

PROCEDURE FOR THE PREPARATION OF ASSESSMENTS

ABC ACCREDITATION BODY

Revision 1

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1.0 PURPOSE

The purpose of this procedure is to give guidance and describe the responsibilities and action in the preparation of documents, arrangements, and logistics for the smooth conduct of assessment.

2.0 SCOPE AND APPLICATION

- 2.1 This procedure is applicable to the preparatory work required for the conduct of assessments such as application review, document review, pre-assessment, assessment, surveillance assessment, re-assessment, and assessment for extension of scope.
- 2.2 The guidance in this procedure is also applicable when ABC Staff is preparing for other assessment activities such as “verification assessment” with specific aim such as verifying the positive or acceptable discharge of Nonconformities.
- 2.3 This procedure should be read in conjunction with the relevant published policy and procedure documents governing ABC’s accreditation programs for laboratories, inspection bodies, certification bodies and others.
- 2.4 The procedure lists, in general terms the preparatory steps required, though not necessarily in any order of implementation.

3.0 REFERENCES

- 3.1 ABC Quality Manual
- 3.2 AB01-Terms and Conditions for Accreditation
- 3.3 ISO/IEC 17025 - General requirements for the competence of calibration and testing Laboratories
- 3.4 ISO 15189 - Medical Laboratories – Particular requirements for quality and competence
- 3.5 ISO/IEC 17020 - General criteria for the operation of various types of bodies performing inspection
- 3.6 ISO/IEC 17065 – Conformity Assessment - Requirements for bodies certified products, processes, and services
- 3.7 ISO 17034 - Conformity Assessment – General requirements for the competence of reference material producers
- 3.8 ISO/IEC 17043 - Conformity Assessment – General requirements for proficiency testing
- 3.9 ISO/IEC 17024 - Conformity Assessment – General requirements for bodies operating certification of persons
- 3.10 ISO/IEC 17021 - Conformity assessment -- Requirements for bodies providing audit and certification of management systems

4.0 PROCEDURE

No	Particulars	Responsibility / Reference Documents
4.1	Obtain formal agreement from CAB on the acceptability of assessment team. (Note: ABC Staff to check reply from the CAB, if CAB is silent, it is deemed that it agrees with suggested Lead Assessor & Assessment team)	ABC Staff
4.2	ABC STAFF obtains agreement on assessment dates with CAB, Lead Assessor, Technical Assessors, and others. The ABC Staff reviews the desired scope of accreditation and determines the need for the appropriate Technical Assessors	ABC Staff Lead Assessor (LA) Technical Assessors (TA)

No	Particulars	Responsibility / Reference Documents
4.3	<p>ABC Staff obtains agreement between CAB and LA on number of man-days to allocate to the assessment activity.</p> <p>Note that the duration of an assessment or reassessment is based on allocating one half of one day onsite for the examination of the QMS (Lead Assessor), one half day onsite to prepare and deliver the assessment report (all team members), and one man-day for each set of eight (8) tests maximum in each technical discipline.</p> <p>For example, a CAB conducting 4 microbiology and 6 organic chemistry tests would need the following time allocation:</p> <ul style="list-style-type: none"> • LA: half day for QMS and half day for report • TA (micro): half day for tests and half day for report • TA (organic): one day for tests and half day for report. • Total = 2 days with report delivered during morning or afternoon of second day. <p>If the TA is qualified for both, then the total is 1.5 days with report delivered during morning of second day.</p>	<p>ABC Staff LA CAB</p>
4.4	Check on availability of technical assessors for the scope of accreditation.	ABC Staff
4.5	Liaise with Lead Assessor and the CAB on agreement of an assessment programme or schedule.	<p>ABC Staff Lead Assessor</p>
4.6	<p>Confirmation of criteria/standards which will be used in the assessment whether ISO/IEC 17025 or ISO 15189 (for medical testing programme), and any other additional criteria and requirements which will be made known to all parties.</p> <p>(ABC STAFF to review Assessment Plan prepared by Lead Assessor)</p>	<p>ABC Staff Lead Assessor</p>
4.7	Ensure on sending of Assessment Notification and Plan according to Assessment Schedule	<p>ABC Staff Assessment Schedule</p>
4.8	Ensure on approval of Assessment Team.	ABC Staff
4.9	Ensure that all members of the assessment team have signed confidentiality and conflict of interest forms.	<p>ABC Staff Conflict of Interest Form</p>
4.10	Ensure that assessment team is provided with up-to-date documents, procedures and instructions and forms, scope of accreditation sought;	ABC Staff
4.11	Assessment team (Lead Assessor) is provided with or has access to CAB's documents and previous assessment reports. Documents include all quality system and technical procedures applicable to the desired scope of accreditation.	<p>ABC Staff LA</p>
4.12	Check the need for evaluation of assessors participating in assessment team.	ABC Staff

No	Particulars	Responsibility / Reference Documents
4.13	Liaise with Lead Assessor/Monitor and inform the CAB on agreement for Monitor's presence in assessment.	ABC Staff

5.0 DETAILED PROCEDURE

No	Procedure / Action	Responsibility
5.1	ABC Staff is to communicate confirmation of arrangements with Lead Assessor for conducting assessment.	ABC Staff
	<p>a). <u>For applicant CAB</u>,</p> <p>- Pre-assessment shall be conducted after ABC Staff is satisfied that the CAB application review demonstrates the implementation of a conformant quality system. ABC Staff may ask the CAB to resubmit after modification or delay further work until the CAB is ready.</p> <p>- Assessment shall be conducted after ABC Staff is satisfied with corrective actions taken by the CAB during pre-assessment.</p>	<p>ABC Staff CAB</p> <p>ABC Staff</p>
	b) <u>For accredited CAB</u> , surveillance through re-assessment shall be conducted based on interval set.	ABC Staff Lead Assessor
5.2	Contact and communicate with the CAB for agreement of date of assessment. Inform the type of assessment and number of man-day (Assessors) required for the assessment.	Lead Assessor ABC Staff
5.3	Prepare assessment plan and schedule in advance of the assessment dates. Forward the assessment schedule/plan to ABC for review and further action.	Lead Assessor Assessment Schedule
5.4	ABC STAFF is to review assessment schedule/plan prepared by Lead Assessor. If satisfied, prepare notification letter and send the notification letter and assessment schedule/plan to the CAB for acceptance and comment. The notification letter can also be sent (fax/email) to the assessment team members involved. ABC Staff to consult Quality Manager for guidance on this matter.	ABC Staff Quality Manager
5.5	If there is valid comment/request, they should be taken into consideration in the preparation of revised assessment plan by the Lead Assessor. Revised assessment plan is then sent to CAB and assessment team members (if any).	ABC Staff Lead Assessor
5.6	<p>As a preparation for assessment (surveillance or reassessment) to be conducted, ABC Staff is required to prepare and send (preferably via email) the previous assessment records to the assessment team. The documents are as follows (where applicable):</p> <ul style="list-style-type: none"> • Assessment Report • Assessment Findings Report Form • Test and Method Checklist • Record on CAB's Participation in PT (as appropriate) • Latest scope of accreditation 	<p>ABC Staff</p> <p>Assessment Report Assessment Findings Form Test and Method Checklist Scope of accreditation</p>

No	Procedure / Action	Responsibility
5.7	In cases where the ABC Staff will be joining the assessment team as ABC representative, the ABC Staff is required to bring the complete previous report for reference during the assessment. The report shall be returned to the respective file after the assessment.	ABC Staff
5.8	Assessment is conducted in accordance with the assessment plan and procedure, including witnessing of site testing/calibration (if applicable).	Lead Assessor
5.9	Lead Assessor/Technical Assessor will prepare assessment report which includes: Attendance list, Assessment Findings Form, Assessment Report, Test and Method Checklist (for every test assessed) and if applicable report of evaluation of signatory etc.	Lead Assessor Assessment Report
5.10	During closing meeting, Lead Assessor is to submit copies of assessment records to the CAB for their retention and action.	Lead Assessor
5.11	Lead Assessor shall submit all appropriate assessment reports/records together with their claims within seven (7) working days from the date of assessment, to ABC.	Lead Assessor Assessment Report

Applicable forms:

Test and Method Checklist
 Assessment Finding Form
 Assessment Report Form
 Assessment Schedule
 Requested scope of Testing
 Requested scope of Calibrations
 Impartiality, Confidentiality & Conflict of Interest form
 Assessment Checklist for ISO/IEC 17025
 ABC Attendance form

Note:

* for Medical and Inspection programme, specific forms have been established under the same series of the form with specific identifier.