

# WEST AFRICAN ACCREDITATION SYSTEM (SOAC)

# **ACCREDITATION RULES**

(C01.02)

Approval		Effective Date
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# 1. PURPOSE AND SCOPE

This document defines the stages of the assessment process and accreditation of laboratories for analysis, testing or calibration, inspection bodies and certification bodies, and specifies the rights and obligations of conformity assessment bodies' candidates for accreditation in accordance with ISO standards (ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO/IEC 17065, ISO/IEC 17024, ISO/IEC 17043, ISO 17034.)

#### 2. REFERENCES

ISO/IEC 17011, Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies

Applicable documents from ILAC, IAF, and AFRAC.

This Regulation refers to the following documents:

- C02- SOAC Mark General Rules;
- C03 Suspensions, Terminations, and Withdrawal of Accreditation
- C04- Confidentiality Impartiality ;
- C05- Accreditation Fees;
- C06- Rates and Price List ;
- C07- Recusals, Complaints, and Appeals;
- C08- Traceability of Measurements
- C09- Rules of Procedure for Accreditation Committees
- C10- Participation in Proficiency Testing Activities
- C11- Estimation of the Uncertainty of Measurement by Laboratories

These documents are available on the SOAC website (www.soacwaas.org).

#### **3. EFFECTIVE DATE AND REVIEW**

This document is applicable from the date mentioned on the cover page. It will be updated as necessary.

#### 4. SUMMARY OF CHANGES

Version 00: creation. Version 01: revision and update for new dispositions addressed. Version 02: revision and update for some sections.

#### 5. TERMS AND DEFINITIONS

#### 5.1 Terms

**UEMOA**: Union Economique et Monétaire Ouest Africaine (West African Economic and Monetary Union)

**ILAC:** International Laboratory Accreditation Cooperation

**IAF:** International Accreditation Forum

**SOAC:** Système Ouest Africain d'Accréditation (West African Accreditation System)

# 5.2 Definitions

Terms used herein are defined as follows:

**On-site Analysis, testing or calibration:** analysis, testing, calibrating, or analysis part, testing (e.g. samples) or calibration carried out directly at the location of the products, materials or substances objects of the service;

**Inspection:** Review of a product, process, service or facility, or design, and determination of their conformity with specific requirements or, on the basis of professional judgment, with against general requirements

Certification: Statement made by a third party relating to products, processes, systems or persons;

**Appeal**: Request by an accredited organization or candidate for accreditation to reconsider a and change decision taken against him by the SOAC;

**Interlaboratory comparison**: organization, implementation, and evaluation of analysis, testing or calibration on the objects (subject to analysis, testing or calibration) identical or similar by two different laboratories under predetermined conditions;

**Applicant***:* an organization with a legal status that is seeking accreditation by SOAC. If the organization has no legal personality, the accreditation of applicant should be the legal entity to which it belongs;

**Contractual document**: document, mentioned in the accreditation agreement or its appendices, which governs relations between SOAC and accredited or seeking accreditation organization;

Technical field: domain of expertise identified by SOAC;

**Difference:** Difference between an expected location and an observed situation under assessment accredited or seeking accreditation;

**Proficiency Testing**: Assessment of performance of a laboratory for analysis, testing or calibration by means of interlaboratory comparisons;

**Follow-up assessment:** Assessment of the conclusions of an assessment in order to verify the implementation and effectiveness of corrections and corrective actions. Follow-up assessment may occur as part of initial accreditation, consecutive assessment, extension or reaccreditation.

**Extraordinary assessment:** Assessment carried out of the accreditation cycle, which is not initiate following the conclusions of a previous assessment;

Examples:

- Assessment following major changes in the organization of the body's means of production
- Other matters that may affect the ability of the conformity assessment body to fulfil requirements for accreditation. The accreditation body shall advise conformity assessment bodies of this possibility.

Extension of accreditation: The process of broadening the scope of accreditation.

**Organization:** Applicant for accreditation as defined in this Regulation.

**Laboratory**: Organization or technical department of an organization whose main activity is the production of analysis, testing or calibration in one or more technical fields and one or more sites. **Permanent laboratory (fixed)**: Laboratory built on a fixed location and the duration of the activity is not restricted a priori.

**Non-permanent laboratory (temporary):** Laboratory built on a site for a limited activity in the period. For example, a laboratory set up in the framework of a specific contract requiring laboratory nearby (construction of a work of art, etc.).

Mobile laboratory: Movable laboratory.

**Complaints or claims**: Expression of dissatisfaction, other than that mentioned under the term "appeal", issued any entity or individual against SOAC and its operations or the operations of SOAC accredited body, and for which an answer is expected ;

**Reduction of accreditation**: the process of restricting the scope of accreditation.

**Scope of assessment**: Specific services of analysis, testing, calibration, inspection or certification assess following an application for accreditation.

**Scope of accreditation application**: formal and specific activities for which accreditation is requested.

**Scope of accreditation**: Formal and precise statement of the activities for which the organization is accredited.

**Consecutive assessment:** Set of assessment activities other than reassessment, to verify that an accredited body continues to meet the requirements of accreditation.

**Suspension of accreditation**: The process of temporarily invalidate accreditation for all or part of its scope of accreditation.

Withdrawal of accreditation: Process of removing accreditation in its entirety.

Note: Other non-specified definitions are to be consulted in ISO / IEC 17000 in force.

#### 6. ACCREDITATION REQUIREMENTS

#### 6.1 General Requirements

The general requirements to be met by accredited organizations or candidates for accreditation are defined in ISO/IEC 17025, ISO 15189, ISO/IEC 17020 or ISO/IEC 17065, ISO/IEC 17024, ISO/IEC 17043, ISO 17034 as applicable.

By signing an accreditation agreement, the organization undertakes to comply with these regulations and other contractual documents, including those relating to the use of the SOAC mark, fees and accreditation fees.

#### 6.2 Specific requirements

When a community or national regulatory text makes obtaining authorization to SOAC accreditation, this accreditation regulation may be supplemented by relevant regulatory requirements. These are then communicated to the applicant for accreditation during the processing of the application. In addition to these rules, there is the obligation not to create, maintain or create ambiguity between SOAC accreditation and the approval issued by the competent authorities.

These rules, add the obligation not to create, maintain or support ambiguity between SOAC accreditation and authorization delivered by the competent authorities.

As part of the harmonization of its practices, SOAC may have to edit technical documents to be

used by assessors and conformity assessment bodies. These technical documents are not specific requirements enforceable against the conformity assessment bodies. They are guides for the application of ISO/IEC 17025, ISO 15189, ISO/IEC 17020, ISO/IEC 17065, ISO/IEC 17024, ISO/IEC 17043, ISO 17034 for specific technical areas.

In all cases, it is up to it to show that its provisions allow to fully meet the accreditation standard.

#### 6.3 Analysis, testing, calibration on-site or in mobile or temporary facilities

The quality management system of a laboratory to perform analyses, testing or calibrations on-site or in mobile or temporary sites must, among others, include:

- an updated list of mobile or temporary laboratories;
- an updated list of equipment used for on-site activities and associated
- documentation with their work;
- an updated list of documents applicable by technicians on-site;
- an updated list of specially qualified staff for analysis, tests or calibrations on-site;

Procedures for ensuring the control of records and reports on the results associated with the results obtained on-site or in a mobile or temporary laboratory.

The applicant must formalize the arrangements for the preservation of the fitness for use of the equipment on the field or in its mobile laboratories (transport, storage, use, etc.).

In its application, the laboratory must have set the boundary conditions of the use of the equipment on-site. The "use boundary conditions" are the fixed terminals for the different experimental parameters: influence of mounting, temperature, atmospheric pressure, humidity, etc.

For calibration laboratories, accreditation is granted for the best opportunities for on-site calibrations. The laboratory must quantify and take into account in the assessment of uncertainty and the expression of the result of the calibration, including its associated uncertainty, the influence of ground conditions.

#### 7. TERMS OF ACCREDITATION

The information gathered by SOAC and its assessors is confidential and covered by professional secrecy (see C04).

#### 7.1 Initial accreditation

As part of a first application, the accreditation process has five main phases described below (§ 7.1.1 to § 7.1.5).

#### 7.1.1 Preliminary Instruction

On receipt of an application for accreditation expressed in writing, SOAC addresses to the applicant, the accreditation application forms allowing him to formally confirm his/her request according to the selected reference system.

These forms provide information on the legal status and organization of the applicant, the scope of the applicant's quality system and the detailed technical activities covered by the application for accreditation. They are also available on the SOAC website (www.soacwaas.org).

The receipt by SOAC of these forms, referenced documents, and other documents, as appropriate, initiates the opening of an accreditation file.

# 7.1.1.1- Information on participation in proficiency testing programs / interlaboratory comparisons (for laboratories testing/calibration)

The results of proficiency testing programs (PT) / interlaboratory comparisons (ILC) and the selfassessment undertaken by the laboratories must be submitted with the application form. If the laboratory used internal methods, validation reports must also be submitted with the application forms.

Participation in proficiency testing programs, interlaboratory comparisons, is a prerequisite for accreditation.

#### 7.1.1.2 Information on traceability measurement

The general requirements on traceability to the International System applicable to accredited organizations that carry out measures to support their activities are defined in the document C08. All equipment used for tests and/or calibrations, including instruments used in measurements having a significant effect on the accuracy or validity of the test results, calibration or sampling, must be calibrated before being put into service. This is a requirement for laboratories to justify the need for calibration.

#### 7.1.1.3 Methods (applicable only for laboratories)

Laboratories should preferably use standardized methods. New versions of the standard methods will be implemented **within 06 months of their publication** unless otherwise specified by the regulatory authorities.

If the laboratory uses a modified standard method (small changes/modifications to a standard method), the changes must be recorded in the documentation of the laboratory. The changes must be validated and the validation report must be documented to show that the results (including the uncertainty of corresponding measures) are the same as those of the standard method. Where a modified standard method is used, the test report/calibration certificate must be indicated.

If another measuring principle is used and/or matrix is modified relative to the standard method, the method should be defined as an internal method. Internal methods based on standardized methods are methods in which the laboratory has made some changes and where the validation data must show that the modified method does not give the same result (including the uncertainty of corresponding measures) as when using the standard method. All modifications of the standard method shall be described in the documentation of the laboratory.

If the laboratory uses a standard method withdrawn, it means that the method is defined as an internal method based on withdrawn standards. Laboratories must document this procedure. If the laboratory uses an earlier version of a standard method more than 06 months after its revision and if it is accepted by SOAC, the method must be defined as an internal method based on the previous version.

# 7.1.1.4 Normative documents (applicable only for certification and inspection bodies)

A normative document can be a standard / guide a national, regional or international law or national legislation, government directives and other documents that are accepted by stakeholders.

The applicant must indicate the normative document used for certification/inspection. SOAC may require the applicant to put at its disposal a copy of this document with SOAC application forms.

#### 7.1.1.5 Resource review

The accreditation request is formalized when the applicant returns to SOAC duly filled forms with additional documents if necessary.

The documents filed are subject to review by SOAC to ensure the admissibility of the application. This is declared when on the one hand the applicant's overall organization is consistent with the accreditation request and on the other hand, SOAC is able to respond to this request. For this statement, SOAC is taking into account its policies and procedures, skills and the availability of appropriate staff for assessment activities and decision-making.

In the case of an initial assessment, the review also includes the ability of the SOAC to carry out the assessment in a timely manner. When it cannot be, the conformity assessment body is informed.

When the application is admissible, SOAC notifies the applicant a pro forma invoice stating the cost of record instruction, assessment and the amount of use of the symbols of accreditation rights. If the file is not complete, the applicant is informed about the missing or incomplete parts. In case of refusal of the application, the decision is notified to the applicant by taking care to specify the reasons for the denial of the request.

#### 7.1.2 Signed an accreditation agreement

At the end of the preliminary instruction stage of the application, and an accreditation agreement is established between SOAC and the applicant. This agreement specifies in particular:

- the name and address of the applicant for accreditation;
- the name and address of the organization for which accreditation is sought;
- mutual commitments of the applicant and SOAC;
- the description of the scope of accreditation accepted by SOAC for assessment;
- list of relevant contractual documents related to the scope to be assessed.

If within one year after the signing of the agreement, the conformity assessment body does not respond to SOAC queries about the progress of his case or has not honoured the bill of instruction costs, it can be closed. The revival of this application is considered as a new application for initial accreditation.

#### 7.1.3 Applicant Assessment

#### 7.1.3.1 Selection of assessors

SOAC contracted a number of assessors/technical experts qualified and registered as required. For each application, SOAC will select in the register appropriate assessors and experts and will propose the team to the conformity assessment body (CAB).

SOAC has 30 calendar days from the date of payment of the assessment invoice to prepare the onsite assessment, namely: the selection and proposal of the assessment team to the CAB as well as the contracts of the members of the selected team.

Depending on the number of accreditation areas and the number of methods and parameters to be assessed, SOAC will determine the duration of the assessment which is also dependent on the assessment team's experience.

A certain number of « trainee » assessor (s) placed under the responsibility of the Team leader, may accompany the assessment team.

The assessment team may also be accompanied by observers appointed by SOAC or by regional or international accreditation organizations (in particular under Mutual Recognition Agreements). Observers do not participate in any case in the assessment of the organization.

Within 07 calendar days of receipt of the proposal for the assessment team, the CAB may challenge reject all or part of the assessment team proposed (see document C07).

If the conformity assessment body refuses the assessment team or team member proposed by SOAC, this must be explained and SOAC must assess whether the reasons are acceptable and propose changes to the composition of the assessment team.

The assessment team selected and proposed by SOAC to the applicant covers all the quality and technical skills required to assess the technical areas of the scope to be assessed.

### 7.1.3.2. Applicant's records review

Prior to the completion of the on-site assessment, the assessment team conducts a review of documents provided by the CAB to assess compliance of its system with standards and other relevant accreditation requirements.

When the review of documented information reveals nonconformities, the CAB is invited to treat and provide proof.

Otherwise, SOAC and the CAB agree to the effective date of the assessment visit.

SOAC may decide not to pursue an assessment on the basis of the review of documented information. In this case, the results and their justification are communicated in writing to the CAB.

#### 7.1.3.3 Preliminary visit

Prior to the formal accreditation process, organizations wishing accreditation can voluntarily submit a request to SOAC to conduct a preliminary visit. The purpose of a preliminary visit is to assess the state of preparations for accreditation. The preliminary visits can, however, be mandatory for new organizations seeking accreditation under the conditions of acceptance of the regulator.

During a preliminary visit, assessors must conduct a pre-assessment of the candidate's management system, premises, equipment and the competence of personnel involved. After such a visit, a brief report will be presented to the candidate. The possible result of the preliminary visit is:

- The initial assessment will be conducted;
- Corrective actions are necessary and the candidate to inform when they are ready for assessment;
- Assessment cannot be performed.

During the preliminary visit missions, assessors are not allowed to give advice on the management system and assessed activities.

SOAC delivers a report to the applicant organization within 15 days after the preliminary visit.

#### 7.1.3.4 Initial assessment

When the decision is to make an initial assessment, this assessment must be done on the premises of the applicant. The assessment team must visit the main office and other premises where key activities are performed. The initial assessment assesses the organization's competence to perform specific a task for which accreditation is sought.

Normally, the assessment may begin upon receipt of the agreement signed by the applicant and SOAC and perception of a part of the assessment fee and investigation (see document C05 and C06).

The Lead assessor shall share with the CAB and SOAC a plan of the conduct of the assessment and any specific requirements relating thereto, including the ability to observe the execution of certain witness work. The on-site assessment includes the following steps:

- → An opening meeting: Chaired by the Lead Assessor and assisted by members of the assessment team, the management of the applicant organization, the representative of the management, staff involved in the locations to be accredited as identified by the applicant organization. During this meeting, the Lead Assessor explains the purpose of the assessment, the assessment activities, accreditation requirements, and confirms the assessment plan and its scope.
- → An assessment of the management system of the applicant organization is carried out to ensure compliance with the requirements by SOAC's assessment team who must also assess the implementation of the system and observe the execution of technical activities. The assessment covers all aspects of the scope of the request of the applicant. The team conducts the assessment based on the confirmed assessment plan.

During the assessment, the candidate must put at the disposal key personnel needed to provide the required information or complementary explanations to the assessors. These latter must have access to all documents related to the Quality Management System.

Assessors should record all nonconformities raised during the assessment and inform the applicant organization about them during the closing meeting.

→ A closing meeting: must take place on-site at the end of the assessment, chaired by the Lead Assessor and assisted by members of the assessment team, the management of the applicant organization, the representative of management and personnel involved in the assessed areas identified by the applicant organization. The purpose of the closing meeting is to inform the applicant organization on the outcome of the assessment, including nonconformities raised during the on-site assessment. The applicant organization must have the opportunity to seek clarification and ask questions.

The assessment team records the nonconformities on the deviation sheets which are confirmed during the meeting by CAB.

After the completion of the on-site assessment, the applicant organization must be invited to:

- $\rightarrow$  identify and propose corrective actions within **07 days** after the end of the assessment,
- $\rightarrow$  demonstrate the clearance of nonconformities identified in a period of **45 days** after the assessment,
- $\rightarrow$  in all cases, the delay shall not exceed 90 days.

#### 7.1.3.5 Assessment Report

After each assessment, the Lead Assessor must submit the assessment report including the data of the members of the assessment team and the corrective action plan commented, SOAC within **30 to 45 days** after the assessment. The report should include all data and recommendations of the assessment team.

SOAC must ensure that the corrective actions decided by the CAB as responses of nonconformities are examined to be adequate and sufficient. Contrary, SOAC may request evidence of the implementation of the actions decided upon or a follow-up assessment to check the implementation of the corrective actions.

SOAC must check the contents of the report and remain responsible for the suitability of the assessment report.

SOAC wait for corrective actions on the part of the applicant organization / accredited in the due time.

When the assessment report is issued before the clearance of all the deviations identified, the accreditation officer monitors and the closing of residual differences in cooperation with the assessment team.

The report once reviewed by SOAC accreditation officer is given to SOAC Accreditation Committee accompanied by the documents related to the committee accreditation recommendation and a copy is sent to the applicant organization.

When the content of the assessment report is different from the results delivered at the closing meeting of the assessment, SOAC ensures that it is forwarded to the CAB accompanied by an explanatory document.

The assessment report must include at least the following:

- unique identification of the CAB;
- date (s) of the on-site assessment;
- name (s) of the assessor (s) and/or experts involved in the assessment;
- unique identification of all premises assessed;
- the proposed scope of accreditation that was assessed;
- a statement on the adequacy of the internal organization and procedures adopted by the conformity assessment body to give confidence in its competence, as determined through its fulfilment of the requirements for accreditation;
- information on the resolution of nonconformities;
- the overall conclusions of the assessment team;
- the technical findings of the assessment team;
- other information that may help determine the requirements and the competence of the CAB; and
- where applicable, a summary of results in proficiency testing or other comparisons conducted by the CAB and any measures taken following the results.

Within **07 calendar days** of receipt, the body can respond to the assessment report from SOAC to indicate any disagreement or to submit a complaint.

In the event that the conformity assessment body terminates the assessment before the completion of the mandate given to the assessment team, no evaluation report is issued and the applicant's file is closed.

#### 7.1.3.6 Witnessing of control activity associated with the application for accreditation

The assessors assess the performance of a sample of the CAB's activities representative of the applicant's scope of accreditation. The assessment should cover a representative sample of locations and staff members to determine the competence of the conformity assessment body in carrying out the activities covered by its scope of accreditation.

The selection of the activities to be assessed depends on the risk associated with the activities, locations, and staff covered by the scope of accreditation.

The scope of the CAB must be witnessed and fully covered during the SOAC accreditation cycle which is **2 years**.

In the case where witnessing is not appropriate or applicable, the team leader must document and justify it in the assessment report. Where the on-site assessment is not applicable, SOAC shall use another assessment technique to achieve the same purpose as the on-site assessment so replaced, and justify the use of these techniques (e.g. remote assessment).

For laboratories, testing/calibration and/or sampling selected are observed during the on-site assessment. The observation of activities held at each location where testing/calibration is

undertaken.

**For certification/inspection body** observation of activities to be accredited is normally performed within the scope of accreditation. However, if some of the normative documents are considered, based on technical reasons, as belonging to the same group, so a sample can be valid for the entire group of normative documents. The observation of control activity should be performed at each location visited.

### 7.1.4 Accreditation decision

For decisions from initial assessments, reassessments, and extensions of new scopes, the accreditation committee must consist of at least two members, one of them must be the Director-General of SOAC except when he is in a situation of impediment or in a conflict of interest for a given CAB. For decisions arising from assessments monitoring and extension of existing scopes and technical signatory, the accreditation committee must consist of at least one member (see C09).

Reasonable response time is indicated to the committee members. As much as possible this period will not exceed **15 days.** 

The decisions resulting from the assessment are based on the findings and conclusions of the assessment report, on the acceptability of the action plans in response to nonconformities, on the outcome of the examination of any evidence of actions submitted by the organization prior to the file review, as well as any other relevant information known to the SOAC and known to the organization.

If these principles are followed, the committee may propose four types of decision:

- **accreditation:** when the proof of mastery of any discrepancy situations that may affect the activities for which accreditation is sought, identified could be made;
- a refusal to accreditation pending the results of the follow-up assessment;
- **a refusal to accreditation**: when control nonconformities situations that may affect the activities for which accreditation is sought could be demonstrated.

The accreditation decision is made by the Director-General of SOAC considering the opinion of the Accreditation Committee.

#### 7.1.5 Communication on the accreditation decision

SOAC notifies its accreditation decision to the applicant within a maximum period of **15 days** after notice of the Accreditation Committee.

This notification specifies the nature and motives of the decision and the possible follow-up to the progress of the file.

After a decision of refusing accreditation, the body may reapply for accreditation if it considers have implemented the provisions comply with the requirements of accreditation.

When the decision is favourable, the SOAC delivers:

- an **accreditation certificate** specifying, in particular, the identity of the accredited body, the accreditation number and the validity of accreditation;
- a **technical annex** to the accreditation certificate describing unambiguously the scope of the certification granted;
- an **accreditation diploma** for promotional purposes (only for initial accreditation);
- SOAC Logotype (s).

The technical Annex is a document that the applicant or the SOAC can communicate on request. The technical annexes of organizations accredited by the SOAC are posted on the website of the SOAC (<u>www.soacwaas.org</u>) throughout the validity of the accreditation.

# 7.1.6 Period of validity of accreditation

Accreditation is granted for a period of **02 years** and begins on **the date of the decision by the Director-General of SOAC.** 

During the period of validity of the accreditation, the CAB is being monitored (see § 7.2) and has the opportunity to request an extension, suspension or termination of accreditation (see § 7.4 and 7.6).

SOAC has the possibility to suspend, reduce or withdraw accreditation if serious breaches of accreditation requirements are identified (see § 7.6).

At the end of the validity period of the certificate, the CAB is subject to reassessment for the renewal of accreditation (see § 7.3). The assessment programme of a CAB is based on the requirements of International Standards and other normative documents containing requirements for conformity assessment bodies. The CAB assessment programme and accreditation scope are assessed taking into consideration the risk.

# 7.1.7 Accreditation application follow-up

If the application for accreditation was not completed within a period of **1 year** from the date of signature of the agreement, due to the applicant's reasons, SOAC may close the current process. In this case, any new application for accreditation is treated identically to an initial

#### 7.2 Consecutive accreditation assessment

Consecutive accreditation assessment (monitoring of accreditation) is carried out notably through annual assessments spaced by **12 months**, with a possibility of shifting  $\pm$  **02 months** compared to the provisional program.

In any case, the interval between consecutive assessments may not exceed 18 months.

The program visits of consecutive assessments and the composition of the assessment team are listed below.

Consecutive assessments visits programme of composition of the assessment team.

Consecutive assessments visits programme	Initial assessment D <sub>0</sub>	Consecutive assessment D <sub>0</sub> + 12 months	Renewal D <sub>0</sub> + 24 months
Composition of the assessment team	QA + TE	QA / TE / TE + QA	QA+ TE

#### Legend

 $\mathsf{D}_0:$  Date of the initial assessment/follow-up assessment for closing deviations in the initial evaluation

QA: Quality Assessor TA/E: Technical Assessor or Technical Expert As part of the surveillance, in addition to the assessment visits scheduled, based on the information in his possession, SOAC may at any time make an assessment visit to the premises of the accredited organization. This visit can be unannounced.

The costs of this assessment visit are the responsibility of SOAC when the resulting report shows that the body continues to meet the requirements of accreditation. Otherwise, the organization supports these fees and may be subject to sanctions of SOAC (see § 7.6).

Under supervision, the technical skills of the selected assessment team and proposed by SOAC are flexible according to the situation of the organization (eg, participation in interlaboratory comparisons, etc.).

On the occasion of the visits, besides the quality documentation review, the assessment team ensure in particular that:

- remedial corrections and actions which the organization had engaged were implemented within the agreed time and are effective;
- internal audits and management reviews are planned and conducted appropriately and efficiently operated results;
- the adjustments made by the body in its organization and its resources, as well as changes in key personnel since the last assessment visit, satisfy the requirements of accreditation;
- the skills of the staff of the CAB are maintained and demonstrated;
- the organization applies implements its quality management system and respects the rules of use of SOAC mark and reference to accreditation;
- the reports and minutes of activity meet the requirements of presentation and traceability;
- The organization's participation (case of laboratories) to proficiency testing/interlaboratory comparisons, when available, is consistent with the scope of accreditation and the results properly exploited.

After each monitoring visit, an assessment report is prepared and transmitted to the body.

SOAC may subordinate maintaining accreditation to the realization of extraordinary assessment in a period determined by SOAC or suspend accreditation if the identified deviations question the organization's ability to meet accreditation requirements (see § 7.5 and 7.6).

In all cases, the decision of SOAC is notified to the organization in writing.

#### 7.3 Renewal of accreditation

The reassessment period is fixed by SOAC so that the new accreditation attestation can be established prior to the date of the expiry of the previous accreditation. SOAC specifies to the CAB the period for this assessment and asked the necessary information for its organization. SOAC reserves the right to suspend the accreditation of the organization which would not provide the information requested after the time specified.

The mission of the assessment team in the renewal is the same as the initial assessment. The reassessment will be planned and implemented taking into consideration the information gathered from the assessments made during the accreditation cycle.

The reassessment confirms the competence of the conformity assessment body and covers all the requirements of the standard (s) for which the conformity assessment body is accredited.

At the end of the renewal assessment, a report is prepared, circulated and reviewed as described in § 7.1.3.5.

When the SOAC grants accreditation, it establishes and gives the body CAB a new accreditation

certificate.

#### 7.4 Extension of accreditation

The accredited body may at any time request an extension of its scope of accreditation to SOAC. The extensions of the scope of accreditation are:

- ✓ new test methods, calibration or sample, parameters or standards;
- ✓ Inspection in a new field;
- ✓ Certification according to new standards or new industries;
- ✓ the inclusion of new locations
- ✓ Etc.

The extension request must be addressed to SOAC at least **03 months** before the desired period for the extension assessment, or **03 months** before the period for the consecutive assessment or renewal (for coupled assessments).

The organization can not, in any case, make a request extension on the day of an assessment visit.

The process of instruction and assessment of an application for extension is identical to an original application. However, they can be simplified according to the results of the previous assessment and the risk associated with the activities or locations to be covered in the scope extension.

The extension assessment report is reviewed under the provisions described in § 7.1.3.5.

When the decision is favourable, SOAC supplies the body with **a new technical annex** taking into account the extension granted.

The validity period of the extension is that of the current accreditation certificate.

SOAC takes into account the extensions granted during the review of the assessment program and the planning of the subsequent.

Depending on the risk associated with the activities or sites to be covered in the scope extension, SOAC defines the appropriate assessment technique (s) to be applied and takes into consideration the normative requirements for the review of resources, the preparation of assessment, review of documented information, assessment, accreditation decision-making, accreditation information and the accreditation cycle.

#### 7.5 Extraordinary assessments

Extraordinary assessments can take place when major changes occur in the case of complaints, change of company name, or other matters that may affect the ability of the conformity assessment body to fulfil requirements for accreditation.

#### 7.6 suspensions, terminations, and withdrawals of accreditation

Accreditation may be suspended or withdrawn if the accreditation conditions are no longer met or after a request by the accredited organization that believes it cannot meet accreditation requirements, such as changes of premises, loss of key personnel, etc. This must be done in writing and according to the requirements described in the document C03.

SOAC may suspend accreditation if nonconformities are not corrected within the agreed period or if the conditions are not met. Examples of serious failures that can lead to the suspension are:

 $\checkmark$  no traceability to measurement standards;

- ✓ loss of key personnel;
- ✓ unacceptable results from comparisons between laboratories ;
- ✓ incompetent key personnel after the change of personnel;
- ✓ lack of performance of corrective actions within the agreed time;
- mistakes the performance test/calibration/certification/inspection that shows serious errors in the management system of the body;
- ✓ misuse of accreditation;
- $\checkmark$  not following the relevant requirements;
- ✓ non-payment of accreditation fees;
- ✓ failure to notify SOAC of changes affecting the status of CABs
- ✓ etc.

During the suspension period, the body should not provide accredited services for the suspended activities. All reports of tests/calibrations, certification or inspection contained in the certification program should not be issued in the area where the suspension was lifted. The organization must inform customers about the suspension and its consequences.

Accreditation will be restored by SOAC when the organization has shown that the conditions are met within the agreed time and satisfy the accreditation requirements. However, if nonconformities are not corrected within the agreed period, SOAC must terminate accreditation.

The provisions for suspensions, terminations, and withdrawals of accreditation are specified in the document C03.

# 8. OUTSOURCING TESTING, CALIBRATION OR INSPECTIONS

An accredited organization (laboratory or inspection body) by SOAC may outsource with another organization of the activities contained in its scope of accreditation.

When an accredited conformity assessment body (laboratory or inspection body) wishes to report the results obtained from the body that provides outsourced services under his SOAC accreditation, an organization must:

- be fully responsible for the testing, calibration or inspection outsourced;
- inform the customer if needed and get his agreement in writing its willingness to outsource its work;
- obtain permission from the body that provides outsourced services to report the results of the work from outsourcing;
- ensure that the body that provides outsourced services is accredited for testing, calibration or inspections included in its scope of accreditation;
- ensure that the body that provides outsourced services is accredited by SOAC or any other accreditation body signatory to the ILAC and AFRAC Mutual Recognition Arrangements for the activities concerned.

#### 9. COMPLAINTS AND APPEALS

The body can issue a complaint or appeal to the accreditation decision of SOAC. The body shall have **30 calendar days** from receipt of the accreditation decision to lodge an appeal in writing to SOAC, together with the reasons and justifications. Complaints other than appeals are handled by General Management, which reports to the Board of Directors at least once a year. (see C07)

SOAC records the complaint or appeal and informs the complainant that the request is received. After review and investigation, the SOAC shall respond to the complainant and keeps records relating to this dossier. The complaint or appeal must be processed in accordance with the document C07. Throughout the investigation of a complaint or appeal, all decisions made before the complaint or appeal stand.

# **10. OBLIGATIONS OF ACCREDITED BODIES**

The obligations of organizations accredited by SOAC or candidates for accreditation are defined in the agreement.

When the already accredited applicant refuses to sign a new agreement or an amendment to it, SOAC acknowledges this refusal. SOAC informs the concerned applicant by recorded delivery letter that the current agreement expires on the expiry date of the certificate in force; and that it is not possible to formulate against SOAC any request for damages.

# 11. TABLE OF MODIFICATIONS

No.	Source	Modification in brief (Relevant changes)			
C01.00- 24 January 2019					
Creation	1				
C01.01-	C01.01- 30 July 2019				
1	§ 7.1.1.5	The paragraph 7.1.1.4 has been revised into two parts to highlight the paragraph 7.1.1.5 dealing with resource review and arrangements made during the initial assessment.			
2	§ 7.1.3.1	For the selection of assessors has a paragraph has been added to address arrangements taken by SOAC for determining the duration of the assessment.			
3	§ 7.1.3.4	Words added to clarify how the team operates and how it conducts the assessment of the candidate CAB's QMS.			
4	§ 7.1.3.5	To specify dispositions related to the review of the relevance of the corrective actions submitted by the CAB to solve of nonconformities.			
5	§ 7.1.3.6	4 points added in this paragraph to specify dispositions made for the witnessing of CAB's activities when applying for accreditation.			
6	§ 7.3	Confirming CAB's competence during the reassessment			
7	§ 7.4	Disposition specified for the review of the current and subsequent assessment program.			
8	§ 7.5	A new paragraph created to address arrangements made for extraordinary assessments.			
C01.02-	03 September 2019				
1	Lower cartridge	The title of the lower cartridge on the cover sheet has been revised			
2	§ 1	The title has been revised			
3	§ 2	The references have been revised in line with the wording of the standards			
4	§ 3	The title has been revised			
5	§ 5	The title has been revised			
6	§ 5.1	The title has been revised			

No.	Source	Modification in brief (Relevant changes)
7		Definitions have been revised on the
	§ 5.2	wording organism replaced by
		''organization''
8	§ 7.1	Taking into account risk requirements
9	§ 7.1.1	Exclusions of forms referred to from
	-	this section.
10	§ 7.1.1.1	Update of the provisions
	§ 7.1.4	Addition of new words addressing
11		the response time of the accreditation
		committee and update of
		accreditation recommendations
	§ 7.1.5	This section has been revised to take
		into account the wording
12		"accreditation diploma" instead of
		"accreditation certificate" already
		used to avoid any redundancy
13	§ 7.1.3.1	This section has been technically
15	§ 7.1.5.1	revised and updated
	§ 7.1.3.3	The title has been revised and the
14		word "pre-assessment" has been
		replaced by "preliminary visit"
15	§ 7.1.3.4	Update of the response time to
		resolve nonconformities after an
		assessment
16	§ 7.2	Update of the legend
17	§ 7.5	Update of the section
18	§ 9	Alignment with C07