in the end of second year, and again desktop surveillance in the end of third years and CAB to reapply for renewal of accreditation prior to six months of expiry of accreditation.

11.2. The on-site surveillance or re-assessment team shall be headed by a Team Leader.

11.3. The on-site surveillance, on receipt of complaint, 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.

11.4. IQAS provides on-site surveillance / re-assessment audit team a copy of relevant parts of the previous assessment report as a background information.

11.5. 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.

11.6. Management System Document / Quality Manual will be made available to members of the assessment team by IQAS prior to the assessment.

11.7. 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 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 IQAS.

11.8. 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 4-year PT/ILC 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.

12. Expression of CMC in the recommended scope of accreditation

12.1. The assessment team shall refer to the ILAC P14: ILAC Policy for Measurement Uncertainty

in Calibration, for expression of CMC in the recommended scope of the calibration CABs.

12.2. The assessment team shall ensure that the accredited calibration laboratories evaluate measurement uncertainty in compliance with the GUM.

12.3. The scope of accreditation of an accredited calibration laboratory shall include the calibration and measurement capability (CMC) expressed in terms of:

i. Measurand or reference material;
ii. Calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;
iii. Measurement range and additional parameters where applicable, e.g. frequency of applied voltage.
iv. Measurement uncertainty.

12.4. The CMC shall be expressed in terms of two significant digits preferably in the same unit or in terms of percentage with two significant digits.

12.5. The examples of significant digits are mentioned below:

Example 1: 0.035 has two significant digits. The zeros are placeholders for locating the decimal point.

Example 2: 3.70 has three significant digits. The zero is significant because it is the last digit. 3.7 has two significant digits.

Example 3: 345.76 has five significant digits. All non-zero digits are significant digits

12.6. The assessment team shall take care of two significant digits at the time of CMC expression in the recommended scope. Also, the rounding off shall be done as per the following rules:

i. If the digit is smaller than 5, drop this digit and leave the remaining number unchanged. Thus, 1.684 becomes 1.68.
ii. If the digit is 5 or larger, drop this digit and add 1 to the preceding digit. Thus, 1.247 becomes 1.25.