



SDAC Accreditation Procedure



HISTORY OF THE DOCUMENT

Version number	Reason(s) of revision	Scope of the revision
Ver 1.0:6/2019	- Replaces SDAC-AP-09 - Update of layout	Full revision
Ver 1.1:3/2020	Updating forms coding	Section 7. related forms
Ver 2:10/2020	Updating the document to be suitable for accreditation of medical laboratories and inspection bodies.	3. References: - deleted "ISO/IEC 17025:2005" -deleted "IAF/ IAC A5" -changed "19011:2011" to "19011:2018" 4.7: deleted 6.1.1 & 6.1.4 : replaced "testing and calibration" with "conformity assessment activities" 6.1.3 : addition of medical Laboratories and Inspection bodies 6.6.1.4: added "and other management system documents"



Table of Contents:	Page
1. Purpose	4
2. Scope	4
3. References	4
4. Definitions	4
5. Responsibilities	5
6. Procedure	5
6.1 General	5
6.2 Application and Resource Review	6
6.3 Preparation of Assessment	7
6.4 Review of documented information	9
6.5 Preliminary visit	11
6.6 Initial Assessment	11
6.7 Surveillance assessment	17
6.8 Extraordinary assessment	18
6.9 Reassessment	19
6.10 No work carried out by a laboratory	20
6.11 Scope of Accreditation	20
6.12 Multi-site CABs	22
7. Related forms	23
Annex A: Time frame of accreditation process	24



1. PURPOSE

The purpose of this document is to define the process for accreditation and to define how SDAC plans and conducts assessments of Conformity Assessment Bodies (CABs) to the SDAC accreditation requirements, the requirements of the applicable standards/guides, International Accreditation Forum (IAF), International Laboratory Accreditation Co-operation (ILAC), The Arab Accreditation Cooperation (ARAC) and The African Accreditation Cooperation (AFRAC).

2. SCOPE

This procedure covers all steps related to assessment for all provided accreditation application by CABs in the field of testing.

3. REFERENCES

SDAC QM	SDAC Quality Manual
SDAC-G-01	Assessors Guidance Handbook
ISO/IEC17025 : 2017	General requirements for the competence of testing and calibration laboratories
ISO/IEC 17011:2017	Conformity Assessment- General requirements for accrediting conformity assessment bodies
ISO 19011:2018	Guidelines for auditing management systems

4. DEFINITIONS

4.1 Assessment Team: SDAC Assessment team consists of a Team Leader and an appropriate number of Technical Assessors/experts to cover the scope of accreditation.

4.2 Team Leader: An assessor who is responsible for the overall management of assessment team activities.

4.3 SDAC: Sudanese Accreditation Council

4.4 CAB : Conformity Assessment Body

4.5 Technical Assessor: An assessor who is responsible for advising the Team Leader on specialist technical matters relating to applicant's scope of accreditation.

4.6 Technical Expert: person assigned by an SDAC, working under the responsibility of the Team Leader, who provides specific knowledge or expertise with respect to the scope of accreditation to be assessed and does not assess independently Extension of



5. RESPONSIBILITIES

Accreditation Manger, Team Leaders , Assessors , Technical Experts , Accreditation Committee and Assessor file Manager are responsible for the development and implementation of this procedure.6.Procedure

6. PROCEDURE:

6.1 GENERAL

- 6.1.1 The function of SDAC is to assess and recognize the competence of CABs to competently perform specified conformity assessment activities and subsequently to ensure, by monitoring, that the required accreditation standards are maintained.
- 6.1.2 Each applicant CAB provides information to SDAC on its staff in the relevant standard and submits it to SDAC together with the pre-requisite documentation as required in the application form.
- 6.1.3 The table below describes areas of accreditation, the applicable accreditation standards and the accreditation cycle.

Areas of Accreditation	Accreditation Standard/Scheme	Accreditation Cycle
Testing Laboratories	ISO/IEC 17025	03 years
Calibration Laboratories	ISO/IEC 17025	03 years
Medical laboratories	ISO 15189	03 years
Inspection bodies	ISO/IEC 17020	03 years

- 6.1.4 Assessment of the competence of CABs is carried out using document reviews, visits to the CABs and other sites where the CAB performs its conformity assessment activities. The purpose of the assessment is to determine whether a CAB complies with the requirements of the applicable standards or guides as well as the relevant SDAC requirements.
- 6.1.5 SDAC uses Technical Assessors (TAs) and/or Experts (TEs) with the relevant specialist knowledge to assess the competence of the CAB to perform the work in the scope for which accreditation is sought. The assessment teams are required by SDAC to maintain confidentiality, and to sign a confidentiality form SDAC-F-45 specifying them the need to declare any potential conflict of



interest. Their activities will be confined to assessing the CAB's activities for compliance with the requirements and reporting their findings to the CAB and to SDAC.

A summary of accreditation stages with the time frame are provided in Annex **A**.

6.2 APPLICATION AND RESOURCE REVIEW

6.2.1 On receipt of a completed application form SDAC-F-o8, and the documentation as required in supplementary application form-Testing SDAC-F-09 the Accreditation Manager shall:

6.2.1.1 Review the application forms for completeness and verify that the required information and documentation has been submitted;

6.2.1.2 Review the acceptability of technical information provided, such as, but not limited to:

- i) Validation information;
- ii) Proficiency Testing performance;
- iii) Uncertainty budgets ;or
- iv) Any other technical aspects or procedures.

6.2.1.3 Verify that the Application form has been signed by the Director or company Representative , there by binding the applicant to the Terms and Conditions of Accreditation ; and verify availability of relevant procedures and policies and personnel for the entire accreditation process including decision making. for this purpose Resource Review form SDAC-F-11 is used SDAC also takes into account its ability to carry out the assessment in a timely manner. Where the initial assessment cannot be undertaken in a timely manner the Accreditation Manager communicates this to the conformity assessment body

6.2.1.4 Seek agreement from the applicant to the appointment of a specified Team leader and assessment team members

Note: All applicant laboratories are required to participate in appropriate proficiency testing or Inter laboratory comparisons for the scope of accreditation required and provide SDAC with the relevant proof on application of participation and satisfactory performance.

Refer to SDAC-PO-03 “SDAC Policy for Participation in Proficiency Testing Activities”.

6.2.2 During the review of the application information, the Accreditation Manager may seek advice from a technical assessor / expert regarding the acceptability



of the technical information provided, should this be required .In this case, the technical assessor / expert will be required to provide a response to the Accreditation Manager in writing

- 6.2.3 At any point in the application or initial assessment process, if there is evidence of fraudulent behaviour, if the conformity assessment body intentionally provides false information or if the conformity assessment body conceals information, the accreditation body shall reject the application or terminate the assessment process.
- 6.2.4 Prior to any work being carried out, SDAC will provide a quotation detailing the cost of the application, the document review and initial assessment. Acceptance and payment of this quotation will be required to proceed to the next stage of the assessment process. A quotation will be sent to the applicant in stages.
- 6.2.5 The SDAC Quality Manual (QM) and all other SDAC documents applicable to the CAB are available on the SDAC website www.sdac.gov.sd .It is the responsibility of the CAB to ensure that they are familiar with the relevant SDAC documents.
- 6.2.6 An application that has not proceeded to the initial assessment stage within 1 year from the date of application will lapse. Unless otherwise agreed with SDAC, this may result in the CAB having to re-apply for accreditation. All application fees will be applied for the re-application.

6.3 PREPARATION OF ASSESSMENT

- 6.3.1 The Accreditation Manager appoints a Team Leader who will ensure the management of the following steps of accreditation process. The Accreditation Manager will select from the pool of approved assessors an assessment team that:
- a) has appropriate knowledge of the specific scope of accreditation;
 - b) has understanding sufficient to make a reliable assessment of the competence of the conformity assessment body to operate within its scope of accreditation
 - c) Has no conflict of interest with the specific accreditation assessment being undertaken.
- 6.3.2 Each approved assessor used by the SDAC have a record that can be considered by the Team leader when identifying suitable members as trainees or observers.
- 6.3.3 For Testing CABs, when assessment team don't possess metrological skill, SDAC appoints a metrologist among this team to ensure relevant examination of metrological aspects and uncertainty calculations. It is



desirable to use assessments as opportunities to train less experienced assessors by involving them in teams.

- 6.3.4 The number of members for each assessment team depends on the scope and complexity of the work to be assessed. For example large laboratories, perhaps focused on a narrow range of activities, only need a team of the Team leader and a single Technical Assessor. On the other hand, a small facility, with a wide range of activities, may require a larger team.
- 6.3.5 When a technical assessor is asked to operate outside their declared area of competence, the relevant file shall include a declaration by the SDAC Accreditation Manager that the technical assessor is deemed competent for the purpose of the assessment.
- 6.3.6 For assessment of laboratories, the assessors selected will have relevant scientific qualifications and practical experience in laboratories with similar activities to those of the applicant. In the case of assessors for calibration assessments, appropriate consideration is given to the assessor's knowledge of measurement uncertainty and the laboratory's least uncertainties of measurement
- 6.3.7 Prior to assessment, the CAB will provide SDAC with all the information required to plan the assessment. This information usually appears in the application form, but SDAC may request additional information.
- 6.3.8 The CAB will be sent notification of the proposed assessment team for acceptance using SDAC-F-11. Objection to the appointment of assessors will only be considered if the CAB has provided clear and valid reasons, in writing and within 3 days of the notification, proving that a conflict of interest exists. The Accreditation Manager will decide whether a change of assessor is warranted or not.
- 6.3.9 Applicants or accredited CABs have certain rights with respect to team selection and may object to a particular individual. A maximum of two objections is permitted but in forming the team, the Accreditation manager must be cognizant of potential conflicts of interest and other likely sources of dissent over team selection.
- 6.3.10 The following categories of reasons may lead to the rejection of the appointed assessor(s)
- a. Conflict of interest between the applicant/accredited CAB and the assessor:
-The assessor was an employee of the CAB during the two last years,



- The assessor had delivered a specific consultancy services (internal audit included) for the CAB or one of his direct competitors, during the two last years (Inter-company and non-tailored trainings are not considered as consultancy),
- The employer of the assessor and the CAB are in direct and current commercial competition (e.g. participation in the same tenders),
- A dispute between the two parties treated in justice.

b. Behavior of the assessor: This reason is acceptable if the assessor was appointed before for the CAB and SDAC has received a formal dissatisfaction from the CAB further to one of the previous assessments conducted by the same assessor, concerning his/her behaviour.

- 6.3.11 After formally receiving the rejection from the CAB, the Accreditation Manager evaluates the credibility of the rejection request on the basis of the reasons given above SDAC shall reply promptly to the CAB, on the reception of the rejection request. If SDAC accepts the rejection request, it shall appoint a new assessor and ask again the approval of the CAB. The CAB has the right to reject once again the new assignment and the same procedure is still applicable. Where it is not possible to find a suitable alternative SDAC reserves the right to keep team composition

6.4 REVIEW OF DOCUMENTED INFORMATION

- 6.4.1 The purpose of a reviewing the documented information is to verify that the CAB's Management System manual and relevant procedures comply with the relevant accreditation standard / guide as well as SDAC accreditation requirements.
- 6.4.2 Document reviews are conducted by the assessment team on application for initial accreditation and again on application for renewal of accreditation.
- 6.4.3 The process to be followed for a reviewing the documented information is as follows :

The CAB conducts a review of their documentation and completes SDAC-F-09 supplementary application form-Testing detailing where in their documents the requirements are met.

Note: Comments on HOW the requirements of the standard have been implemented, Clause no's, sub-clause no's, procedure numbers must be captured.

- 6.4.4 The CAB submits the completed application form, the management System documentation and where required, procedures to SDAC.



Note: For re-assessments, this documentation is required at least 6 months prior to the expiry of the Certificate of Accreditation. Should this time frame not be met, a re-assessment may not be conducted prior to the expiry of the Certificate of Accreditation, resulting in the CAB having to re-apply for accreditation. All application fees and time frames will be applied for the re-application.

- 6.4.5 SDAC records the date of receipt and forwards the information submitted to the appointed Team leader.
- 6.4.6 The Team leader confirms from the information submitted whether the requirements of the relevant standard are substantially addressed in the Management System Manual.
- 6.4.7 The Team leader may seek advice from a technical assessor / expert regarding the acceptability of any technical information provided, should this be required. In this case, the Team leader will liaise with the technical assessor / expert via the SDAC office. The technical assessor / expert will be required to provide a response to the Team leader in writing.
- 6.4.8 The Team leader shall compile and submit to the SDAC Accreditation manager a document review report SDAC-F-12 within 2 weeks of receiving the information. The report shall contain comments on any deficiencies / omissions and a recommendation on the way forward. The report may be accompanied by the appropriate completed SDAC checklist SDAC-F--17.
- 6.4.9 SDAC can decide not to proceed with further assessment based on the review of the documented information. In such cases, the results with their justification shall be reported in writing to the conformity assessment body.
- 6.4.10 In the case of an initial assessment, a maximum period of 2 months is allowed for applicant CABs to address the findings, after which the application will cease.
- 6.4.11 In the case of an application for renewal of accreditation, SDAC will not require evidence of corrective actions prior to the assessment, as these will be verified on-site during the assessment.



6.4.12 The SDAC assessment team will confirm implementation of the standard requirements during the assessment of the CAB (including at branch offices operating under the same management system as the Head Office).

6.5 PRELIMINARY VISIT

6.5.1 Although not mandatory, a **preliminary visit** can be carried out (normally by the Team leader) to:

- 6.5.1.1 Discuss any findings related to the documentation;
- 6.5.1.2 Seek further information on the management system;
- 6.5.1.3 Briefly examine the systems which have been established and implemented;
- 6.5.1.4 Discuss any arrangements which have been made to include multiple locations, subcontracted activities, etc. within the management system;
- 6.5.1.5 agree on the proposed scope of accreditation;
- 6.5.1.6 Finalize the expertise required for the assessment team. The CAB will be quoted on the request of a pre-assessment visit.

6.5.2 The preliminary visit will normally be completed within one day. The Team leader will supply the CAB with at least a recommendation report SDAC-F-13, and a list of findings to be addressed or completed non-conformance forms SDACF-14.

6.5.3 The CAB may need to make changes to its policies, procedures and practices prior to SDAC undertaking the initial assessment. The CAB is responsible to inform SDAC when they have addressed the findings and are ready for the initial assessment.

6.5.4 Where SDAC conducts a preliminary visit before the initial assessment, it shall be conducted with the agreement of the conformity assessment body. SDAC shall have clear rules for the conduct of preliminary visits and shall exercise due care to avoid consultancy

6.6 INITIAL ASSESSMENT

6.6.1 General

6.6.1.1 The time required for the initial assessment is normally 2days, but will be left to the Accreditation Manager's discretion depending on the complexity of the organization, the geographical spread of its activities, the proposed scope of accreditation, the structure of the supporting management system, and where relevant, the combination of multi-standards for accreditation.



6.6.1.2 The nature of the initial assessment will depend on the scope of accreditation required by the CAB and the complexity of the supporting management system that is being operated. However, the following elements will be covered:

- I. Assessment of the central office and sample collection sites;
- II. Assessment of multiple locations (Satellites/branches/temporary sites) where applicable;
- III. Assessment of on-site activities where applicable.

Refer to SDAC-PR-09 “Sampling for Assessment”, which defines SDAC’ procedure and specific requirements for sampling of sites, personnel and the scope of accreditation, within the accreditation cycle.

6.6.1.3 A plan (SDAC-F-15) for the assessment visit is prepared by the accreditation manager .The plan aims to agree, together with the applicant and the assessment team, on the practical arrangements of the assessment, such as

- Timing and persons to be present during the Introduction meeting, the evaluation of activities, the final meeting between assessors and the closing meeting;
- Organization of activities that have certain constraints about time and place (e.g. security, uptime of a machine or installation) and available persons (e.g. working hours);
- Witnessing of actual activities.

6.6.1.4 Once approval on the proposed provisions for carrying out the evaluation has been received, the secretariat formally notifies every member of the team of their assignment. The secretariat sends them a copy of

- the application form;
- the quality manual and other management system documents;
- the description of the activities subject to accreditation;
- a copy of the previous assessment report when relevant and
- further documentation when relevant.

6.6.1.5 Every team member must formally accept their assignment and all applicable confidentiality clauses, by returning the standard form with which they are supplied.

Should one of the members approached decline (with the exception of trainee assessors) , an alternative suggestion will be made by the secretariat. Any assessor who declines must immediately destroy any documents received from the secretariat.



6.6.2 Opening meeting

6.6.2.1 The SDAC assessment team will hold an opening meeting with the applicant organization (Refer to SDAC-F-16).

6.6.3 The Assessment

6.6.3.1 The SDAC assessment team will seek to establish through objective evidence and by using various techniques that:

- i) The management system supports competence against their schedule of accreditation, it is appropriate to the laboratory's needs, organizational arrangements and methods of operation, including multiple location operations and number of staff members;
- ii) All of the requirements of the relevant standard/ guide have been appropriately addressed;
- iii) The laboratory has implemented all the requirements of the management system to ensure valid results/ data are generated each and every day;
- iv) The operational, administrative and technical procedures used to support the management system manual are complete, technically valid and appropriate.

6.6.3.2 The initial assessment is done so as to establish full confidence in the competence of the laboratory. Where it is the initial assessment of a satellite laboratory, the implementation of the management system within the satellite, the knowledge of the laboratory staff of the management system and the interface/ communication between the satellite laboratory and central office is crucial. Implementation within the satellite laboratory of the above will be assessed.

6.6.3.3 The following techniques will be employed to establish that procedures are being correctly and fully implemented:

- i) Questioning of management and staff who have an involvement in or bearing upon the quality of calibration or test work;
- ii) Questioning of staff involved with specimen collection, handling and transportation (in the case of Medical Laboratories),
- iii) Examination of records;
- iv) Examination of the suitability, maintenance, calibration, control and use of equipment;



- v) Examination of the arrangements for exercising controls over subcontractors and suppliers.

6.6.3.4 All fields and types of calibration/ test/ scope will be subject to a laboratory assessment and technical review. The team will assess the technical competence of the laboratory personnel in the field or type of calibration/ test/ scope covered by the schedule. This will be done through:

- i) The examination of the records outlined above;
- ii) Discussions with staff, supervisors and managers;
- iii) Assessment of the performance of the staff whilst performing work in the scope of application. The performance of staff is assessed in the laboratory and where applicable ,at other sites where work in the scope of application may be performed;
- iv) If a laboratory applied for on-site accreditation, a suitable site needs to be visited and the work in the scope of application performed there will be assessed and reported on. In the case of calibration laboratories, form SDAC-F-20 shall be completed. If a suitable site is not available, a simulation may be considered.
- v) Assessment of certificates/ reports, as applicable, issued by the laboratory.
- vi) In the case of Proficiency Testing Schemes, the Team leader will decide which of the above-mentioned techniques are to be applied, if any.

6.6.3.5 SDAC assessors' role during witnessing of work in the scope of application is one of observer. They will not influence the work being performed. The team will be looking to see that as a minimum:

- i) The Laboratory personnel member has the competence for the activity performed;
- ii) The Laboratory personnel member's competence is consistent with the records;
- iii) The Laboratory personnel member has been supplied with all necessary documented methods and procedures;
- iv) The procedures are up-to-date;
- v) The Laboratory personnel member implements the procedures in full and correctly, i.e. no shortcuts, no personalized application where it is not permissible to do so;
- vi) Records of all observations are made while on site as required by the procedure;
- vii) Records clearly identify the activity performed, the method/ procedure used, and when it was done;



- viii) All records and raw data are signed/ initialled, stamped and traceable as applicable;
 - ix) reports/ certificates issued comply with the CAB's, SDAC', and relevant standard requirements;
 - x) Facilities and equipment are fit for accreditation purposes.
- 6.6.3.6 If a Laboratory cannot provide at least one witnessing and/ or sufficient supporting evidence in order for a vertical assessment to be conducted on the day of the assessment, the Assessor has the right to abandon the assessment, and re-schedule for another day at full cost to the Laboratory. It is permissible for a CAB to “stage” a test for this purpose.
- 6.6.3.7 The Assessors will record all information gathered during the assessment on the relevant SDAC forms provided for this purpose SDAC-F-17/18/19/20/21/.The assessor records will be sufficiently comprehensive as to allow the Approval Committee, to support the recommendation made by the assessment team.
- 6.6.3.8 The Technical Assessors and / or Technical Experts will record all information gathered whilst witnessing the performance of an activity and viewing records in the Laboratory. This information will be used to make a decision on the competence of the Laboratory. Where necessary, additional supporting documentation will be attached as evidence of non-compliance or otherwise.
- 6.6.3.9 Each Assessor will record his / her own observations during the assessment as they encounter them by fully completing a separate SDACF-14(Non-conformance, Corrective Action and Clearance Report) for each observation raised . The Assessor will obtain the signature of the Laboratory representative in that area for each observation raised. SDAC -F-14 shall contain only factual observations related to possible non-conformance with a specific clause of the relevant Guide /Standard or any of the other SDAC accreditation documents.
- 6.6.3.10The Calibration Accreditation Manager may at his or her discretion include arte facts, measuring devices or instruments to be used during the witnessing of a calibration during the assessment .The measurement results obtained during this witnessing may not be used as a measure of the competence of the calibration activity.
- 6.6.4 **Assessor Meeting**
- 6.6.4.1 After the members of the assessment team have completed their individual assignments, the Team leader will hold a private meeting at which each team member summarises their conclusions and contributes to a co-ordinated view of the status of the applicant Laboratory.
- 6.6.4.2 The assessors will reach agreement on whether observations are converted into non-conformances and whether they are classified as major or minor non-conformances.



6.6.4.3 The Team leader will summarise the conclusions of the assessment team with regard to the competency and conformity of the Laboratory on the form SDAC-F-24 CAB assessment report The Team leader will report any matters for the attention of the Accreditation Manager i.e. assessment team cannot reach a conclusion on a finding SDAC-F-22 “Feedback from Assessment”.

6.6.5 The closing Meeting and Summary of Findings

6.6.5.1 The closing meeting and the presentation of the summary of the assessment team’s findings and recommendation will follow the guidelines as indicated in the closing meeting agenda (SDAC-F-23).

6.6.5.2 At this meeting, the assessment team shall report on the findings identified during the assessment and a copy of the non-conformance reports SDAC-F-14 shall be left with the CAB after being signed by the Authorised Representative of the CAB.

6.6.5.3 The Team leader will provide the Laboratory with an opportunity to discuss the assessment and to ask any questions.

6.6.6 The Report and Recommendation

6.6.6.1 An assessment Report SDAC-F-24 prepared by the Team Leader will be provided to the CAB through SDAC within one week after the closing meeting. The applicant will be requested to give written approval of the contents of the report and will be reminded of the possibility to submit, within 15 working days of receipt of the report, its comments and remarks for consideration by the Technical Committee. Where corrective action by the Laboratory is required, an action plan shall be proposed to SDAC after 2weeks from the closing meeting and a period of 2 months is allowed for effective clearance of non-conformances. After an initial assessment, the Accreditation Manager may allow a total of 6 months for clearance..The Laboratory shall provide sufficient evidence that the corrective action has been satisfactorily carried out.

6.6.7 Factors Affecting Recommendation for Initial Accreditation

6.6.7.1 Where the team cannot recommend immediate accreditation it will normally be recommended that accreditation be deferred until the Laboratory provides SDAC with evidence that appropriate corrective action has been implemented.

6.6.7.2 Where the number and seriousness of the non-conformance(s) found is such that the whole of the Laboratory’s management system and organization is demonstrably inadequate, the Team leader’s recommendation will be that accreditation is denied.

6.6.7.3 On completion of all actions, including those arising from visits to multiple locations and on-site activities, the assessment documentation will be submitted to the Accreditation Committee, who will review the information submitted and make a decision.



6.6.7.4 On approval of accreditation, and once any outstanding fees have been paid, the Laboratory will be granted accreditation and a certificate and schedule of accreditation will be issued to the Laboratory.

6.7 SURVEILLANCE ASSESSMENT

- 6.7.1 Upon granting accreditation SDAC applies an assessment programme that consist of set of assessments for assessing the conformity assessment body activities during the accreditation cycle to ensure that the conformity assessment activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle.
- 6.7.2 A **surveillance** assessment to the main office is conducted approximately 6 months, but not exceeding 12 months after accreditation has been granted. On recommendation by the Team leader and approval by the relevant Accreditation Manager, a branch of laboratory may also be included in the 6-month **surveillance** visit.
- 6.7.3 The purpose of this assessment is to check for continued compliance with accreditation requirements and **surveillance** on any non-conformances raised at the initial assessment and to ensure that the management system is still implemented and functioning properly.
- 6.7.4 The assessment programme will be planned to cover all the scope of accreditation over the applicable assessment cycle. Assessment matrix form SDAC-F-25 are used by the Team leader to track the coverage of scope at each assessment within a cycle.
- 6.7.5 An assessment report SDAC-F-24 and where applicable a non-conformance report(s) SDAC-F-14 will be provided to the Laboratory at the time of the assessment. The Laboratory may request any additional copies of the assessment documentation. Where corrective action is required by the Laboratory,
- 6.7.6 In most cases evidence of corrective action can be provided to SDAC by hand ,post or email. The assessment team may however recommend that an "On-site Clearance of Findings Visit" is required to allow the assessor(s) to clear the non-conformances on-site.
- 6.7.7 Should an accredited Laboratory fail to correct any non-conformances raised within 60 days, the Accreditation Manager shall implement procedures in accordance with **SDAC-PR-13** "Scope Extension, Suspension, Withdrawal or Reduction of CABs".
- 6.7.8 Accreditation of on-site activities form part of the schedule of accreditation and will be assessed at least once in the assessment cycle. The Team leader and Accreditation Manager



are responsible for planning such assessments to coincide where possible, with the normal **surveillance** assessment visit.

- 6.7.9 Reassessments will be conducted at least six (6) months before the end of an assessment cycle. The reassessment is planned and performed taking into account the information gathered from the assessments performed over the accreditation cycle
- 6.7.10 The re-assessment shall be a complete assessment covering the organization's scope of accreditation and including all elements of the relevant standard. An accreditation decision shall be made after the reassessment.

6.8 EXTRAORDINARY ASSESSMENT

6.8.1 Accreditation bodies requirements

- 6.8.1.1 SDAC plans and schedules assessment activities to monitor the continued fulfillment of requirements for accreditation by conformity assessment bodies (CABs). The CAB shall be informed of the date and assessment team members well in advance to allow the CAB an opportunity to accept/object to the appointed team members.
- 6.8.1.2 SDAC may also conduct extraordinary assessments or unscheduled visits as may be reasonably required to confirm ongoing compliance with accreditation requirements over and above the scheduled assessments.
- 6.8.1.3 All unscheduled visits shall be conducted by an assessor appointed by the accreditation Manager.
- 6.8.1.4 All unscheduled visits shall normally be scheduled during the normal working hours of the CAB at any of the registered addresses of the CAB, including any satellite facility or branch office.
- 6.8.1.5 The accreditation Manager shall inform the organization's management at least 2 days prior to the extraordinary assessment/unscheduled visit.
- 6.8.1.6 Upon arrival at the organization, the appointed assessor shall identify him or herself using a SDAC introduction letter.
- 6.8.1.7 Extraordinary assessments or unscheduled visits need only be as extensive as necessary to confirm a particular aspect of the accreditation requirements, for example, compliance with a particular SDAC technical requirement, to follow up on the investigation and resolution of a complaint against the CAB or to follow up on significant changes relevant to the CAB.



6.8.2 Conformity assessment bodies requirements

6.8.2.1 Accredited CABs shall notify SDAC of any significant revisions to their management system or any other changes that can affect their technical competency (such as loss of or new technical signatories, change of methods, etc.), which will be reviewed during the surveillance assessment visit. Where SDAC was notified in sufficient time (6 weeks prior to the scheduled assessment) verification of changes will be done as part of the next scheduled assessment, or where not possible, through an additional assessment. No schedule changes will be accepted after the assessment. The need for an additional assessment will be determined by the period within which the change needs to be effected. Laboratories shall be responsible for any additional costs incurred for additional assessments.

6.8.2.2 The CAB shall provide SDAC with reasonable access and cooperation during any scheduled or extraordinary assessment to any of the CAB.

6.8.2.3 The CAB shall provide SDAC with reasonable access to all relevant information related to their accredited activities. This may include but is not necessarily limited to, certificates, reports, raw data, records (technical, complaints, environment, internal audits, management review, contract reviews, personnel, method validation, proficiency testing results and equipment), uncertainty of measurements estimations, quotations, invoices, etc, during any scheduled or extraordinary assessments.

6.9 REASSESSMENT

6.9.1 At least 6 months prior to the expiry of the Certificate and Schedule of Accreditation, the Laboratory is required to re-apply to SDAC should they wish to renew their accreditation. This requirement also applies to Laboratory who are under suspension at this time.

6.9.2 Subject to clause 10.1, and the requirements for application and document review being met, SDAC will schedule re-assessment at least 3 months prior to the expiry of the Certificate and Schedule of Accreditation.

6.9.3 Reassessment visits will involve a comprehensive re-examination of the CABs accredited activities, and will be similar to the initial assessment, except that experience gained during previous assessment will be taken into account. The same criteria used for the initial assessment will be considered when determining the number and type of conformity assessment activities, and the organizations personnel to be assessed.



6.10 No work carried out by a laboratory

- 6.10.1 If an accredited laboratory cannot provide proof of work performed in a technical scope during the assessments, and cannot provide evidence that competence is maintained in any particular scope, that scope is to be suspended and the SDAC procedure SDAC-PR-13 process instituted.
- 6.10.2 If the Laboratory performs any work in the suspended scope during the suspension period, they must inform SDAC at their earliest opportunity for arrangements for a re-instatement assessment.
- 6.10.3 If the laboratory does not perform any technical work in the suspended scope within the suspension period, the suspension process will be followed and withdrawal will be recommended to the SDAC Secretary General as required by SDAC Procedure SDAC-PR-13

6.11 Scope of Accreditation

- 6.11.1 It is SDAC's policy to define the scope of CAB's accreditation as precisely as possible. CABs will therefore be asked to specify in detail the field, type and range of conformity assessment activities for which accreditation is sought and the locations at which these activities are to be carried out. This scope will be agreed upon as far as possible before the assessment in order to determine the extent of the assessment activities. Following successful assessment, the scope, including standard specifications/ methods/ procedures relevant to the testing & calibration concerned will be identified on the accreditation schedule.
- 6.11.2 Following accreditation, the certificate and associated schedule is the property of SDAC, and shall be returned to SDAC on request.
- 6.11.3 The effective date of accreditation is the date of the accreditation decision.
- 6.11.4 SDAC doesn't offer flexible scope
- 6.11.5 SDAC provides information on the accreditation to the accredited CAB. This information identifies the following:
- The identity and, where relevant, the accreditation body logo;
 - The name of the accredited conformity assessment body and the name of the legal entity, if different;
 - Scope of accreditation;
 - Locations of the accredited conformity assessment body and, as applicable, the conformity assessment activities performed at each location and covered by the scope of accreditation;
 - The unique accreditation identification of the accredited conformity assessment body;



f) The effective date of accreditation and, if applicable, its expiry or renewal date.

6.11.6 The scope of accreditation shall, at least, identify the following.

a) For certification bodies:

- The type of certification (e.g. management systems, products, processes, services or persons);
- Certification scheme(s);
- The standards, normative documents and/or regulatory requirements to which management systems, products, processes and services, or persons are certified, as applicable;
- Industry sectors, where relevant;
- Product, processes, service and persons categories where relevant.

b) For inspection bodies:

- The type of inspection body (as defined in ISO/IEC 17020);
- Inspection schemes, where relevant;
- The field and range of inspection for which accreditation has been granted;
- The regulations, inspection methods, standards and/or specifications containing the requirements against which the inspection is to be performed, as applicable.

c) For calibration laboratories:

- The calibration and measurement capability (CMC) expressed in terms of:
 - Measurand or reference material;
 - Calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;
 - Measurement range and additional parameters where applicable, e.g. frequency of applied voltage;
 - Measurement uncertainty.

d) For testing laboratories (including medical laboratories):

- Materials or products tested;
- Component, parameter or characteristic tested;
- Tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used.



6.12 MULTI-SITE CABS

- 6.12.1 An applicant that operates from a central office through a number of locations may seek a single accreditation provided that the conditions specified in the relevant standard or guides are fulfilled. Groups of branches or laboratories operating under the same management system are allocated individual accreditation numbers, and each branch or laboratory shall be individually assessed.
- 6.12.2 CABS shall under no circumstances franchise their accreditation activities to other CABS or organizations. During the initial assessment all locations will be assessed.
- 6.12.3 SDAC will seek to establish through objective evidence and by using various techniques that:
- 6.12.3.1 All locations are operating under the same management system;
- 6.12.3.2 All locations are included in the internal audit programme and central review process.
- 6.12.3.3 Temporary locations must be working to the same accreditation requirements and shall be subject to assessment as part of the accreditation process to provide evidence of the operation and effectiveness of the system.
- 6.12.3.4 During the main office assessment SDAC may need to see records of certain activities, which are being carried out at different locations.
- 6.12.3.5 If SDAC observes non-compliances at the main CAB or at any one of the locations of a CAB with multiple locations, the corrective action procedure shall apply to all locations where applicable. In the event that the results of any of the assessments reveal that there is a significant weakness or inconsistency in the application of the management system, SDAC will review the assessment program.
- 6.12.3.6 Failure by one location to comply with SDAC requirements and the requirements of the applicable standard may lead to removal of the location from the schedule of accreditation. If the cause of non-compliance is the lack of central control then the corporate accreditation will be the subject of review by SDAC and may lead to suspension or withdrawal of accreditation of all locations.
- 6.12.3.7 SDAC must be advised of any changes to location addresses and activities. The establishment of any new locations from which the CAB proposes to offer an accredited service must be notified to SDAC before these can be included in the scope of accreditation. The need for assessment of the new location will be reviewed via internal audit reports, the schedule of accreditation will be amended as appropriate and the location will be included in the assessment program and reassessment.
- 6.12.3.8 The initial assessment is done so as to establish full confidence in the CAB. Where it is the initial assessment of a satellite LAB /branch, the implementation of the management



system within the satellite, the knowledge of the LAB or the branch staff of the management system and the interface/ communication between the satellite and main office is crucial. Implementation within the satellite LAB/branch of the above will be assessed.

7. RELATED FORMS

- SDAC-F-08 “application form for accreditation”
- SDAC-F-09 “supplementary application form-Testing”
- SDAC-F-10 “Acceptance of Assessment Team”
- SDAC-F-11 “Resource review form”
- SDAC-F-12 “Document Review Report for Laboratories - ISO-IEC 17025”
- SDAC-F-13 “Preliminary Visit Report for Laboratories”
- SDAC-F-14 “Nonconformity Form”
- SDAC-F-15 “Assessment Plan”
- SDAC-F-16 “ Onsite Assessment - Opening Meeting Agenda”
- SDAC-F-17 “Check-list [ISO/IEC 17025:2017”
- SDAC-F-18 “Witnessing of Activity”
- SDAC-F-19 “On-site Evaluation of a Calibration Laboratory”
- SDAC-F-20 “Vertical Assessment Laboratories ISO/IEC 17025:2017”
- SDAC-F-21 “Proficiency Testing Requirements ISO/IEC 17025”
- SDAC-F-22 “Feedback from Assessment”
- SDAC-F-23 “ Onsite Assessment - Closing Meeting Agenda”
- SDAC-F-24 “CAB assessment report”
- SDAC-F-25 “Assessment matrix form”



Annex A: Time frame of accreditation process

STEPS	ACTIVITY	TIMELINES
1	Response to an enquiry from conformity assessment body/individual	Within 1 week of receipt of enquiry
2	Application Acknowledgement of receipt of application forms and quality manual from applicant conformity assessment body (CAB)	Within 1week of receipt of application
3	Completeness Check Completeness check and request for any additional information from the applicant where required.	1 Week after receipt of application
4	Quotation <ul style="list-style-type: none"> • On acceptance of the application, identification of a Team Leader to undertake the Document Review and the Technical Assessor(s) according to the scopes of accreditation applied for • Proposal of the Team Leader to applicant CAB • Preparation of the quotation covering the accreditation process 	1 week after completeness check
5	The CAB approval of the assessment team and the quotation	3 days from quotation receipt
6	Issuance of invoice for application fee	1 week maximum after receipt of the approved quotation by CAB



STEPS	ACTIVITY	TIMELINES
7	Document Review	
	applicant documents sent to be reviewed by the Assessment Team	3 days after receipt of application fee
	Team Leader to submit the document review report to SDAC	2 weeks after receipt of CAB's document
	Applicant CAB to undertake corrective action on any findings raised in the Document Review report and to notify SDAC about its readiness for the preliminary visit /initial assessment to be arranged.	Up to 2 months after receipt of the Document Review report
8	Issuance of an invoice for preliminary visit /initial assessment	1 week after receipt of notification from applicant CAB
9	Pre-assessment	
	<i>Note: Pre-assessment is an optional stage</i> - Applicant CAB to address findings raised during the preliminary visit - Initial assessment to be arranged	Within 6 months after pre - assessment
10	Initial assessment	
	Identify proposed corrective actions to nonconformities raised	Within 2 weeks after assessment
	Clearance of corrective actions by the assessment team	Within 2 months after assessment



STEPS	ACTIVITY	TIMELINES
	Accreditation program within accreditation cycle	
	Surveillance assessment to be arranged	Not more than 12 months after accreditation, thereafter
	Identify proposed corrective actions to nonconformities raised	Within 2 weeks after assessment
11.	Clearance of corrective actions by the assessment team	Within 2 months after assessment
	CAB's notification of changes to SDAC	6 weeks before scheduled assessment
	SDAC notification of extra ordinary assessment to CAB	2 days prior to the extraordinary assessment/unscheduled visit
12.	Reassessment Submission of application for renewal of accreditation by CAB	6 months prior to the expiry of the certificate of accreditation