

# SYSTEME OUEST AFRICAIN D'ACCREDITATION (SOAC)

## Assessment for Product Certification Bodies (I02P06CE)

Approbation		Effective date
Date	15/07/19	
Signature	Scan me	15/07/19

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### 1. PURPOSE & SCOPE

The purpose of this document is to describe the requirements in conducting the process of accreditation assessment (pre-assessment, initial assessment, consecutive assessment, and re-assessments) for products CBs in accordance with ISO/IEC 17065:2012, IAF, AFRAC & SOAC regulations and requirements.

The scope of this procedure covers the pre-assessment, initial assessment, consecutive assessment, extension of scope and re-assessment for products CBs that seek and maintain accreditation status to ISO/IEC 17065:2012.

### **2. REFERENCE**

C01- Accreditation Rules P06- accreditation process management ISO/IEC 17011:2017 ISO/IEC 17065:2012 ISO/IEC 17067:2013 IAF Guidelines AFRAC Requirements. Certification schemes for products for which accreditation is sought

### **3. BROADCAST LIST**

All services concerned.

#### **4. EFFECTIVE AND REVIEW**

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

### **5. SUMMARY OF CHANGES**

This document is the first version.

### 6. ABBREVIATIONS AND DEFINITIONS

#### 6.1. Technical Experts:

SOAC may also use technical experts to work alongside the assessment team to assist in the assessment process. This will normally be to assess the technical content of certification schemes, e.g., the criteria of technical competence for CB personnel, the suitability of training programmers; the adequacy of the competencies needs analysis, etc. As technical experts are not designated as assessors they are accompanied by a competent assessor.

#### 6.2. Multi-location CB:

A CB with a head office function by which key activities are performed or managed with one or more fixed office locations at which such activities are fully or partially carried out. All fixed offices shall have a direct legal or contractual link with the legal entity that is the head office of the CB and are subject to the CB's management system and management control from the head office.

#### 6.3. Audit:

The process by which a CB determines whether an organization, individual, product or service meets the requirements for certification to be granted.

#### 6.4. Auditor:

The CB personnel (permanent or contracted) are undertaking the audit.

#### 6.5. Fixed Office Location:

A permanent premise, apart from the head office, where certification activities are performed and/or managed for the CB, regardless of location and relationship with the CB. (Note: This does not include personal homes of remote based workers).

#### 6.6. Finding:

A recorded observation from a SOAC assessment where there is potential for improvement by the CB. Mandatory findings highlight a situation where a non-conformity is present, recommended findings highlight a situation where there is opportunity for improvement but no non-conformance.

#### 6.7. Accredited certificate:

A certificate issued by a CB in accordance with the conditions of its accreditation and bearing an accreditation mark or statement.

#### 6.8. Professional Certificate:

A certified person who achieved a summary test certificate applied the skills in industry and demonstrated the skills by evidence which are assessed by a committee of experts.

#### 6.9. Attendance Certificate:

A person attended the course and passed the test (based on a pool of tests practice and/ or questions to be applied as an authoritative benchmark for assessing performance).

#### 7. PROCESS DESCRIPTION

#### General

- 1. This document is applicable to applicant and accredited CBs providing services under ISO/IEC 17065:2012.
- 2.One of the functions of SOAC is to assess and accredit the competence of CBs to carry out certification of products/processes/services, in specified areas and subsequently to ensure by monitoring that the required standards are maintained. Each applicant and accredited CB provides information to SOAC on its activities, organization and staff.
- 3.Assessment of the competence of a CB is performed using a range of assessment techniques, which can include, but is not limited to: document

review; assessment of the CB's management and control of its activities; assessment of any fixed office location; witnessed assessments of CB's audit processes; and/or post audit reviews of certified persons or products/processes/services.

- 4. The purpose of the assessment is to determine whether a CB is performing its audits in a competent and fit for purpose manner and in conformance with the requirements of ISO/IEC 17065:2012 Conformity Assessment Requirements for bodies providing certification of products, processes and services as applicable (hereafter referred to as 'the standard') and other applicable documents, e.g. AFRAC & IAF application documents.
- 5.All information obtained before, during or after assessment, including the fact that a particular CB has applied for accreditation, or that an application has been deferred or rejected, will be treated as strictly confidential by SOAC staff and contracted assessors/technical experts. This is the case except when SOAC is required by law to disclose information.
- 6. This document outlines how SOAC plans and conducts assessments. Consecutive assessment and reassessment visits to CBs working to the standard are on a two year cycle basis. Other visit types (e.g. extensions to scope) are on a required basis. This document also refers to the assessment techniques normally employed.
- 7.Every CB is unique and the assessment plan must recognize this. However, a structure to ensure an impartial and consistent assessment approach within which judgments are made is needed. By outlining the minimum requirements this document provides such a structure.
- 8.All circumstances cannot be anticipated and it may be necessary to deviate from these requirements in order to conduct an effective assessment. Where an alternative approach is used by SOAC then it will explain the reasons for this to the affected CB(s).

#### Note:

SOAC accreditation personnel and committees keep an eye to the interested parties relations with CAB's as a risk and preceded assessment steps to stop the assessment process for any impartiality broken reasons.

### 7.1. Processing of Applications

- 7.1.1. Processing of application shall be conducted exactly in accordance with SOAC procedure P06\_ accreditation process management.
- 7.1.2. Applicant CB shall submit the following:
  - Fully completed form F01P06CE\_SOAC CBs application form;
  - Two copies of form F04P06\_SOAC CAB Assessment and accreditation Agreement to be signed;
  - Self-assessment checklist for Product CBs F03P06CE;
  - Electronic copies of the applicant's management system and relevant associated documentation;

- List of all forthcoming audit activities (the fields and types of activity, the assigned auditors and client details);
- Application fee according to C06-fees;
- Evidence of the identity of the legal entity applying for accreditation;
- When applicable (i.e. Côte d'Ivoire), the official authorization to exercise activity issued by ministerial order of the technical minister concerned by the activity;
- 7.1.3. Applications submitted without of all the above documentation will not be accepted until all documentation is provided. It is expected that all applications are submitted in electronic format. All applicant organizations are subject to credit check; credit terms will only be extended to organizations with a good and proven credit history.
- 7.1.4. SOAC normally accepts applications from CBs whose head office function are not established in UEMOA Member States, SOAC may be use IAF MLA signatory ABs where possible to conduct the assessments according to cross frontier policy.
- 7.1.5. On acceptance of an application for accreditation from a CB, SOAC product CBs accreditation officer will be responsible for the case management of that CB. SOAC product CBs accreditation officer will contact the CB to:
  - confirm the standard(s) and scope of certification for which the CB is seeking accreditation;
  - confirm the structural and managerial organization of the CB including the legal entity which is seeking accreditation;
  - Confirm the different fixed office locations from which the certification service is managed and/or delivered and whether any key activities are carried out at each of these; (according IAF MD12 Assessment of certification activities for cross frontier accreditation).
- 7.1.6. Following review of the application; SOAC will provide an estimate of the effort (in man days) that will be required to conduct a documentation review (including where relevant sector scheme pre-assessment (where required) and review), а initial assessment, including; head office assessment; all associated (exceptionally replaced witnessed assessments bv postassessment reviews) and fixed office location assessments. Prior to any work being carried out, a quotation will be provided.
- 7.1.7. In the case of product certification schemes, ISO/IEC 17067:2013 is the reference for scheme requirements.
- 7.1.8. At the end of this stage, SOAC product CBs accreditation officer shall submit for both the nominated team leader and the assessor/s a copy of record F03P06CE\_Self-assessment checklist for Product CBs, quality manual (if any) and CB procedures for document review.
- 7.1.9. The assessment team shall sign confidentiality and impartiality agreement form F10P06 before starting any activity of the assessment, including document review.

### 7.2. Resource review

- 7.2.1. The data base of product CBs assessment personnel is kept and updated by Quality & Technical Accreditation officer in coordination with SOAC product CBs accreditation officer and SOAC Quality and Technical Accreditation Officer.
- 7.2.2. SOAC product CBs accreditation officer, in consultancy with SOAC Quality & Technical Management officer, shall identify an appropriate team leader and assessors and/or technical expert according to their area of expertise to allow for a full initial assessment of the applicant for the scope of accreditation. All assessors shall be totally independent of any connection whatsoever with the applicant to be accredited. All assessors appointed for a specific assessment shall comply with the requirements in SOAC procedure P09 skills management.
- 7.2.3. SOAC shall notify the applicant in writing of the names and affiliations of the nominated assessors on the form F01P07-Proposal of assessment team. The notification shall seek the approval of the applicant to the nominated team. Objection to any nominated team members shall be in writing, include a detailed justification from the CBs to his objection, and shall be lodged with SOAC within seven calendar days of receipt of the nominations. Failure by the applicant to object to any of the nominated team members shall be considered as acceptance of the team as a whole.
- 7.2.4. Objections from the CB to any of the nominated assessors will be investigated by the SOAC product CBs accreditation officer. If SOAC product CBs accreditation officer is satisfied with the CB's justification to his objection, he/she will change this nominated assessors, otherwise he/she shall inform the CB that it objection is not accepted and SOAC will keep the nominated assessors. SOAC product CBs accreditation officer's decision shall be final.
- 7.2.5. All team members shall be informed of the proposed assessment. SOAC product CBs accreditation officer shall give both the team leader and the assessor a copy of the CBs quality system documents and relevant procedures for document review according to the ISO/IEC 17065:2012.

### 7.3. Documentation Reviews

- 7.3.1. Prior to commencement of a pre or initial assessment, the CB's management system documentation will be examined for compliance with the standard and other relevant documents.
- 7.3.2. The team leader and the assessor/s review F03P06CE\_Self-assessment checklist for Product CBs and supporting documentation supplied by the CB.
- 7.3.3. Document review will be done by the CB accreditation officer reported at the same form of F03P06CE\_ Self-assessment checklist for Product CBs which was provided by SOAC product CBs

accreditation officer, giving general and detailed comments on the CB's apparent compliance with the requirements of ISO/IEC 17065:2012 and SOAC requirements.

- 7.3.4. Where the CB's application includes schemes for which SOAC has not previously granted accreditation, SOAC will need to determine whether the schemes meet the relevant requirements.
- 7.3.5. The purpose of the documentation review is for SOAC to gain an understanding of the applicant body's legal constitution, governance, organizational structure, scope and location of activities, the management system and controls and the extent to which the accreditation requirements appear to have been addressed.
- 7.3.6. Where SOAC identifies that the documented management system deviates significantly from the requirements, the CB will be contacted to discuss whether it is appropriate to proceed with an onsite assessment at this time.
- 7.3.7. Pertinent information from the outcome of the document review will be communicated to the CB via F03P06CE\_Self-assessment checklist for Product CBs and associated improvement actions, as relevant.
- 7.3.8. According to document review team leader shall recommend which of the following actions should be taken:
  - The CB is in a position to proceed to the initial assessment/reassessment.
  - The CB is not in a position to proceed to the initial assessment/re-assessment until response to the determined NCs/Cms of team document review and providing additional documents or information.
- 7.3.9. All NCs/Cms of team document review are to be listed within the same form F03P06CE\_Self-assessment checklist for Product CBs report itself and to be answered by the CB within the same report.
- 7.3.10. SOAC product CBs accreditation officer routinely ask the CB before each visit about any major changes in their documents, SOAC requires a document review before the on-site assessment visit whenever there is a substantial change in the CB documents. This could be a major change in the documents of the CB.

### 7.4. Pre-Assessment

- 7.4.1. It is not a mandatory requirement for an organization to have a pre-assessment in order to progress an application, and the decision on whether to proceed with this step rests with the applicant. However, SOAC strongly recommends that organizations new to accreditation have a pre-assessment, prior to initial assessment, as they often assist in the timely and effective attainment of accreditation.
- 7.4.2. SOAC conduct the pre-assessment visit according to: - CB request

- A document review recommendation by the product CBs accreditation officer.
- During the initial assessment visit team leader in discussing with SOAC technical & quality officer and SOAC product CBs accreditation officer will convert the initial assessment visit to be pre-assessment visit then SOAC product CBs accreditation officer will make the arrangements to be pre-assessment visit, including a quotation for the fee.
- 7.4.3. The pre-assessment visit, is normally carried out by the team leader and SOAC product CBs accreditation officer accompanied by assessor where appropriate, and is usually completed in one day.
- 7.4.4. The pre-assessment visit allows the team leader and SOAC product CBs accreditation officer to:
  - Discuss with the CB management the extent to which the CB's quality system and operating procedures appear to comply, or not, with the requirement of ISO/IEC 17065:2012 and the requirements of SOAC.
  - provide the CB with greater understanding of the assessment process and requirements of SOAC accreditation;
  - provide SOAC with a better understanding of the operations of the CB and any logistical or technical constraints of the organization such as to help ensure an effective and efficient initial assessment;
  - discuss any findings related to the documentation review;
  - seek further information on the management system;
  - discuss the management controls covering the certification activities, including multiple fixed office locations, outsourced (subcontracted) activities, etc.;
  - obtain any additional information necessary to develop the assessment plan and to produce the assessment quotation;
  - agree the proposed scope of accreditation;
  - Determine the assessment team requirements.
- 7.4.5. CBs have the right to object to the appointment of any nominated assessment team member(s) and in such cases SOAC will endeavor to offer an alternative. In the event that a suitable alternative cannot be identified, or the grounds for the objection are considered to be unreasonable, SOAC reserves the right to appoint the assessor(s) originally selected.
- 7.4.6. Following the visit a report is prepared which includes observations raised and agreements made during the preassessment. The report recommends whether or not the CB is sufficiently prepared to proceed with initial assessment. If the recommendation is to proceed, SOAC product CBs accreditation officer will make arrangements to plan the initial assessment, in writing on the form F01P07- Proposal of assessment team.
- 7.4.7. The CB may need to make changes to its policies, processes, procedures and practices prior to SOAC undertaking any initial assessment.

- 7.4.8. Where the pre-assessment identifies that the CB is structured or operates in a significantly different way to that which was understood when SOAC reviewed the application, then any quote for initial assessment may need to be revised and reissued.
- 7.4.9. The report shall indicate:
  - Whether plans for initial assessment of the CB can proceed.
  - Specific reasons why plans cannot proceed.

The findings of the pre-assessment visit shall be reported briefly to the CB where they will facilitate the preparations for the initial assessment visit.

- 7.4.10. During or immediately after the visit, the team leader and SOAC product CBs accreditation officer will determine the composition of the assessment team, and the time (in man-day) required for the visit including preparation time.
- 7.4.11. The F02P07CE\_Pre-Assessment visit report will be submitted to the quality & technical officer for approval. A copy of the report will be send to the CB.

### 7.5. The Schedule of Accreditation

- 7.5.1. It is SOAC policy to define the CB's draft schedule of accreditation as precisely as possible. This ensures that clients are provided with an accurate and unambiguous description of CB activities covered by a CB's accreditation according to their application.
- 7.5.2. CBs are therefore asked to specify, in detail, CB types of activities for which accreditation is sought. They are required to list, on their application form, the standard specifications, scheme or other methods or procedures relevant to CB activities concerned.
- 7.5.3. The assessment team shall consider and discuss with SOAC product CBs accreditation officer and the CB the precise terms in which the accreditation is to be defined on the draft schedule of accreditation, this shall be done as early as possible in the accreditation process.
- 7.5.4. In some cases, as the assessment proceeds, it may become clear that the CB is not really in a position to achieve accreditation in certain areas within the proposed scope. In such cases, the team leader in conjunction with SOAC product CBs accreditation officer may be able to recommend accreditation for a suitably reduced or redefined draft schedule.
- 7.5.5. Schedules of accredited CB are regarded as being in the public domain (SOAC official website/SOAC directory of accredited organizations).

#### 7.6. The Initial Assessment Visit

7.6.1. Preparations for the Initial Assessment Visit- New Applicant 7.6.1.1. SOAC product CBs accreditation officer will determine the

overall plan for the initial assessment including the assessment team members and technical activities that will be subject to witnessed assessment. At initial assessment, all technical areas and fixed office locations performing key activities will be subject to assessment using a variety of assessment techniques.

- 7.6.1.2. The witnessing of the audit activities of a product CB will depend upon the nature of the certification scheme(s) concerned.
- 7.6.1.3. SOAC product CBs accreditation officer will provide the CB with an estimate of the man-days effort required to conduct the assessment along with details of the proposed assessment team members. CBs have the right to object to the appointment of any nominated team member(s) and in such cases SOAC will endeavor to offer an alternative. In the event that a suitable alternative cannot be identified, or the grounds for the objection are considered to be unreasonable, SOAC reserves the right to appoint the assessor(s) originally selected.
- 7.6.1.4. Prior to initial assessment, the CB shall provide SOAC with a list of all forthcoming audit activities, the fields and types of activity, the assigned auditors and client details, from which SOAC product CBs accreditation officer selects the witnessed assessments.
- 7.6.1.5. Once the assessment is booked the CB will be provided with a quotation and a breakdown of the dates and times of the assessment. At least 2 weeks prior to the assessment, the quality and technical accreditation officer will provide the CB and assessment team with a detailed visit plan covering the specifics of the assessment.
- 7.6.1.6. The assessment effort including the number of witnessed assessments required for initial assessment will be dependent on the number of standards applied for, the size and complexity of accreditation scope sought, the size and complexity of the organization, the geographical spread of its activities and the structure of its management system.
- 7.6.1.7. The following elements will need to be covered at initial assessment:
  - Full review of the implementation of the management system;
  - Head office assessment;
  - Assessment of all fixed office locations where key activities take place;
  - Witnessed assessments for different standards, scopes and types of certification.
- 7.6.1.8. The team for initial assessments will comprise a minimum of two persons, one of whom will be the lead assessor.
- 7.6.2. The Initial Assessment
  - 7.6.2.1. SOAC assessment team will seek to establish, by using various techniques, that the management system is

appropriate to the CB's needs, organizational arrangements, processes, scope and scale of its operations, Including multiple fixed locations, overseas activities and client base;

- all of the accreditation requirements have been satisfactorily addressed;
- the CB has the necessary competence to conduct the activities for which it seeks accreditation;
- the CB has implemented all the requirements of its management system effectively;
- SOAC can have confidence in the validity of the certification decisions made by the CB.
- 7.6.2.2. During the initial assessment it is the responsibility of the CB to demonstrate its competence and conformity to SOAC via interaction with the assessment team and provision of information and documentation as requested.
- 7.6.2.3. The structure and timings of the initial assessment will be documented in the assessment plan. Each initial office assessment will consist, at least, of the following elements:
  - Opening meeting F13P07\_assessment opening and closing meeting – at which the assessment team and CB introduce themselves to each other and clarify roles and responsibilities, for example who can agree actions to address findings on behalf of the CB;
  - Assessment activity This forms the bulk of the assessment and is conducted via file review, observation of activities being performed and/or interviews of key staff members, and examination of records applicable to the implementation of the management system. If findings are identified they will, whenever possible, be discussed as they arise with the CB representative accompanying the assessor. However, it is the responsibility of the CB to propose the action to be taken to address the finding: Agreement between CB and assessors on this action, and of the supporting evidence to be provided by the CB to address the finding is to be reached prior to closure of the assessment;
  - Closing meeting F13P07\_assessment opening and closing meeting at which the assessment team delivers their summary and conclusions of the assessment to the CB, and confirms their recommendation on accreditation.
- 7.6.2.4. SOAC assessors shall seek objective evidence of the implementation of the CB's policies and procedures. Team leader will provide an oral summary report; and all mandatory findings raised (non-conformity/comment) will be confirmed in writing and signed by CB throw non- conformity/comment form F08P07 finding. within 15 calendar days of the completion of the assessment the CB send the corrective actions plan to the assessors on the form F10P07- gap treatment. The follow-up and clearance of nonconformity/comment is carried out through the form F10P07-

gap treatment. Within 30 till 45 calendar days of the completion of the assessment the SOAC team leader will provide the form F03P07CE\_assessment report to SOAC, and SOAC is issued in the same form the assessment report to the CB within 15 calendar days after receipt.

- 7.6.2.5. For initial assessment, witnessed assessments will need to be completed and any associated non-conformities cleared before grant of accreditation. The witnessed assessment requirements for an initial assessment will comprise of:
  - at least 25% of the scopes applied for, although this may be higher where the scopes applied for are deemed 'high risk' scopes, or where a sector scheme or statutory requirements demand a higher level of witnessing;
  - Assessment of a suitable sample of the auditors employed or contracted by the CB.
- 7.6.2.6. The process for conducting a witnessed assessment is described in section 6.11.
- 7.6.2.7. Where mandatory findings are raised at an initial assessment, a maximum of 3 months will normally be allowed for the CB to submit evidence to demonstrate the implementation of agreed corrective actions, demonstration of root cause investigation, determination of suitable corrective actions and any actions to prevent recurrence. It may be possible for the evidence to be reviewed remotely by SOAC and its assessors to determine whether the findings have been satisfactorily addressed, although there will be situations where additional visits to the CB are required to verify the effectiveness and implementation of the actions taken. CBs must provide evidence to demonstrate that mandatory findings have been adequately and appropriately addressed to enable SOAC to clear them. SOAC will review the evidence provided and decide upon its acceptability within 4 weeks of receipt.
- 7.6.2.8. An assessment report will be issued to the CB on completion of each assessment. The report will include a recommendation on accreditation. Where the assessment plan form F05P07 requires several assessments to be completed (i.e. a head office and several fixed office locations), this recommendation will relate to the situation as it currently stands, subsequent assessments in the plan may alter that recommendation.
- 7.6.2.9. The CB will have to take the appropriate action for all mandatory findings raised during the initial assessment and any associated witnessed or fixed office location assessments and SOAC will need to clear the finding prior to any grant of accreditation.
- 7.6.3. Grant of Accreditation
  - 7.6.3.1. Upon satisfactory completion of all of the identified assessment activities the SOAC product CBs accreditation

officer will review all of the information gathered and submit to SOAC accreditation committee their recommendation on accreditation.

- 7.6.3.2. When evidences of the corrective actions of all nonconformities are obtained, the SOAC product CBs accreditation officer will inform SOAC Quality and Technical Accreditation Officer who convenes accreditation committee to examine and issue a recommendation on accreditation in accordance with procedure P08\_decision making and granting accreditation of SOAC.
- 7.6.3.3. The decision on accreditation will be taken by the CEO of SOAC based on the recommendation of the accreditation committee.
- 7.6.3.4. Once the independent decision maker are satisfied that all findings have been satisfactorily addressed, then a final decision will be made and accreditation can be granted. The grant letter is sent to the CB with an accreditation certificate for each standard granted. A copy of the agreed schedule(s) of accreditation will be published on SOAC' website following grant of accreditation. The schedule(s) will detail the scopes of relevant product certification standards or schemes and/or persons certification.
- 7.6.3.5. Where a CB disagrees with an accreditation decision taken by SOAC, it has the right to appeal. Such an appeal must be in writing and must be received by SOAC within one month of the date of the SOAC letter confirming the decision. SOAC appeals Process C07 is published on the SOAC website,
- 7.6.4. The 2 Year Accreditation Cycle
  - 7.6.4.1. Accreditation is granted for a period of 2 years from the date of granting. During the 2 year cycle each CB is subject to an annual consecutive assessment visit (if applicable) and a full reassessment in the 2<sup>nd</sup> year.
  - 7.6.4.2. The first consecutive assessment visit (if applicable) shall take place 12 months after the date that initial accreditation was granted; the month of this visit will be assigned as the profile month of the CB. Thereafter all annual visits will occur annually at or around the profile month for the CB.
  - 7.6.4.3. Where there has been an extended period between initial assessment and grant of accreditation, the time between grant and first consecutive assessment may be shortened.
  - 7.6.4.4. Where an existing accredited body is granted accreditation for an additional standard, the annual assessment for the new standard will occur within the same profile month as the existing accreditation, and have the same expiry date as the existing accreditation. This is the case even if it means that the first consecutive assessment for this new standard will be conducted less than one year from date of its grant.
  - 7.6.4.5. To maintain and renew accreditation the annual program for

all head office, fixed office locations and witnessed assessment activities must be completed within the required timeframes (defined in the plan described in 6.6.5.1) and all mandatory findings must be cleared within agreed timeframes (C01).

- 7.6.5. Planning the 2 Year Accreditation Cycle
  - 7.6.5.1. For each CB SOAC will produce a 2 year program, detailing the intended assessment activities (head office, fixed office location(s) and witnessed assessments) to be covered during each year of the accreditation cycle. The program is subject to review and potential revision following the completion of each annual assessment program and any extension to scope. The program will be communicated to the CB upon creation and subsequent revision.
  - 7.6.5.2. Where a CB uses a committee for safeguarding impartiality, SOAC will observe at least one of its meetings during the cycle as part of the assessment plan. If the CB uses an alternative mechanism to safeguard impartiality then this will be reviewed accordingly. Where possible this will be conducted alongside annual consecutive assessment and reassessment visits.
  - 7.6.5.3. To help plan the detail of annual visits, and to monitor the on-going performance of CBs, each accredited body shall be required to complete and return an annual questionnaire regarding operational metrics of its organization around 6 months in advance of its profile month. Responses to this questionnaire shall provide the following information, where relevant to the CB:
    - countries in which the body has fixed office locations, and the key activities that those locations perform;
    - countries into which certificates are issued;
    - the scope of accredited services offered in countries with fixed office locations;
    - details of the locations (countries) of any remote based workers;
    - number of certificates (by certification standard) issued from each fixed office location;
    - number of auditors (by certification standard) operating from each fixed office location;
    - the legal relationship between the head office and any fixed office locations;
    - details of any other accreditation(s) held by foreign fixed office locations;
    - details of external training providers, approved examination centers and approved training centers (Persons CBs only);
    - details of any relationships with, or connections to, other organizations involving the CB's senior management/directors, which could represent a risk to impartiality;
    - details of any significant changes to the structure and/or operations of the CB in the last 12 months;
    - number of overdue consecutive assessment or recertification

audits at the time of completion of the survey;

- number of transfers of certification from other CBs, including scope details
- number of suspensions and/or terminations of accredited certification in the last 12 months;
- Details of the arrangements for management and control of foreign fixed office locations and remote based staff.
- 7.6.5.4. Witnessed assessments associated with annual consecutive assessment (if applicable) and reassessment visits will be conducted within a 12 month calendar period. During the last quarter of each year SOAC will communicate to the CB any witnessed assessments to be conducted in the following calendar year based on the 2 year cycle and the review of the annual questionnaire details. The witnessed assessment program will, as a minimum, cover the scope of accreditation over the 2 year cycle.
- 7.6.5.5. The frequency and volume of witnessed assessments is dependent on several factors, including:
  - the nature of risks and complexity associated with the certification activities, scopes of certification of management system, product or persons, and countries involved;
  - the CB's procedures for selecting, training, authorizing and monitoring personnel, having regard to the competences required for different technical areas, scopes and schemes of certification;
  - The internal auditing arrangements of the CB.
  - The locations from which auditors operate.
  - Any sector scheme or statutory requirements.

### 7.7. Consecutive Assessment

- 7.7.1. Following grant of accreditation, SOAC will check for continuing compliance with SOAC requirements by carrying out consecutive assessment visits to the CB's head office and any fixed office locations and witnessed assessments according to the 2 Year Plan (see 6.6.5).
- 7.7.2. SOAC will contact the CB between 3-4 months in advance of their profile month to begin arrangements for the booking of any head office visit associated with the consecutive assessment. A detailed plan covering the activities of the assessment team will be produced by SOAC product CBs accreditation officer and sent to the certification around 4 weeks in advance of the commencement of the assessment.
- 7.7.3. Consecutive assessment visits covering the first year of the 2 year cycle will be planned to sample aspects of the management system and technical scope. Key aspects of the management system such as, for example, internal auditing, impartiality and management review will be covered on an annual basis (refer to SOAC publication for full details).
- 7.7.4. The structure of a consecutive assessment visit will follow

that outlined in above.

- 7.7.5. Reporting for consecutive assessment visits will follow the process outlined in above.
- 7.7.6. Where mandatory findings require action to be taken by the CB it must complete the improvement actions and provide evidence to SOAC within an agreed timeframe (normally within one month of the consecutive assessment visit). Where SOAC does not require evidence of action taken to be submitted for review then the CB shall be required to confirm that the action has been taken and the verification of the effectiveness of this action will normally be carried out by SOAC at the next visit to the CB, although SOAC reserves the right to carry out this verification at any time after the agreed completion date.
- 7.7.7. Following confirmation of the clearance of all mandatory findings raised at the consecutive assessment visit SOAC product CBs accreditation officer will confirm on-going maintenance of accreditation.

### **7.8.** Sampling in assessment of Product certification bodies

7.8.1. For Initial Assessment

The initial assessment of head office (HO) and all other locations undertaking any of the critical elements will be assessed as part of the initial assessment. All scopes applied for, will be subject to an office assessment and technical review.

The minimum number of witnessed assessments in initial assessment is will be determined according to IAF MD17 & MD16.

SOAC will cover the scope for each applicant CB through the use of the following mechanisms that are available, including:

- Office assessment activities
- Witnessing activities:

Where an organization operates from a number of offices, witness assessments will be selected from a cross section of locations. It will not be necessary to witness the range of scopes per office.

7.8.2. For consecutive assessment during [2 years]

Assessment visits are conducted as explained in the assessment process (P06 & P07). Each critical location will be visited at least once during the validity period of the accreditation certificate. This visit will include a witnessed assessment where appropriate.

A witnessed assessment will be carried out in each scope area not covered at the initial assessment according to MD17 & MD16. The witnessing activities of the CBs will be covering the requirements of MD16 for considering the cluster 2 as the highest risk cluster and will be witnessed every year if in the accredited scope.

A planning record (examined staff) (F14P07) will be provided to the assessment team before the visit so that they can assure the examination of a good representative sample of all auditors of the CB during the whole

accreditation cycle. Another form F15P07 \_assessment matrix is used to specify the scopes witnessed in each assessment activity to assure the coverage of the required codes/categories according to MD17 & MD16.

The minimum number of witnessed assessments is 1 per year.

7.8.3. For re-assessment

The re-assessment of HO and all other locations undertaking any of the critical elements will be assessed as part of the re-assessment. All scopes applied for, will be subject to an office assessment and technical review. In general re-assessment resembles initial assessment in HO and witnessing in accordance with MD17 & MD16.

#### Note:

This procedure follows IAF MD17 clause 2 & 3) applicable to product certification.

SOAC deciding sampling of activities and witnessed assessments in product certification by using the concept of product group under a certification scheme having similar characteristics/technical audit requirements or following certification scheme requirements.

The form F15P07 \_assessment matrix is used for ISO/IEC 17065:2012 witnessing assessment.

### 7.9. Reassessment visit

- 7.9.1. Reassessment visits involve a comprehensive reexamination of the CB's management system and certification activities and will be similar in approach and content to the initial assessment although the emphasis may be different dependent upon performance and changes over the past two year cycle.
- 7.9.2. The process for booking reassessments will follow that outlined in above.
- 7.9.3. The structure of a reassessment visit will follow that outlined in above.
- 7.9.4. Reporting for reassessment visits will follow the process outlined in above.
- 7.9.5. The requirements for closing out mandatory findings including submission of any evidence to SOAC are as for consecutive assessment in above.
- 7.9.6. Following the completion of the reassessment plan but prior to the clearance of mandatory findings (where relevant), SOAC product CBs accreditation officer will submit the associated reports and recommendation for a decision on renewal of accreditation to be conducted by SOAC staff independent of the assessment.
- 7.9.7. Following clearance of all mandatory findings raised at the reassessment and confirmation of this clearance by the accreditation committee, SOAC will renew accreditation for a further 2 years from the date of expiry of accreditation.

### **7.10.** Fixed Office Locations

- 7.10.1. Fixed office locations performing key activities for all applicant and accredited product CBs shall:
  - all be visited and assessed by SOAC or another MLA signatory AB, operating under SOAC' direction during an initial assessment;
  - be assessed at the same frequency as the head office of the CB during consecutive assessment and reassessment, this being normally once per year.
- 7.10.2. For consecutive assessment and reassessment, the frequency of assessment of fixed office locations can be reduced where the CB has demonstrated (via assessments) a history of effective management and control of its fixed office locations. Where frequency is reduced, assessment of fixed office locations performing critical activities shall not be less than once every 2 years (i.e. within the accreditation cycle). Other fixed office locations, which do not perform critical activities, will be assessed as required according to a sampling plan. This will result in the production of a sampling plan, determining how often each fixed office location cycle.
- 7.10.3. SOAC may increase the frequency of assessment of fixed office locations, including to more than once per year, where it (or other MLA signatory AB) has identified concerns regarding the management and control of the fixed office locations through either on-site or remote assessment. Issues identified at one fixed office location may impact upon the frequency of assessment of any other fixed office locations, depending on whether the issues identified are isolated or systemic.
- 7.10.4. To monitor the effectiveness of the CB's management and control of its fixed office locations SOAC can utilize a range of tools, including:
  - remote assessment of the fixed office location's activities;
  - assessment of the arrangements for on-going management and control of fixed office locations by the CB's head office;
  - on-site assessment of the fixed office location by SOAC or other MLA signatory AB;
  - assessment of the CB's arrangements for establishing any new fixed office locations or expanding existing ones;
  - review of information provided by the CB in the annual operational metrics questionnaire;
  - review of reports from other MLA signatory ABs, where the fixed office location holds accreditation from a Local AB;
  - monitoring of feedback, including complaints, for the CB's clients and stakeholders relating to the operations of its fixed office locations;
  - Witnessing of audit activities performed by staff managed by the fixed office location.

- 7.10.5. If SOAC raises findings that require improvement action at the head office or at any one of the locations, the improvement action shall apply to all relevant locations.
- 7.10.6. Failure by one location to comply with SOAC requirements may lead to removal of the location from the published details of the accreditation. If the cause of the nonconformity is lack of central control then the entire accreditation will be subject to review by SOAC and may lead to sanctions across all locations.
- 7.10.7. Where a CB wishes to remove a fixed office location from its SOAC schedule of accreditation, the CB will be required to demonstrate how the specific responsibilities for that location have been reassigned to ensure continued service to clients and continued compliance with the conformity assessment standards.
- 7.10.8. Fixed office locations in territories which SOAC or other MLA signatory ABs cannot attend due to safety, security or political reasons (e.g. where the territory is under a trade embargo) cannot be added to the schedule of accreditation. This shall be the case even if a remote assessment could be performed due to the need for SOAC or other MLA signatory AB to be able to physically visit the location at some point during the accreditation cycle.
- 7.10.9. Where a CB has a fixed office location already present on its schedule of accreditation and subsequently SOAC or other MLA signatory ABs are unable to visit that location due to safety, security or political reasons then remote assessment tools will be utilized to assess that location according to the sampling plan. However, if it is not possible to visit the location during the accreditation cycle then it will be removed from the schedule of accreditation following completion of the accreditation cycle (i.e. at the time of renewal of accreditation following successful reassessment).
- 7.10.10. If significant concerns are raised about the operations of a fixed office location which subsequently cannot be visited to confirm or otherwise these concerns, then this location may be removed from the schedule of accreditation before completion of the accreditation cycle. Reinstatement of such a fixed office location will require the CB to submit an application for extension to scope, and cannot be granted until an on-site assessment has demonstrated that the concerns have been addressed.
- 7.10.11. Where fixed office locations operate in a language other than French, SOAC will utilise independent translation or interpretation services to conduct the assessment. Any associated costs to provide these services shall be met by the CB.
- 7.10.12. Where outsourced assessment reports from MLA signatory ABs are provided to SOAC in a language other than French, SOAC will utilize independent translation services to translate the reports. Any associated costs to provide these services shall be met by the CB.

### 7.11. Witnessed Assessments

- 7.11.1. The objective of the witnessed assessment is to support assessment in determining whether the CB can demonstrate competence and conformity with the required standard. It is the responsibility of the CB to ensure that its clients give full access to SOAC assessment teams for this purpose. In particular the witnessed assessment is essential in confirming that the CB's personnel can:
- apply the procedures and instructions of the CB;
- exhibit the necessary characteristics of an auditor;
- demonstrate the required competence for which the assessment activity is being undertaken;
- identify the required competence and assign appropriate personnel;
- Undertake the conformity assessment activity effectively.
  - 7.11.2. The witnessed assessment will also assist in determining the effectiveness of the CB's processes, typically its contract review and planning processes and its internal assessment and approval process of personnel competence.
  - 7.11.3. SOAC will collect objective evidence to assist in the determination of competence which will specifically include:
- conformity with the CB's own documented system and procedures;
- Conformity to the requirements of the required standards and any other requirement of SOAC, AFRAC and IAF or the sector scheme as appropriate.
  - 7.11.4. The assessment of the competence of the CB's auditor or audit team shall include the following:
- preparedness for the audit;
- audit technique and conformity with the procedures and guidance on audit;
- knowledge of the certification requirements;
- knowledge of and adherence to the CB's own documented system and procedures;
- Knowledge of the industry being audited.
  - 7.11.5. Wherever possible the SOAC Assessor will hold an opening meeting with the CB's audit team, at which the assessor shall explain the objectives of witnessing and the processes to be followed during the witnessed activity. If circumstances do not allow for a direct meeting prior to the witness activity, the SOAC assessor shall ensure that the information is provided by other means (e.g. telephone call prior to the audit, discussion with the CB in advance).
  - 7.11.6. SOAC Assessor shall not involve themselves directly in the audit in which the CB auditor(s) is/are being witnessed. However, the assessor can ask the CB auditor for clarification and additional information if necessary to ensure a clear understanding of the audit process taking place. This should be done at a suitable time so as not to interrupt the audit or inconvenience the CB's client in

any way. It is expected that the SOAC Assessor will be provided with access to the client's documentation that the CB reviews as part of its audit. Any documentation reviewed by the CB during the conduct of the audit should be made available to the SOAC Assessor to review.

- 7.11.7. If the situation arises where the SOAC Assessor observes a nonconformity in the CB's client's operations which is not reported by the CB's team, the SOAC Assessor shall inform the CB's team about such findings during the post-witness closing meeting rather than in front of the CB's client. The only exception is when the SOAC Assessor observes a practice or nonconformity that presents an immediate risk to health and safety. In these cases, the SOAC Assessor has a duty of care to report the issue without delay.
- 7.11.8. SOAC Assessor may record observations of the audit as notes or by using a witnessed assessment checklist. The SOAC Assessor shall record any nonconformity on the improvement action report; it may be necessary to revise or refine the findings following further discussion with the CB after the audit has finished.
- 7.11.9. All activities of the CB's audit should be witnessed, including the opening and closing meeting. Where the CB utilizes a team to conduct the audit SOAC may require additional assessors to ensure it can observe the entire audit process.
- 7.11.10. SOAC Assessor shall hold a closing meeting with the auditors(s) and/or representatives from the CB as soon as practicable after the CB's closing meeting with their client. The assessor should provide clear findings to the CB and shall give the CB the opportunity to discuss the findings.
  - 7.11.10.1. Where it is not possible to conduct this meeting at the end of the audit, it may be conducted after the witnessed assessment by additional meeting or phone call.
  - 7.11.10.2. Where CB personnel present are not empowered to agree corrective action on findings raised, SOAC will contact the CB to discuss and agree the findings and corrective action to be taken with a suitable representative.
- 7.11.11. 6.11.11 SOAC assessor shall, in light of findings during the witnessed activity, consider whether the CB's methods for determining audit requirements, duration and audit team competence, are sufficient to address accreditation requirements for an effective audit.

#### 7.12. Post Audit Review

7.12.1. In exceptional cases and at the discretion of SOAC a post audit review may be utilized as an alternative to a witnessed assessment. The general principle for the format of a post audit review is to complete an in depth interview with an audit team using the output from the selected audit which will provide the equivalent confidence to a witnessed assessment. In the process of arranging a post audit review SOAC product CBs accreditation officer will determine the plan taking into consideration the following points:

- Location of post audit review to be conducted;
- 7.12.2. Attendees in addition to audit team.
- 7.12.3. SOAC will review objective evidence to assist in the determination of competence which will specifically include:
- Conformity with the CB's own documented system and procedures
- Conformity to the requirements of the required standards and any other requirement of SOAC, AFRAC and IAF or the sector scheme as appropriate.
- 7.12.4. In addition SOAC will review the following CB documentation from the audit:
- Certification cycle audit program
- audit plan
- audit report
- Nonconformity reports
- Other audit related documentation as requested
- 7.12.5. The assessment of CB auditor or audit team competence shall include the following elements:
- preparedness for the audit;
- audit technique and conformity with the procedures and guidance on audit;
- Knowledge of the certification requirements;
- Knowledge of and adherence to the CB's own documented system and procedures;
- Knowledge of the industry being evaluated.
- 7.12.6. SOAC assessor will hold an opening meeting with the CB's, at the agreed location, at which the assessor shall explain the objectives of the post audit review and the processes to be followed during the activity.
- 7.12.7. SOAC assessor will use interview and review techniques to assess the audit trails and findings by arranging for the attending auditors to describe the audit completed.
- 7.12.8. SOAC assessor shall hold a closing meeting with the auditor(s) and/or representatives from the CB at the end of the post audit review. The Assessor should provide clear findings to the CB and shall give the CB the opportunity to discuss the findings.
  - 7.12.8.1. Where CB personnel present are not empowered to agree corrective action on findings raised, SOAC will contact the CB to discuss and agree the findings and corrective action to be taken with a suitable representative.
  - 7.12.8.2. SOAC assessor shall, in light of findings during the post audit review activity, consider whether the CB's methods for determining audit requirements, duration and audit team competence, are sufficient to address accreditation requirements for an effective audit.

### 7.13. Additional Assessment

- 7.13.1. SOAC may identify the need for extra assessment additional to that planned. Extra assessment will be required when:
- the CB has been unable to demonstrate compliance or conformity with respect to one or more significant areas of its scope or management system;
- SOAC has identified significant findings that require additional assessment to determine effective implementation of corrective action;
- SOAC' ability to conduct the assessment plan has been impeded by the CB;
- Third party complaints have raised concerns that require assessment to verify and assess impact.
- 7.13.2. SOAC may conduct extra visits unannounced (i.e. without prior notification) for example where third party complaints regarding the certification raise significant concerns regarding the operational integrity of the CB.
  - 7.13.2.1. Some sector schemes require routine unannounced visits as part of the scheme requirements.
  - 7.13.2.2. The process for any extra or unannounced visit shall be that described in above, although visit plans will not be sent in advance of unannounced assessments.
  - 7.13.2.3. 6.13.3 In the event of significant feedback or repeated complaints, SOAC may elect to carry out market consecutive assessment activities in accordance with IAF-ID4:2012 market surveillance visits to certified organizations. Where this is the case such activities will be in consultation with the CB.

### 7.14. Extensions of Scope

- 7.14.1. The accredited scopes of product certification schemes, sector schemes, standards, or the economic sectors/activities and the locations from which these activities are managed and controlled. Accreditation is either granted for a full or limited scope.
- 7.14.2. If a CB wishes to extend it scope of accreditation, either into new schemes or standards, then the CB must apply for an extension to scope using an application form available from the SOAC website. This form must be completed and submitted to SOAC along with all required accompanying documentation.
  - 7.14.2.1. 6.14.2.1 Where the CB's application includes schemes for which SOAC has not previously granted accreditation, SOAC will need to determine whether the schemes meet the relevant requirements. In the case of product certification schemes ISO/IEC 17067:2013 is the reference for scheme requirements.
  - 7.14.2.2. Following receipt of an application for an extension to scope SOAC will determine whether or not there is a need for a head office and/or fixed office location assessment and/or witnessed assessments to take place. Factors that will be

taken into consideration will include the:

- range of existing scope of accreditation;
- volume of business in the new scope area;
- The locations at which the extension to scope is sought.
- The risk (high/low) of the extension to scope.
  - 7.14.2.3. Normally extensions to scope will require a head office (or fixed office location) assessment and witnessed assessments. The assessment process for head or fixed office locations is as described in above. The volume of witnessed assessments required is determined as per in above although a minimum of one (not two) witnessed assessments are required. The process for conducting witnessed assessments for extensions to scope is as described in above.
  - 7.14.2.4. 6.14.4.1 Where the extension to scope forms part of a SOAC development project, then the assessment approach will be determined in the terms of reference for the project. The assessment approach may differ from that defined above and may require more or less assessment depending on the requirements of the development project.
- 7.14.3. A quotation will be provided for the extra work associated with an extension to scope. The estimated effort required for subsequent consecutive assessment and reassessment will be reviewed and may be revised once accreditation for the new activity has been granted.
- 7.14.4. Where a CB applies for an extension to scope specific to an existing fixed office location(s), SOAC will review the application and determine whether the assessment requires a visit to the fixed office location. SOAC will consider the following in reaching its decision on the assessment approach:
  - current scope of accreditation and similarity to the scope sought;
  - the CB's recent history in the implementation of extensions to scope;
  - The fixed office location's known skills, competences and history in effective implementation of extensions to scope.
- 7.14.5. Where a CB applies for a new fixed office location which performs critical activities to be added to its schedule of accreditation, SOAC will review the application to determine the appropriate assessment approach. A new fixed office location must be visited by SOAC or other MLA signatory AB.
- 7.14.6. The process for granting accreditation for an extension to scope is as described in section 6.14, although depending on the scope sought, a new accreditation certificate or 4 year cycle effort estimate may not be required.

### **8. RELATED FORMS:**

Forms to be used for procedure implementation

7.1	CBs application	F01P06CE
7.2	Schedule of accreditation for product CB	F02P06CE
7.3	Self-assessment checklist for Product CBs	F03P06CE
7.4	Pre-Assessment	F02P07CE
7.5	Assessment report	F03P07CE

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