

## 1 PURPOSE AND SCOPE

The purpose of this procedure is to explain how accreditation applications of Conformity Assessment Bodies (CABs) will be handled, evaluated, assessed and finalized by NBE according to the principles of national and international standards. It also informs the Conformity Assessment Bodies about pre-assessment (when requested), initial accreditation, and surveillance and re-accreditation processes after accreditation, and explains the obligations of the accredited organizations. It also describes the procedures and operations for the suspension, reduction, withdrawal and scope change of granted accreditation at the request of the accredited conformity assessment body or if the circumstances so require.

This procedure includes the general principles and rules of preparation, communication, implementation and reporting processes related to the pre-assessment, accreditation assessment, follow-up assessment, accreditation decision, surveillance and re-accreditation to be made for the organizations providing conformity assessment services. It also covers the procedures for partial or complete suspension, reduction, withdrawal, lifting of suspension, scope change and re-application of organizations with withdrawn accreditation related to the accreditation of conformity assessment bodies accredited by NBE.

## 2 DEFINITIONS

### **Accreditation**

It is an official recognition by a third party that a CAB is in compliance with certain requirements and is competent to carry out the appropriate conformity assessment activities.

### **Accreditation Department**

Each one of Product, Service and Inspection Accreditation Departments, **Testing Accreditation Department, Calibration Accreditation Department, Certification Accreditation Department** within NBE and working under the NBE Presidential.

### **Accreditation Cycle Program**

Program showing the necessary information on the assessments of a specific conformity assessment body during an accreditation cycle in accordance with the accreditation schemes run by NBE.

### **Accreditation Decision**

Accreditation decisions by NBE Accreditation Decision Board on granting accreditation, maintaining, partial or full suspension, partial or full withdrawal, scope change or re-accreditation of CABs that applied for accreditation or are already accredited.

### **Accreditation Scheme**

Rules and processes in which the same requirements are applied to the accreditation of conformity assessment bodies.

### **Expertise Committee**

It is a committee formed to provide technical support for the development and regulation of activities of the Macedonian Accreditation Agency, and is composed of impartial experts who have the necessary education, experience, technical competency in specific accreditation areas and know the relevant sector well.

### **Assessment**

NBE's process to assess a CAB's competency according to certain standards and/or other normative documents and conducted within the scope of a specific accreditation.

Note: Covers the evaluation of a CAB's competency in all activities including the assessment of a CAB's competency; competency of CAB's personnel, accuracy of its conformity assessment methodology and its conformity assessment results.

### **Document**

Information prepared and/or used to regulate the quality system and accreditation activities or management systems within NBE and stored in all kinds of physical, electronic, magnetic, etc. mediums and is reproducible, is called a document.

### **Corrective Action**

An activity related to the measures taken to resolve the causes to prevent the re-occurrence of existing nonconformity, defect or other unwanted situations.

### **Team Leader**

It is the lead assessor with full responsibility for managing an accreditation assessment. (An assessor can also be appointed as the team leader in the witness and follow-up assessments).

### **Flexible Scope**

The scope of accreditation for the competency of the conformity assessment body determined by NBE expressed in a way to allow the conformity assessment body to modify its methodology or other parameters.

### **Validation Audit**

It is the audit of CAB's customer by the NBE assessment team in order to determine that the audits carried out by the conformity assessment body have been carried out in accordance with the relevant accreditation and certification program.

### **Surveillance**

A series of activities including monitoring of the accredited CAB to see if it continues to meet the accreditation requirements, except for re-accreditation

Surveillance includes on-site surveillance and other surveillance activities such as the following:

- a) Assessment done in CAB by the accreditation body on issues related to accreditation
- b) Review of CAB's statements on what the accreditation covers
- c) Requesting CAB to provide documentation and records (e.g., assessment reports, internal quality control results to verify the validity of CAB services, complaint records, management review records)
- d) Monitoring CAB's performance (such as the participation results in a proficiency test).

### **Appeal**

CAB's request for re-evaluation of a negative decision concerning the desired accreditation status.

### **Minor Nonconformity**

Nonconformities that do not have a direct impact on the results of the relevant conformity assessment activity.

### **Interlaboratory Comparison**

Organization, performance and evaluation of measurements or tests of two or more laboratories or inspection bodies on the same or similar items according to pre-determined criteria.

### **Location**

Addresses where conformity assessment and related activities are carried out (branches, addresses where important activities are carried out, mobile facility, travelling facility, virtual site, location where remote personnel work, representation office, liaison office etc.)

### **Measurement Audit**

In the assessment of conformity assessment bodies in certain technical areas, auditing the competency of the body by using a measurement audit object. Although this method can generally be applied in laboratories, it can also be used in the evaluation of the technical competency of other conformity assessment bodies.

### **Important Activities**

Processes that affect CAB's competency and are considered in this framework such as policy development, process and/or procedure development and review of the contract as appropriate, planning of conformity assessment activities, review of the results of conformity assessment activities, approval and decision, etc.

### **Major Nonconformity**

Nonconformities that have a direct impact on the results of the relevant conformity assessment activity.

### **Virtual Site**

The site that enables the management of processes in Internet or in various communication environments, e.g., Cloud environment etc.

### **Complaint**

Negative applications, except appeals, by natural or legal persons made to NBE regarding NBE's accreditation activities on the performance, procedures, policies, personnel and experts working for NBE, NBE's activities, accreditation assessment process carried out for NBE and any issue related to a CAB's activities.

### **Witness Assessment**

Observation by NBE of a conformity assessment body carrying out conformity assessment activities within its scope of accreditation.

### **Case Officer (File Officer)**

NBE technical personnel, who are appointed by the relevant NBE Accreditation Departments, and are responsible for all kinds of technical and administrative communication, coordination and secretariat operations with the organization that applied for accreditation or is already accredited, at every stage of the accreditation activities. If they meet the required competencies, they can be appointed as case officers, team leader, lead assessor, assessor, trainee assessor, observer or technical expert.

### **NBE Document Verification System**

NBE service platform, where some records and information (application, evaluation/certification, scope, audit, test/calibration, inspection, etc.) are entered regarding test/calibration/inspection services and product/management system/personnel certification given or to be given to customers receiving services from conformity assessment bodies.

### **Conformity Assessment Body**

Body that performs conformity assessment activities and that can be the object of accreditation.

### **Nonconformity**

Non-fulfilment of a requirement.

### **Remote Assessment**

Assessment of virtual or physical sites of a conformity assessment body by electronic means

### **Proficiency Testing**

Evaluation of the performance of the participant according to pre-determined criteria by inter-laboratory comparison.

In addition to the terms and definitions given in this section, the terms and definitions given in ISO/IEC 17011, ISO/IEC 17000, ISO/IEC 17000 series accreditation standards and relevant NBE legislation shall apply.

## **3 IMPLEMENTATION**

The accreditation process is composed of the following main stages;

- Application,
- Preparations before assessment,
- Pre-assessment (if requested by the applicant body),
- Accreditation assessment,
- Evaluations made after assessment (including follow-up assessment),
- Decision,
- Surveillance,
- Re-accreditation

One of the following assessment techniques or a combination of several techniques is/are used in the accreditation process. Which assessment technique is used at which stage of the accreditation process is described in the relevant chapters of this procedure?

- Review of documents,
- Review of records,
- On-site assessment (witness assessment and office assessment),
- Performance review as a result of proficiency testing and interlaboratory comparisons,
- Unplanned visits,
- Interview,
- Remote assessment,
- Measurement audits,
- Validation audits.

### **3.1 APPLICATION**

#### **3.1.1 Application Documents**

CAB wanting to apply for accreditation can obtain the information required for application from NBE web site [www.nbeglobal.org](http://www.nbeglobal.org) or via the relevant NBE Accreditation Department.

The documents to be submitted to our Agency for application are specified in detail in the forms of documents requested during application for the relevant accreditation area (FR-7-01-8, ..., FR-7-01-12, FR-7-01-64, FR-7-01-73, ...) or in the application forms.

A CAB that applied for accreditation, must have established a management system according to the relevant accreditation standard and must have operated this system for at least 3 (three) months.

The Accreditation application shall be filed by filling of "Application Form" related to CAB's engagement area, "FR-7-01-71 Accreditation Services, Conformity Assessment Body Authorized Person Notification Form" and 2 copies of "FR-7-01-39 Accreditation Contract" and communicating these forms to NBE after they are signed by the person authorized for representation and signature for the organization.

The application form, accreditation contract and Conformity Assessment Body Authorized Person Notification Form shall be signed by CAB's top management or someone authorized by the top management. Where the applied accreditation scope includes scope(s) subject to the consent of the scheme owner, the document indicating the necessary consents for the said scheme(s) shall

be attached to the application. In such cases, where necessary, a protocol may be executed between the scheme owner and NBE on the respective responsibilities of parties for accreditation under the said scheme, or a document may be drawn up defining the functions of each party.

Organizations shall also specify their virtual sites, if available, in other addresses section when filling in the application forms.

### **3.1.2 Accreditation Scope**

The applying CAB shall specify and clearly define the accreditation scope relevant to the application. Prior to making the accreditation application, CAB shall clearly specify the accreditation scope by obtaining support, when necessary, from the relevant Accreditation Department.

### **3.1.3 Taking and reviewing an application**

The relevant Head of Accreditation Department assigns the case officer who will carry out the processes related to the application. The assigned case officer shall enter the CAB's application data in NBE (NBE System). A different file number is designated to each application and the all processes within the accreditation process are followed by this file number.

The case officer shall review the resources and evaluates the application against the following criteria.

- a) Whether the scope applied for is accreditable (considering whether member organizations of IAF and ILAC accredit such scope),
- b) Competency of the assessment team infrastructure and the decision-making mechanism, and their accessibility at projected times,
- c) Whether the availability of an expertise committee is required to evaluate the technical competency of the applicant organization,
- d) Compliance of the status and working style of the applicant organization with policies and principles nationally and internationally recognized and adopted by NBE,
- e) Whether NBE offers services in the field for which CAB requests accreditation, and the existence of a mutual recognition agreement,
- f) NBE's cross-frontier accreditation policy,
- g) Whether the application requirements that are defined by the scheme owner in the relevant accreditation scheme are met.

When evaluating applications for initial accreditation, scope extension, scope change and re-assessments, the case officer shall fill in FR-7-01-85 "Application Review Form". When the application is reviewed, it is checked whether the organization's scope declarations are in compliance with the scope declaration guidance in the relevant sector; if an application for flexible scope is made, whether the requirements are met in G-2-28 Guidance on Flexible Scope Accreditation of Testing and Medical Laboratories, in G-3-01 Guidance on Accreditation of Personnel Certification Bodies and in other relevant guidelines.

Where the case officer is not sure about any issue during the review, s/he shall take the matter to the Head of Accreditation Department, and where necessary, the opinion of a working group/expertise committee or relevant parties may be consulted.

Where the evaluation is negative for the entire application or for some of the scopes, the proposal as to reject the application fully or partially shall be submitted along with reasons to the NBE Presidential. The NBE Presidential shall decide on the proposal, and the reasoned decision shall be notified to CAB. This process shall not apply to changes/reductions made to application scope in agreement with the organization in question.

Where records or evidence emerge showing that CAB is involved in fraud, CAB's intentionally submitting false information or hiding some information in the process of application evaluation or initial accreditation assessment, accreditation application is rejected and the process is terminated. For these reasons, re-application of a conformity assessment body for accreditation, whose application is rejected or whose process has been terminated, is accepted at least 12 months after the application's rejection date or after the end of the process, and this application is treated as an initial accreditation application. However, during the new accreditation process the reasons for rejection or process termination and the previous process records are taken into account.

Where the outcome of the review is positive, the case officer shall notify CAB with FR-7-01-13 Application Registration Form indicating that the file has been accepted as accreditation application and the file number. CAB shall by NBE to send the documents required in the application to the special field in the NBE's e-mail.

When the installation of the required documents is completed, the case officer is informed by CAB. The integrity and completeness of sent documents/records are checked by the case officer, and CAB is notified of any missing documents.

Such action should be completed within 1 (one) month following the registration of the application. In cases of force majeure, CAB may be allowed an additional term of 2 (two) months. If at the expiry of this term the documents required in the application are not fully sent, the application file shall be closed and CAB be informed accordingly.

NBE may re-evaluate an accepted application in the following stages of the accreditation process as a result of the examination of the documents submitted after the acceptance of the application in accordance with the above-mentioned criteria, and may reject the application.

Following the full sending of the documents required in the application to the NBE, the assessment process shall be initiated.

Where the initial accreditation assessment cannot be carried out in a timely manner, CAB is informed of the issue.

### **3.2 PREPARATIONS BEFORE ASSESSMENT**

If the applicant has requested a pre-assessment, the pre-assessment is carried out pursuant to article 3.2.1. If no pre-assessment is requested, the process proceeds to the next step.

### 3.2.1 Pre-assessment

If requested by the applicant organization, pre-assessment can be made. Pre-assessment is a short assessment with limited scope. According to this;

- a) Assessment proposal form is prepared by the case officer, is presented to CAB and is mutually agreed.
- b) Pre-assessment can be performed by a lead assessor, and by an assessor/technical expert when deemed necessary.
- c) CAB's key personnel should be accessible during the pre-assessment visit.
- d) During the assessment, how the management system is implemented is examined at the very least. The assessment team may also wish to see CAB's relevant units and equipment.
- e) A separate form is filled in for each nonconformity seen during the assessment and a copy is given to CAB at the closing meeting.
- f) The assessment team send the assessment report to the NBE no later than 15 days after the completion of pre-assessment.
- g) After the pre-assessment, within at most 3 months of the assessment report's send, CAB should communicate to NBE in writing its decision on whether it wants to continue with the accreditation or not. If the decision is positive, the accreditation process is continued. Otherwise, the file is closed.

### 3.2.2 Forming the Assessment Team

If the applicant organization does not request a pre-assessment or requests to continue the accreditation process as a result of pre-assessment, the case officer initiates the process of forming the assessment team.

After the required documents have been fully sent to the NBE, if pre-assessment is not requested or if it is decided to continue the accreditation process as a result of pre- assessment, the case officer will start forming an assessment team suitable for the application scope to review the contents of the sent documents.

The assessment team for the initial accreditation process shall always consist of a lead assessor, one or more assessor depending on the scope to be accredited, a technical expert, and if deemed necessary by NBE, a trainee assessor, an observer and the case officer. The assessment team members shall be selected from NBE's assessor and technical expert pool against such criteria as expertise areas, availability, or any conflict of interest that may arise with the CAB to be assessed.

Selection of the team leader in assessments may vary according to the assessment type (initial accreditation, surveillance, witness, etc.) and the assessment techniques to be employed.

The case officer shall examine and verify the information on various locations where conformity assessment activities are conducted and which engages in important activities. Such matters shall be considered in forming the assessment team and the time to be devoted to assessment.

To guarantee impartiality, FR-7-01-17 Assessment Team Commitment forms shall be sent to the assessment team members who will fill them in and send to the NBE for CAB.

The NBE Presidential may make monthly schedules or other periods to form the assessment team fully or partially. The case officer forms the assessment team in accordance with the planning. The assessment team so formed shall be dispatched to CAB along with FR-7-01-59 Assessment Team Proposal Form. If the applicant CAB agrees with the Assessment Team Proposal, the assessment team shall commence reviewing CAB's documents. In case of objection to the proposal, CAB submits its application with reasons to NBE in writing according to "PR-5-07 Complaint and Appeal Procedure".

If CAB makes a request of scope extension after the delivery of the Assessment Team Proposal, the case officer shall evaluate such request considering the following issues.

- Whether the existing assessment team can assess the scopes included in the scope extension request,
- Inclusion of a new assessor/technical expert in the assessment team.

If it is deemed necessary as a result of the evaluation, the assessment team shall be revised and renewed. No request of scope extension shall be admitted for consideration after the assessment is planned and the proposal is sent to CAB.

I-7-01-013 Assessment Team Working Instructions lays down how the assessment team shall work before, during and after the assessment. The activities that should be carried out by the case officer are given in "I-7-01-12 Case Officer Working Instructions" in detail.

### **3.2.3 Review and Evaluation of Documents and Records by the Assessment Team**

After the sent "Assessment Team Proposal Form" is accepted by CAB, CAB's documents at the NBE are made available to the assessment team.

The documentation and records are reviewed by the assessment team before the onsite assessment. Following the assignment of the assessment team, document and records review shall be completed within 1 month.

As a result of the review of documents and records, FR-7-01-34 Document and Record Review Report is prepared by the members of the assessment team in a way to include record-based verification of locations where important activities are carried out, is filed to the relevant section in the CAB File allocated to CAB in the NBE and is sent to the case officer.

If the assessment team identifies major nonconformities that may preclude proceeding with the onsite assessment, the assessment process shall be continued after the said nonconformities are remedied by the applicant organization. CAB is also expected to undertake corrective action for other findings if any which do not preclude the conduct of assessment. The assessment may however proceed in case of such findings without the corrective actions being completed.

In order to conduct an on-site assessment, the applicant CAB must have operated its management system for at least 6 months, and internal audit and management review must have been carried out. Furthermore, adequate work must have been done in the scope for which accreditation application was made, and records of this work shall be submitted to the assessment team. If the above requirements are not met, assessment cannot be carried out, as it would not be possible to

form an idea about the competency of the organization.

If the assessment could not be performed due to CAB not becoming ready within one year from the application date, the application file is closed. The time spent for pre-assessment (if performed) is also included in this period. After the file is closed, CAB can reapply if so desires.

As a result of the document and record review process, assessment proposal should be submitted to CAB within one month after reporting that it would be appropriate to carry out an on-site assessment. CAB should take this situation into account and make the necessary preparations for on-site assessment in a timely manner and cooperate with the case officer and the assessment team to organize the on-site assessment as soon as possible. Any delays caused by CAB are recorded.

### **3.3 ACCREDITATION ASSESSMENT**

#### **3.3.1 Assessment Proposal**

Where, as a result of the review of the documentation and records as specified in Article 3.2.3, there is nothing that precludes proceeding with the assessment or after CAB completes necessary activities following the review of the documentation and records, the case officer will in cooperation with the assessment team prepare an assessment program.

Apart from cases of necessity, an assessment is made with the assessment team assigned to review the documents and records in the Assessment Team Proposal. But under necessity, it is possible to make changes in the assessment team and add a new member to the assessment team.

The case officer sends FR-7-01-15 Assessment Proposal Form to CAB, which contains the assessment fee determined according to the assessment program and the appointed assessment team.

After the assessment proposal is confirmed by CAB, necessary preparations are made for on-site assessment in coordination of the team leader.

#### **3.3.2 On-site Assessment**

Following the acceptance of the assessment proposal and the assessment program by CAB, on-site assessment is performed according to the schedule specified in the assessment program.

The purpose of an assessment visit is to understand whether the management system and technical competency of the applicant organization meets the requirements of the documents including complementary criteria and international standards (EA, IAF, ILAC and NBE Guidelines, EU Directives, legal regulations, etc.) related to the accreditation scope for which the organization applies and collect the necessary information about the sustainability of the system.

On-site assessment consists of two main parts: witness assessment and office assessment. If necessary, such techniques as unplanned visits, remote assessment, measurement audits, verification audits etc. can also be used.

During the office assessment, such assessment techniques as reviewing CAB documents, reviewing records, proficiency tests and performance review as a result of interlaboratory comparisons, interview etc. can be used.

If CAB operates in other locations in addition to its head office, these locations are included in the initial accreditation assessment. All locations where CAB carries out important activities are visited in the initial accreditation assessment. The locations where other activities are carried out are also visited by sampling according to the results of risk assessment.

The details of which activities are important activities for an accreditation scheme and how other activities will be sampled have been defined in documents related to the accreditation area (I-7-01-12, I-7-01-13, G-1-10, G-2-09, G-3-01, G-4-05, G-4-10, G-5-01, G-5-04, G-5-07 etc.).

Conformity assessment activities to be assessed in witness and office assessments and sampling of CAB personnel to be observed during the conformity assessment activities to be witnessed are performed according to the risk factors defined in the relevant documents (I-7-01-12, I-7-01-13, G-1-10, G-2-09, G-3-01, G-4-05, G-4-10, G-5-01, G-5-04, G-5-07 etc.).

The assessment team comes together with the management of the applicant organization at the opening meeting chaired by the team leader. At the opening meeting; information is given on the purpose of the on-site assessment, its scope, the assessment program, and the participants; other issues such as confidentiality, security, and other related issues are shared with the management of the organization.

If the organization for which accreditation assessment is carried out is a product or management systems certification organization, a certain number of certification audits carried out by this organization in this area are monitored by NBE Assessment Team and findings about the competency of the organization's practices and audits are obtained. The rules of witness assessment are given in G-4-05, G-5-01, G-5-04. During the accreditation assessment process, the members of the NBE Assessment Team visit and evaluate the firms/enterprises where certification work was carried out by the product or management systems certification body being assessed.

If necessary, firms certified by the accredited management systems certification body can be visited to get an idea about the way that the certification body operates and the competency of its auditors by evaluating the quality of its documented management system.

In the assessment of personnel certification bodies, a certain number of certification activities carried out by the relevant organization are monitored by the NBE Assessment Team including certification examination and evaluation, and findings are obtained about the competency of the personnel involved in the practices of the organization and in its certification activities.

For personnel certification bodies, the rules of witness assessment are given in detail in "G-3-01 Guidance on Accreditation of Personnel Certification Bodies". Furthermore, members of the NBE Assessment Team may also hold meetings with the personnel certified by the personnel

certification body during the accreditation assessment process.

Assessors and technical experts involved in the assessment of laboratories and inspection bodies carry out the assessment by interviewing the relevant personnel and by having them apply the methods to determine the competency of methods found in the application scope and the competency of the personnel applying these methods. Where the requested accreditation scope is broad, methods can be selected using the sampling method within the scope applied by the laboratory. What is important in this case is to carry out the assessment by selecting as many methods as necessary to prove that the technical competency is provided in the relevant scope.

Moreover, as part of the assessment, laboratories shall participate in proficiency tests or interlaboratory comparisons in accordance with the criteria specified in "PR-7-04 Procedure for Proficiency Testing and Inter-Laboratory Comparison Schemes".

The findings identified during the assessment are clearly and intelligibly recorded in the relevant NBE forms based on objective evidence. If the assessment team cannot reach a conclusion on the findings, they can refer to the knowledge of the case officer or the related NBE Manager to clarify this situation.

Before the assessment is completed, the assessment team members meet up to classify the nonconformities found and record these nonconformities in the "Nonconformity and Corrective Action Notification Form".

If non-compliance with NBE, ILAC and IAF policies or deviations from the requirements set by NBE is identified, these findings are also recorded in the "Nonconformity and Corrective Action Notification Form", and the relevant policy is cited in the form.

On-site assessment shall be finalized by a closing meeting chaired by the team leader with participation of CAB management.

All the nonconformities determined and, if any, follow-up assessment, suspension, withdrawal etc. suggestions are explained in the closing meeting before the assessment team leaves the organization; and the authorized person of CAB is asked to put his/her signature that s/he accepts the nonconformities and suggestions by the assessment team. Where CAB refrains from signing the nonconformities and the suggestions of the assessment team, explanation is given that they may apply NBE in writing with reasons according to "PR-5-07 Complaint and Appeal Procedure". If the authorized person of CAB does not sign, the nonconformities and suggestions by the assessment team shall be reported by signatures of the assessment team.

The assessment team leaves a copy of the Nonconformity and Corrective Action Notification Form to CAB so that the corrective actions can be performed, the cause analysis, the extent of nonconformity (spread to other areas) and the completion dates can be written on it.

CAB shall send to the NBE and inform the team leader and the relevant assessment team member about the corrective actions it will carry out in terms of the nonconformities determined during

the assessment and their deadlines within two weeks at the latest following the assessment with confirmation from the relevant assessment team member. Furthermore, the originals of the Nonconformity and Corrective Action Notification Forms are sent by CAB to NBE.

CAB shall successfully complete its corrective actions within 3 (three) months after the assessment date. For this reason, the deadlines of corrective actions should be determined in a way not to exceed this date by taking into account the feedback from the assessment team.

### **3.3.3 Interruption or Postponement of the Planned Assessment**

The cases where the assessment should be interrupted/postponed are listed below;

#### **I. Before the Assessment:**

Critical changes in the status of CAB, such as changes due to natural disasters, concerning the legal status or the address, key personnel quitting the job, withdrawal of the certification applications of the client firms where witnesses will be realized, etc. might occur. In such cases, after discussing with the relevant CAB authorities, the case officer may postpone the assessment date to the earliest date possible. When necessary, the assessment team might be changed and assessment program and proposal are updated.

Where CAB quits the assessment or request for accreditation after it has signed the assessment proposal, half of the total price proposed for assessment shall be invoiced to CAB.

#### **II. During the Assessment:**

After assessment starts, it might be necessary to interrupt due to conditions for example including but not limited to the following where:

- a) Assessment conditions adversely affect the health or jeopardize the safety of the assessment team,
- b) Significant environmental or safety risks arise depending on the nonconformity identified,
- c) It is determined that CAB is not ready for assessment in terms of infrastructure, personnel or documentation although it has declared its readiness,
- d) Adequate records of implementation are not available in areas for which accreditation is requested and/or CAB precludes access to records and/or conditions are not present for the assessment team to collect objective evidence,
- e) CAB authorities have failed to organizational preparations including logistics etc. to proceed with the assessment;
- f) It is determined that records reviewed at the on-site assessment are substantially false or records are created partially or fully in a misleading manner deliberately or incorrect information or documents or records are deliberately presented; CAB prevents access to records;
- g) CAB makes proposals of financial benefits to the assessment teammembers,

The reason for interrupting the assessment shall be captured in an incident report by the

assessment team and CAB authorities.

If the assessment is interrupted due to a reason not arising from the client, the assessment is realized/completed on an appropriate date without charging any additional fees to CAB. However, if the assessment is interrupted due to reasons such as CAB not completing its preparations, not making its key personnel available during the assessment and/or their other deficiencies, misconduct or negligence; pursuant to the terms of the Assessment Contract, it is considered that the assessment is executed completely and the fee mentioned in the assessment proposal is invoiced fully to CAB; and the assessment is finalized as unsuccessful.

If the interrupted assessment is an initial accreditation assessment, a new assessment shall be scheduled within one year from the application date. The duration/scope of the newly scheduled assessment may be reduced considering the successful parts of the interrupted assessment. If an assessment cannot be conducted within one year from the application date due to reasons attributable to CAB, the application file shall be closed.

If the interrupted assessment is a surveillance assessment, a new surveillance assessment shall be scheduled. The duration/scope of the newly scheduled assessment may be reduced considering the successful parts of the interrupted assessment. If the time limit specified for surveillance assessment is exceeded, suspension/withdrawal procedures shall be executed.

If the interrupted assessment is a re-assessment, a new re-assessment shall be scheduled within 48 months from the date of accreditation decision. The duration/scope of the newly scheduled assessment may be reduced considering the successful parts of the interrupted assessment.

### **3.3.4 Assessment Report**

Assessment team members shall send their assessment reports within a month following the completion of the assessment to the NBE in the “Assessment Report” section under the CAB's File.

The assessment team never makes a written or verbal commitment related to the accreditation decision.

Since the assessment reports and other records relating to the assessment are accessible via NBE, these records shall not be sent to the CAB in print.

All records produced during the assessment process (e.g. assessment report, nonconformities, evidence of corrective and preventive actions etc.) shall be will be put in the file by the assessment team. This file can only be accessed by CAB authorized person, case officer and assessment team.

### **3.3.5 Corrective Actions**

CAB should submit the records of the corrective actions that it carried out in order to resolve nonconformities detected during the accreditation assessment to NBE within 3 months at most. The corrective action records shall be sent by CAB's authorized person to the NBE, and the

assessment team be informed accordingly. All members of the assessment team evaluate the records of corrective actions carried out for the nonconformities determined by themselves, write evaluation results in FR-7-01- 19 Assessment Final Report, and communicate to the team leader. Each assessment team member may send the assessment final report s/he prepares to the NBE for CAB file or alternatively communicate his/her evaluations for the corrective actions to the team leader who shall consolidate all evaluations from team members, finalize the final report and load to the NBE. Initial accreditation assessments should be finalized within 6 months following the assessment date.

Assessment final reports shall be communicated to NBE within 1 (one) month following the sending to the NBE of records that corrective actions are completed or the expiry of the time given to CAB to complete corrective actions.

Where NBE deems necessary upon the review of corrective actions by the assessment team, a follow-up assessment pursuant to Article 3.4 may be conducted.

Where nonconformities are not successfully closed in the prescribed time, it is required to repeat the initial accreditation assessment before the expiry of one year from the application date in order to proceed with the accreditation process.

Where there are differences in the findings stated in the closing meeting and the content of the assessment reports, CAB shall be given written information with reasons.

### **3.4 FOLLOW-UP ASSESSMENT**

Follow-up Assessment is an extra visit made generally related to nonconformities when requested by NBE or assessment team.

The follow-up assessment is planned as accreditation assessment; however, its scope is limited in general with the reasons making the assessment necessary. The follow-up assessment shall be scheduled after CAB completes within 3 months at the latest the relevant corrective actions and held within 4 months (from the date of identification of the relevant nonconformity). (Such 4-month limit shall not apply to the follow-up assessment that is to be held when CAB's accreditation is partially or fully suspended).

If there is an assessment yet to be finalized, assessment conducted upon complaint or in other circumstances deemed necessary by NBE shall be considered follow-up assessments in order to verify that reasons for suspension no longer exist where CAB's accreditation is suspended partially or fully. However, if an additional assessment is needed when CAB has no ongoing assessment, such assessment shall be treated as a surveillance assessment.

Where CAB is found to be competent as a result of the follow-up or surveillance assessment in order to terminate suspension of the suspended scopes where CAB's accreditation partially or fully suspended due to CAB's relocation, personnel turnover, equipment change etc. reasons; FR-7-01-18 Nonconformity and Corrective Action Notification Form shall be used in cases of partial suspension, or FR-7-01-18 and Assessment Final Report in cases of suspension of all scopes to

urgently make a report and communicate to the case officer. The case officer shall submit the proposal to the Accreditation Decision Board and finalize the suspension removal as quickly as possible. Where CAB is found to be not competent according to result of the assessment or in scopes determined not competent, necessary reporting and decision processes shall be followed to maintain suspension or withdrawal pursuant to this procedure.

The follow-up assessment is usually done with the recommendation of the assessment team to check the implementation of the corrective actions. However, follow-up assessment can be done for the following reasons or similar reasons:

- a) To support the assessment with new evidence where the assessment does not provide full confidence in CAB's competency,
- b) Where inadequate results in a proficiency test or interlaboratory comparison measurements are obtained (for laboratories and inspection bodies),
- c) If there is a non-finalized surveillance assessment, in case CAB's accreditation is suspended in whole or in part, to confirm that the reason for suspension is resolved.

If the nonconformities are still not resolved at the end of the follow-up assessment after the initial accreditation assessment, assessment is completed with failure in the scope of nonconformities or in all scopes in accordance with the opinion of the assessment team.

If the follow-up assessment is carried out on the findings of the surveillance assessment, in case the nonconformities cannot be resolved, suspension/withdrawal procedures are applied in accordance with the related NBE procedure.

### **3.5 ACCREDITATION DECISION**

Accreditation decisions can be taken based on the results of accreditation assessments, legal status of CABs and/or, changes in CAB's technical competency, international accreditation associations related to an accreditation offered in a specific area, or a technical decision taken by NBE.

After the assessment team submits its final evaluation on the accreditation assessment and its recommendation regarding accreditation to NBE, the case officer compiles the assessment report and additional documents and records for the assessment, as well as other relevant documents, if available, and the proposed scope, reviews the entire file, checks it, and initiates the work necessary for accreditation decision.

Where necessary (stated below), the case officer, after taking the necessary approvals, appoints one or more persons to undertake a technical review prior to the accreditation decision, and submits the file for review by the member/members in question. Upon the completion of the technical review, the file is submitted to the head of the relevant accreditation department.

The relevant Head of Accreditation Department shall as a member of the Accreditation Decision Board, review the prepared file prior to decision. After completing the review in respect of the content and appropriateness of assessment reports, confirmation of sufficiency of evidence of corrective actions relating to nonconformities, appropriateness of scope definitions, consistency

and integrity of assessment records; s/he shall write evaluations regarding the decision to be made in FR-7-01-70 Accreditation Decision Review Form. If the Head of Accreditation Department has participated in the said assessment as a member of the assessment team, s/he shall designate a competent person within the department to conduct the review, or have another Head of Accreditation Department do the review.

All decisions related to CAB's accreditation (decisions for granting, maintaining, scope change, renewal, suspension, scope reduction, withdrawal of accreditation etc.) are taken by the Accreditation Decision Board.

The conditions under which accreditation decision mechanism and technical review prior to accreditation decision will be conducted is specified below according to different accreditation decisions:

- a) Decisions on files about the initial accreditation, re-accreditation, scope extension, scope change, lifting suspension are made, after a technical review prior to decision, by the two people decision board consisting of the head of relevant accreditation department and assistant secretary general or secretary general by unanimous vote.
- b) Decisions on the suspension, scope reduction and withdrawal of accreditation outside the request of Conformity Assessment Body (CAB) are made, if necessary, after a technical review prior to decision, by the two people decision board consisting of the head of relevant accreditation department and assistant secretary general or secretary general by unanimous vote.
- c) Where unanimity cannot be achieved, the same board meets in seven days to negotiate the situation. In the absence of a consensus, the three-person decision board consisting of the head of relevant accreditation department, the assistant secretary general and the secretary general convenes and takes the decision on a majority vote basis. Members cannot abstain from voting.
- d) Decisions for the maintaining of accreditation with the current scope shall be made by the relevant head of accreditation department after a technical review prior to decision.
- e) In cases of preparing the accreditation certificate and scope in a foreign language, scope reduction, withdrawal or suspension of accreditation with the request of CAB, address change, title change, writing changes in the scope, the decision recommendation is made by the case officer without requiring assessment. Accreditation decision is taken by the head of the relevant accreditation department.

If a member of the Decision Board is involved in CAB's assessment or s/he has conflict of interest with CAB, the said member cannot participate in the decision. In this case, or in the event that the relevant board member is on duty, on vacation, on leave, one of the other Head of Accreditation Departments, Assistant Secretary Generals and Secretary General, or a personnel with assessor or lead assessor qualifications on the relevant accreditation area appointed by the relevant Head of Accreditation Department or NBE Presidential serves as a member of the decision board instead of the member in question. For decisions taken in boards consisting of two or three-persons to be valid, at least one of the members shall be the Assistant Secretary General or the Secretary General.

The President may delegate these powers to one of the other Assistant with the competency to make decisions.

It is essential that accreditation decisions be taken after an assessment. However, in cases where CAB's accreditation is withdrawn, or it does not accept or respond to the assessment proposal etc., it is possible to make a decision without an assessment with the decisions mentioned in paragraph (e) above.

Simultaneously with the decision to grant accreditation, CAB is registered in the list of accredited organizations and its accreditation status is published at the web page by stating the scopes for which it is accredited.

CAB may make its possible appeal to the accreditation decision according to "PR-5-07 Complaint and Appeal Procedure".

### **3.5.1 Preparation of the Accreditation Certificate**

CAB assessed shall be informed by the case officer after the accreditation decision has been made.

"Accreditation Certificate" stating the scope of accreditation in its annexes, is prepared for the accredited organizations. Additionally, scopes for which accredited organizations have been accredited are published on the NBE web page as stated in accordance with the relevant declaration and accreditation guidelines.

The addresses of all locations where CAB carries out the conformity assessment activities within the scope of its accreditation, and information about the activities carried out at each location are clearly specified on the accreditation certificates, on the scope attachments, or on the web page where the accreditation information is published.

The accreditation certificate shall have the accreditation decision date as the starting date of the initial accreditation. The validity date of the reformulated accreditation certificate is not changed except for accreditation renewal.

After all documents to be sent to the accredited organization are prepared, Accreditation Certificate and Accreditation Scope documents are sent along with the "Accreditation Documents Received Form". When the documents are received, the relevant organization officer checks the contents of the documents, approves the form, and sends it back to the case officer.

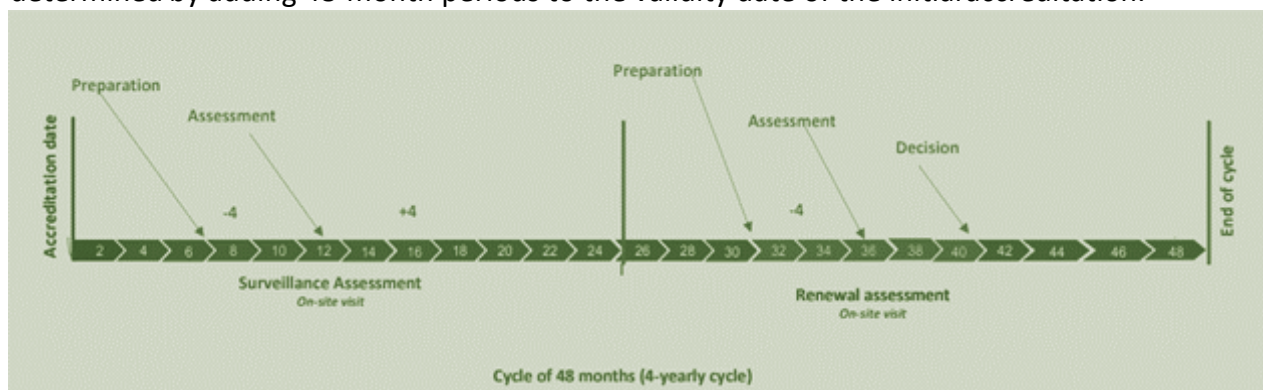
When any changes need to be made to the accreditation requirements, NBE shall send a "Rule Change Opinion Request Form" to all Conformity Assessment Bodies.

Conformity Assessment Bodies specify their opinions on this subject and send the form back to NBE. The final amendment is communicated to the parties concerned via the NBE web page and with a letter, when necessary.

If so requested by CAB, the accreditation certificate and/or annexes shall be prepared in English, after submission of scope annexes in English prepared by CAB, they are controlled then prepared and published on the NBE web page. Where changes are made to the original accreditation certificate in Macedonian, the English version shall be updated if requested by CAB; if not requested, the English version of the scope annexes are removed from the web page.

### 3.6. ACCREDITATION CYCLE

The first accreditation cycle begins on the date of initial accreditation decision. The duration of the accreditation cycle and the validity period of the certificate is 48 months from the date of initial accreditation provided that the surveillance assessment and re-assessment are successful. In accreditation renewals, the validity period of the new cycle and certificate is always determined by adding 48-month periods to the validity date of the initial accreditation.



Effective date of re-accreditation decisions taken inside the accreditation cycle period is the next day from the validity date of the certificate. If re-accreditation decision is received within 4 months after the expiration of the certificate's validity period (accreditation is not valid within this period), the effective date of the certificate becomes the date on which the decision is taken. Similarly, the validity period of the new cycle and the certificate is determined by adding 48-month periods to the validity date of the initial accreditation.

File is closed if a decision cannot be taken within 4 months due to reasons originating from CAB. CAB makes an initial accreditation application if it wants to be re-accredited.

The validity date of the reformulated accreditation certificate does not change except for re-accreditation.

#### 3.6.1 Surveillance Activities

Potential surveillance activities include the following, and when necessary, are always applicable:

- a) Questioning whether the documentation in organization's management system is up-to-date,
- b) Review of the declarations made by the organization regarding its activities,
- c) Internal audits,

- d) Management review,
- e) Complaints/appeals,
- f) Analysis of situations that may cause a conflict of interest,
- g) Management of impartiality,
- h) Revised documents,
- i) Corrective/preventive actions (both on nonconformities in previous assessment and conducted after CAB's internal audits, etc.),
- j) Personnel competency and availability
- k) CAB's legal personality and/or organizational structure (related to the coming changes, if any),
- l) CAB's performance records,
- m) Witnessing some of the conformity assessment activities according to the planning in the accreditation cycle program,
- n) For laboratory and inspection bodies;
  - Documentation and records related to comparison measurements and participation in proficiency testing,
  - Calibration of devices and references and their national/international traceability,
  - Methods, method changes and validation studies.

An accreditation cycle program is prepared for each CAB that will enable assessment in related locations in a way to represent all activities in the scope of accreditation (scope in the annex to the accreditation certificate) together with the management system throughout the cycle. When the cycle program is prepared, information on CAB's management system, activities and performance is taken into account. The accreditation cycle program is established after the initial accreditation decision, and is updated prior to and after each assessment, and in necessary situations.

Within the framework of the accreditation cycle program, the 1<sup>st</sup> surveillance assessment of the accredited organization shall be carried out at the 12<sup>th</sup> month from the start date of the cycle. The 2<sup>nd</sup> surveillance assessment is conducted 15 months after the 1<sup>st</sup> surveillance assessment. A maximum deviation of 2 months can be allowed in routine assessments. For reasonable grounds (request for scope extension, complaint, changes in regulations and standards of CAB's activity area, changes in CAB's structure, suspension of accreditation etc.), an additional 2 months deviation may be allowed in assessments; however, the time between sequential surveillance/re-assessments shall not exceed 24 months under any circumstances. While 2 routine surveillance assessments are contemplated for an accreditation cycle, this number may be increased for reasons mentioned below:

- \* Request for scope extension, complaint, changes in regulations and standards of CAB's activity area, changes in CAB's structure, suspension of accreditation, etc.
- \* The requirements given in relevant accreditation program and accreditation cycle program,
- \* When witness assessments cannot be carried out in succession with office assessments.

Where possible, attention is paid to carry out witness assessments together with routine surveillance and re-assessments. However, in cases where the witness assessment cannot be carried out together with the surveillance and renewal assessment within 3 months period, independent witness assessments can be performed before or after the related assessment in accordance with the accreditation cycle program.

The accreditation cycle program (including surveillance assessments and reassessment) is planned to represent all activities found in the accreditation scope (scope in the annex to the accreditation certificate) together with the management system. The details of this planning are specified in the relevant NBE documents for each accreditation program (I-7-01-12, I-7-01-13, G-1-10, G-2-09, G-3-01, G-4-05, G-4-10, G-5-01, G-5-04, G-5-07 etc.). The scope of each surveillance assessment consists of at least the elements of management system; internal audits, management review, and evaluation of corrective actions.

During the accreditation cycle, the locations where the organization performs important activities are prioritized within the framework of a risk-based approach by taking into account the issues defined in NBE documents (I-7-01-12, I-7-01-13, G-1-10, G-2-09, G-3-01, G-4-05, G-4-10, G-5-01, G-5-04, G-5-07 et al.), and are visited at least once in every accreditation cycle (48 months) in addition to the initial accreditation assessment. The locations where other activities are carried out are also visited by sampling according to the results of risk assessment.

CAB should also continuously meet the accreditation criteria for conformity assessment activities for which it is accredited but cannot perform for a certain period due to lack of customers, and submit evidence of competency to NBE.

As in the initial assessment, surveillance consists of reviewing documents, on-site assessment, checking corrective actions, and reviewing reports and documents. The surveillance assessment is planned, carried out and reported in a similar way to the initial accreditation assessment. Unlike the initial accreditation assessment, the assessment team proposal is skipped and the assessment process is started with the assessment proposal; document review is performed after the assessment proposal and (if not needed) without giving feedback to CAB with the Document and Record Review Form. Corrective action and reporting periods defined in the initial accreditation assessment also apply to the surveillance assessment.

If a major finding which inhibits maintaining the accreditation is detected during the surveillance assessment, the assessment team shall communicate its report on nonconformities (FR-7-01-18 Nonconformity and Corrective Action Notification Form) to NBE without delay. The case officer shall promptly submit the file to the Decision Board for decision. Where an important finding which inhibits maintaining the accreditation is detected by the assessment team during the surveillance assessment, it shall be indicated that a follow-up assessment shall be conducted for the nonconformities.

CAB shall send the records of corrective actions to the NBE in the CAB file for CAB within 3 months following the surveillance assessment and accordingly inform the case officer and assessment team members. The assessment team shall evaluate the corrective actions relating to the nonconformities, prepare its assessment final report and send to the NBE. If sufficient corrective action is not taken by CAB during the specified period, the process for partial or full suspension of accreditation is executed.

The case officer completes the records related to the assessment and submits the report prepared by the assessment team and the completed file to the Accreditation Decision Board.

The surveillance assessment shall be finalized within 6 months following the date of assessment.

### **3.6.2 Re-assessment**

In case, the accredited CAB requests the renewal of the Accreditation Certificate, it applies to NBE in written form at least 12 months before the end of the validity of its accreditation certificate.

Re-assessment is normally carried out at the 42<sup>nd</sup> month of the cycle. If the re-accreditation application has been made late or if the re-assessment could not be done in time due to reasons arising from CAB, then the responsibility lies with the CAB of not conducting of re-assessment before the cycle ends and consequently the loss of its accreditation status at the end of the cycle. If re-assessment is not performed before the end of the cycle, the accreditation status is lost and the file is closed. CAB makes an initial accreditation application if it wants to be re-accredited.

Re-assessment is planned, performed and reported similar to the initial accreditation assessment. Unlike the initial accreditation assessment, the assessment process is started with the assessment proposal without an assessment team proposal; document review is performed after the assessment proposal and (if not needed) without giving feedback to CAB with the Document and Record Review Form. Corrective action and reporting periods defined in the initial accreditation assessment also apply to the re-assessment.

The re-assessment shall be carried out to confirm CAB's competency and to cover all requirements of the standard for which the conformity assessment body has been accredited. When planning re-assessment to confirm CAB's competency, information on the personnel and other resources for CAB's entire scope is evaluated, the assessment team is formed in a way to include expertise for the scopes needed for review. Within this framework, scopes and all locations where important activities are carried out that were not assessed in previous assessments in the cycle, and other activities and locations determined by a sampling method within the framework of a risk based approach by taking into account previous assessments and the issues defined in relevant NBE documents (I-7-01-12, I-7-01-13, G-1-10, G-2-09, G-3-01, G-4-05, G-4-10, G-5-01, G-5-04, G-5-07 etc.) are assessed.

If the organization does not request for re-accreditation, the case officer shall confirm that CAB has no re-accreditation request two months prior to the expiry of the 48-month period and start the approval process of the NBE Presidential for closing the file; the file shall be closed upon the expiry of the period.

By the end of the accreditation period, the name of CAB is deleted from NBE website.

### **3.7. SUSPENSION, WITHDRAWAL, SCOPE CHANGE**

#### **3.7.1. Accreditation's Suspension, Withdrawal and Scope Reduction at the Request of CAB:**

Accredited conformity assessment body informs NBE of its request for accreditation's suspension/withdrawal/scope reduction by a letter signed by the CAB official. The request for

suspension/withdrawal/scope reduction shall be evaluated by the relevant case officer and submitted to the Accreditation Decision Board for decision via NBE.

An organization may request the suspension of accreditation at most once in an accreditation cycle.

### **3.7.2. Suspension, Withdrawal and Extension of CAB's Accreditation by NBE:**

#### **3.7.2.1 Suspension of accreditation**

CAB's accreditation is suspended in part or in whole under the following conditions:

- a) If it is determined by objective evidence such as assessments or complaints that CAB no longer has competency,
- b) If it is determined by objective evidence such as assessments or complaints that CAB's structure or activities violate the impartiality requirements in the relevant accreditation standards,
- c) If there are personnel, settlement, equipment and management changes affecting CAB's accredited activities and NBE evaluates these changes as potential risks,
- d) If CAB has not notified NBE of the following changes within the period specified in the accreditation agreement,
  - Legal, commercial or organizational status,
  - Organizational structure, top management and authorized personnel,
  - Main policies and procedures,
  - Settlement status and resources, personnel and equipment,
  - Other issues that may affect the accreditation activities and the ability to meet accreditation requirements,
  - Changes related to the scope, representation, address and people regarding the abroad activities.
- e) If the records of the performed corrective action on non-conformities identified during surveillance assessments has not been submitted to NBE within 3 months or if the submitted corrective actions were found to be insufficient,
- f) If the planned surveillance assessment is rejected by the organization without a force majeure or necessity, or if it cannot be carried out on time due to reasons arising from the organization,
- g) If CAB fails to fulfil its obligations in the agreements signed with NBE,
- h) If CAB fails to comply with new accreditation requirements and criteria in a given timeframe announced by NBE,
- i) If the organization does not fulfil its financial obligations within 2 months after the invoice date,
- j) If CAB uses its accreditation certificate and accreditation mark in a misleading way,
- k) If the assessment is interrupted due to reasons arising from CAB or CAB employees during the assessment,
- l) In case, CAB appoints people who were proven by objective evidence to have been involved in confidence shaking activities in accreditation and conformity assessment activities in last 3 years such as; fake report preparation for audit/inspection/test/calibration and making deliberate changes in audit/inspection/calibration/test data etc., giving deliberate

misinformation, unrecorded document preparation as manager, decision maker, assessor, evaluator, examiner, document organizer, document/certificate/report endorser in CAB's conformity assessment activities.

- m) If people, who have been convicted of such crimes of infamy as embezzlement, malversation, bribery, theft, fraud, forgery, abuse of office, fraudulent bankruptcy and crimes of smuggling, crimes of bid rigging a tender, are CAB's partners or if they take part in the conformity assessment activities as managers,
- n) If CAB has not demonstrated the minimum practices specified in the relevant guidelines within the accreditation cycle in scopes for which it is accredited, has not organized witness assessments, or has not carried out its accredited conformity assessment activity within the period specified in related documents,
- o) If CAB is involved in activities such as issuing certification, accreditation, recognition or competency within the scope of ISO/IEC 17025, ISO 15189 and similar standards, which NBE uses as the basis for its accreditation activities,
- p) If there are other conditions specifically mentioned in the relevant accreditation program that require suspension.

The suspension period and the procedures for lifting of suspension of CAB whose accreditation was suspended are described in section 3.7.4.

### **3.7.2.2 Withdrawal of accreditation**

CAB's accreditation is withdrawn under the following conditions:

- a) If the reasons for the suspension of accreditation cannot be resolved in time or if the corrective actions are found to be insufficient,
- b) If there exists objective evidence of fraud in CAB's conformity assessment activities and/or if it is determined that CAB prepares false record/report/certificate and has severe and intentional negligence,
- c) If CAB deliberately misinforms NBE, deliberately conceals information or submits false record or evidence to NBE,
- d) If CAB deliberately violates accreditation rules,
- e) If CAB intentionally uses NBE accreditation mark or ILAC/IAF mark in scopes or areas for which it is not accredited,
- f) If NBE unilaterally cancels accreditation agreements due to conditions such as security issues, natural disaster etc.; due to conditions that arise in a specific sector/country/region/accreditation area that will weaken the confidence in accreditation; due to changes in international accreditation rules and policies or the requirements arising from the sanctions of IAF, ILAC,
- g) If CAB is involved in declarations and behaviours that damage the prestige and reputation of its accreditation or NBE,
- h) If the confidence in accreditation disappears due to CAB losing its competency or impartiality in conformity assessment activities,
- i) If there are other conditions specifically mentioned in the relevant accreditation program that require withdrawal.

However, if the conditions specified in sub-paragraphs 3.7.2.2 (a), (h) and (i) are only for a particular activity area, the accreditation scope reduction is applied for these areas.

### **3.7.3. Decision Taking and its Notification**

The decision to suspend, withdraw, or reduce the scope of an accreditation is taken by the Accreditation Decision Board. The suspension period is also specified in the suspension decision, when necessary.

The notification letter regarding the decision is sent by the relevant case officer to the conformity assessment body by fax or e-mail, and it is confirmed by phone whether the fax/e-mail has been received. The letter is also sent by mail to CAB's address. The obligation of CAB to fulfil the requirements of the decision begins with the receipt of confirmation after the fax/e-mail is sent. If no confirmation is received, it will start 3 (three) business days from the date of the letter's shipment. However, if there is an accreditation mark document issued from the decision date to the notification date, these documents should be withdrawn by CAB as they are not in the accreditation scope.

For suspension and withdrawal decisions, the decision date shall be taken as the date on the Accreditation Decision Board's decision proceedings.

CAB cannot use the NBE accreditation mark and refer to the accreditation in report, certificate and advertisement documents related to the suspended/withdrawn/reduced scope after the decision date.

The conformity assessment body, which is notified of the decision about the withdrawal of its accreditation, returns its accreditation certificate to NBE.

In the event that CAB is faced with accreditation suspension, reduction or withdrawal sanctions, CAB shall inform the affected customers about the said sanctions and their consequences without any delay. CAB may be required to withdraw documents or reports bearing its accreditation mark due to the suspension, reduction or withdrawal of its accreditation.

The certification body, whose accreditation scope has been reduced or its accreditation is withdrawn, shall notify its customers that it has certified in this scope by registered mail, notification or e-notification. Furthermore, when its accreditation is withdrawn, it should also withdraw the certificates that it has awarded within the scope of its accreditation. It shall also submit records of activities performed about this matter to NBE as soon as possible. On the other hand, when its accreditation is withdrawn, CAB takes the necessary measures to protect the rights of its customers it has certified in the past.

Necessary revisions are done in the accreditation certificates of a conformity assessment body whose accreditation scope is partially suspended or reduced.

The current information on the accreditation of CAB whose accreditation is suspended, is published on NBE website under "accredited organization search" page. If the accreditation is completely suspended then it is published as "suspended", if partially suspended then it is

published as "some scopes are suspended"; if completely withdrawn then it is published for one year long from the withdrawal date as "accreditation is withdrawn", if partially withdrawn then it is published as "the scope is reduced". If the withdrawal/suspension is due to the CAB's request, "at the organization's request" note is added; if the suspension is due to an address change, "address change" note is added. In case of a partial suspension/withdrawal, suspended/withdrawn scopes are indicated by an appropriate definition after the current scope.

The final state of the accredited scopes of conformity assessment bodies, whose accreditation scopes have been suspended, withdrawn or reduced, will be published on the NBE web page.

### **3.7.3.1 Notification of IAF**

In case of sanctions for CABs whose accreditation is completely withdrawn due to one of the reasons stated in 3.7.2.2 (b), (c), (d) and (e), or suspended due to a reason stated in 3.7.2.1 (o) and is active in accreditation programs under IAF MLA, IAF Secretariat is notified in the following format according to IAF MD 7 at the end of the appeal period; in the event of an appeal, after the appeal is finalized. According to the said IAF document, IAF Secretariat shall notify other accreditation bodies as necessary.

"[Name of AB] [state the action as 'withdrew' or 'suspended'] accreditation of [Name of CAB] on [date] for [state the proven offence]".

"[NBE] [suspended/withdrew] [CAB's title]'s accreditation on [date] due to [identified nonconformity]".

### **3.7.4 Applications of Conformity Assessment Bodies for their Suspended, Withdrawn and Reduced Accreditation Scopes**

The accreditation application of a conformity assessment body whose accreditation is withdrawn for the reasons stated in Article 3.7.2.2 (b), (c), (d), (e) and (g), shall be accepted at least 12 months after the withdrawal decision, and this application is treated as an initial accreditation application. However, in the new accreditation process, the reasons for withdrawal and the previous period records are taken into consideration.

The accreditation application of a CAB whose accreditation was withdrawn for the second time due to the reasons stated in Article 3.7.2.2 (b), (c), (d), (e) and (g) is not accepted.

The application of a conformity assessment body whose accreditation is reduced for the reasons stated in subparagraphs 3.7.2.2 (a), (h) and (i) related to this scope, shall be accepted at least 6 (six) months after the decision date to reduce the scope. However, in scope reductions due to delays in address change, personnel recruitment and device procurement etc. processes, 6 (six) month time limit for re-application shall not be applied. If it is determined by a performed assessment that the applicant organization resolved the nonconformities, and this is reported, it is decided to expand the scope, and the necessary revisions are made to the existing accreditation certificates.

For accreditation application of a conformity assessment body whose accreditation is withdrawn for reasons outside of those stated in article 3.7.2.2 (b), (c), (d), (e) and (g), 12-month time limit shall not be applied.

Accreditation suspension is continued for a maximum period of 6 months. Within this period, CAB should complete the necessary corrective actions and the assessment should be conducted. If the projected assessment cannot be performed within this period due to reasons arising from CAB, CAB's accreditation is withdrawn or its scope is reduced.

After a conformity assessment body with suspended accreditation has reported that it has resolved all nonconformities by corrective actions that caused the suspension decision, if it is verified and reported after the necessary review, assessment and evaluation that the nonconformities have been resolved, it is decided to end the suspension. If the nonconformities cannot be resolved in due time, it is decided to withdraw the accreditation/reduce its scope.

### **3.7.5 Extending Accreditation Scope**

An organization may apply NBE to be accredited for other subject matters in addition to the current accreditation scope. In this case, it is essential that the organization is evaluated only by its technical competency.

Applications for extending the accreditation scope are made similar to the initial accreditation applications. The scope extension application is assessed similar to the initial accreditation application and a decision is made on the acceptance of the application.

Where necessary, for copies requested in scope extension applications, those associated with the documents requested at the application shall be sent to the NBE before the application date.

In scope extension applications, it is essential to examine CAB documents and records related to the scopes requested in scope extension application with the Document and Record Review Form before the on-site assessment. As a result of the document and record review, if any major nonconformities are identified by the assessment team that may be an obstacle to an on-site assessment, then the assessment process for scopes requested in the scope extension application shall be continued after the said nonconformities are resolved by the applicant organization.

For laboratories and inspection organizations, if the scope to be extended is the continuation of the previously accredited scope, that is, it does not require any additional methods or capabilities in terms of the organization's measurement capability, then the scope extension can be performed by reviewing the documents submitted by the organization without the need for an on-site assessment.

Extension requests in areas other than these are carried out according to the relevant NBE, ILAC and/or IAF rules.

When possible, attention should be paid to carry out the assessments related to the organization's scope expansion requests in conjunction with the surveillance assessments. However, scope extension requests made after the assessment proposal for a surveillance assessment has been sent to CAB is not assessed together with that surveillance assessment. To carry out assessments for such scope extension applications, it is waited for open assessments to be finalized.

The assessment visit to be made for the accreditation scope extension request is planned, carried out and finalized in accordance with this procedure.

Since the previously signed "Accreditation Agreement" with the organization is valid, a new Accreditation Agreement is not concluded.

#### **4. OBLIGATIONS OF CONFORMITY ASSESSMENT ORGANIZATIONS**

##### **4.1. CAB's OBLIGATIONS**

CABs shall fulfil the following obligations:

- Comply with the relevant accreditation standard, the relevant requirements in the documents published by NBE for CABs (communiqué, regulations, guidelines, procedures, policies etc.) and the accreditation rules set by ILAC/IAF.
- Limit their accreditation declaration only to the scope for which they are accredited. They should establish and implement procedures to help customers distinguish between the conformity assessment services they provide; the scope being accredited and the activity areas outside of the accreditation scope.
- Not use its accreditation in a way to damage NBE's reputation and to create a dispute, and cannot make statements that will disempower or mislead NBE.
- If their accreditation is suspended or withdrawn, they cannot use promotional materials containing information on accreditation and shall return all documents requested by NBE related to accreditation.
- If the accreditation is suspended or withdrawn, they shall immediately stop using the material showing their accreditation status, and discontinue advertisements indicating their status as an accredited organization.
- CAB, whose accreditation is withdrawn or scope is reduced, shall inform its customers about the withdrawal/reduction of its accreditation and about its consequences. It shall submit to NBE records of its activities performed for this matter.
- Prevent the use of accreditation from being used to mean that the suitability of a product, process, system or the person is approved by NBE.
- Prevent the use of any accreditation document, mark (sign), report or any part of them in a misleading manner.
- Comply with the rules laid down by NBE in references made in communication tools such as documents, brochures or advertising materials related to its accreditation status. They shall adhere to the requirements specified in the relevant national and international documents in advertisements, promotional works and public information activities, and do what is necessary to fulfil the revision requests and warnings from NBE.
- Inform NBE of the following important changes related to its own accreditation in due

time:

- Legal, commercial or organizational status,
  - Organizational structure, senior management and authorized personnel,
  - Main policies and procedures,
  - Locations, settlement status and resources (personnel and equipment etc.),
  - Other issues that may affect its accreditation activities and its ability to meet accreditation requirements
  - Changes related to the scope, representation, address and people regarding its abroad activities
- Obligated to pay the fees charged for the accreditation in accordance with the stated time and requirements specified in "G-1-02 Service Charges Guide".
  - Have an adequate professional liability insurance covering the conformity assessment activities for which they are accredited (but it is sufficient for public institutions to provide a declaration of assurance).
  - Record conformity assessment activities in the areas reported by NBE with video recording, vehicle tracking system and other electronic recording systems.
  - Provide services to NBE accredited CAB customers within the provisions of the relevant standard for which they are accredited and NBE rules in accordance with the prescribed requirements.
  - Enter data related to their conformity assessment activities in web applications created by NBE, and fulfil other similar obligations.
  - The agreement between NBE and CAB does not prevent CAB from fulfilling its legal obligations and responsibilities to a third party. All legal, financial and technical responsibility by third parties in relation to the use of the document within the scope of accreditation belongs to the Conformity Assessment Body.
  - Issuing follow the criteria of NBE in your certificates.
  - Keep records of its activities performed within the scope of its accreditation for a period of at least 5 years unless there is a special arrangement.
  - Provide the necessary cooperation for the investigation and resolution of complaints related to its accreditation directed by NBE.
  - Inform the affected customers about the suspension, reduction or withdrawal of their accreditation and about the associated consequences without any delay.
  - They accept to include the necessary articles in customer contracts that would enable, when necessary and applicable, NBE to visit them on-site and to obtain necessary information on the assessment carried out by CAB in order to evaluate the service provided by CAB.

Moreover, CABs are obliged to fulfil all obligations in the Accreditation Agreement signed with NBE.

## **4.2 OBLIGATIONS RELATED TO THE USE OF SUBCONTRACTORS**

### **4.2.1 Accredited Subcontractor Use**

- CAB shall learn whether the subcontractor that it intends to use in conformity assessment

services is accredited and the validity period of its accreditation, and document this information. The Conformity Assessment Body shall present these documents to NBE when necessary.

- CAB shall clearly state the results of test, measurement, inspection or certification performed by the subcontractor in any document, report or certificate issued. CAB is responsible for the test, measurement, inspection or certification results obtained from the subcontractor.

#### 4.2.2 Non-Accredited Subcontractor Use

- The use of a non-accredited subcontractor is only available in special cases. Before using a subcontractor, CAB shall check and evaluate the competency of the subcontractor to be used according to the requirements of the relevant standard for which it is accredited. The results of the evaluation shall be documented and submitted to the client and to NBE when necessary. NBE may add a provision in the assessment program that it will witness the said activities carried out by the subcontractor or, if deemed necessary, assessment team may visit the subcontractor together with the CAB to observe the activities performed by subcontractor. CAB shall take measures related to this situation.

## 5 OTHER MATTERS

All accreditation records are maintained in accordance with "PR-5-02 Records Control Procedure". Records related to CABs, including those belonging to the previous accreditation cycle, are maintained during the current accreditation cycle.

When a special case, not defined in NBE documents, at any stage or on any subject related to the accreditation process is encountered, the necessary evaluations are made about the matter, and the final decision is recorded with the signature of a head of accreditation department, assistant secretary general, the quality manager and with the approval of the Secretary General, and is implemented as specified. If a similar situation occurs, the decisions taken shall be maintained in a way to make them accessible to those concerned in order to implement the same decision.

## 6 AUTHORIZATION AND RESPONSIBILITIES

ACTIVITIES		GS	AD	CO	AT	CAB	RU
1	General Document Entry of the Application		I	I			IM
2	Assignment of Case Officer		D	I		I	
3	Registration of Application		I	IM		I	
4	Checking of Application Documents		I	IM		I	
5	Signing of the Accreditation Contract	D	I	IM		D	
6	Evaluation and Acceptance of the Application	I	I	I/D/IM	C		
7	Rejection of Application	D	D	IM		I	
8	Creation of Assessment Plans (monthly)	D	IM	C	I		
9	Formation and Assignment of the Assessment Team	D	D	IM	I	IM	

10	Review of the Documentation and Records			C/I	IM	I	
11	Preparation of the Assessment Program	I	I	IM	C	I	
12	Assessment Proposal	D	I	IM		I	
13	Realization of the Assessment		I	C	IM	C	
14	Preparation of the Assessment Report		I	I	IM	I	
15	Submission of Evidence for Corrective Actions			I	I	IM	
16	Evaluation and Follow-up of Corrective Actions			I	IM	I	
17	Preparation of the Accreditation Decision Draft		C	IM			
18	Accreditation Decision	D	D	C		I	
19	Preparation of the Accreditation Cycle Program	D	D	IM	C	C	
20	Signing of Accreditation Documents	IM	I	C			
21	Delivery of Accreditation Documents		I	IM		I	
22	Archiving the File		I	IM		I	

**Abbreviations:** CAB: Conformity Assessment Body,

**GS: NBE Presidential  
(President and Assistants)**

**AD:** Accreditation Department

**CO:** Case Officer

**AT:** Assessment Team

**C:** Cooperation

**RU:** Records Unit

**D:** Decision

**IM:** Implementation

**I:** Information

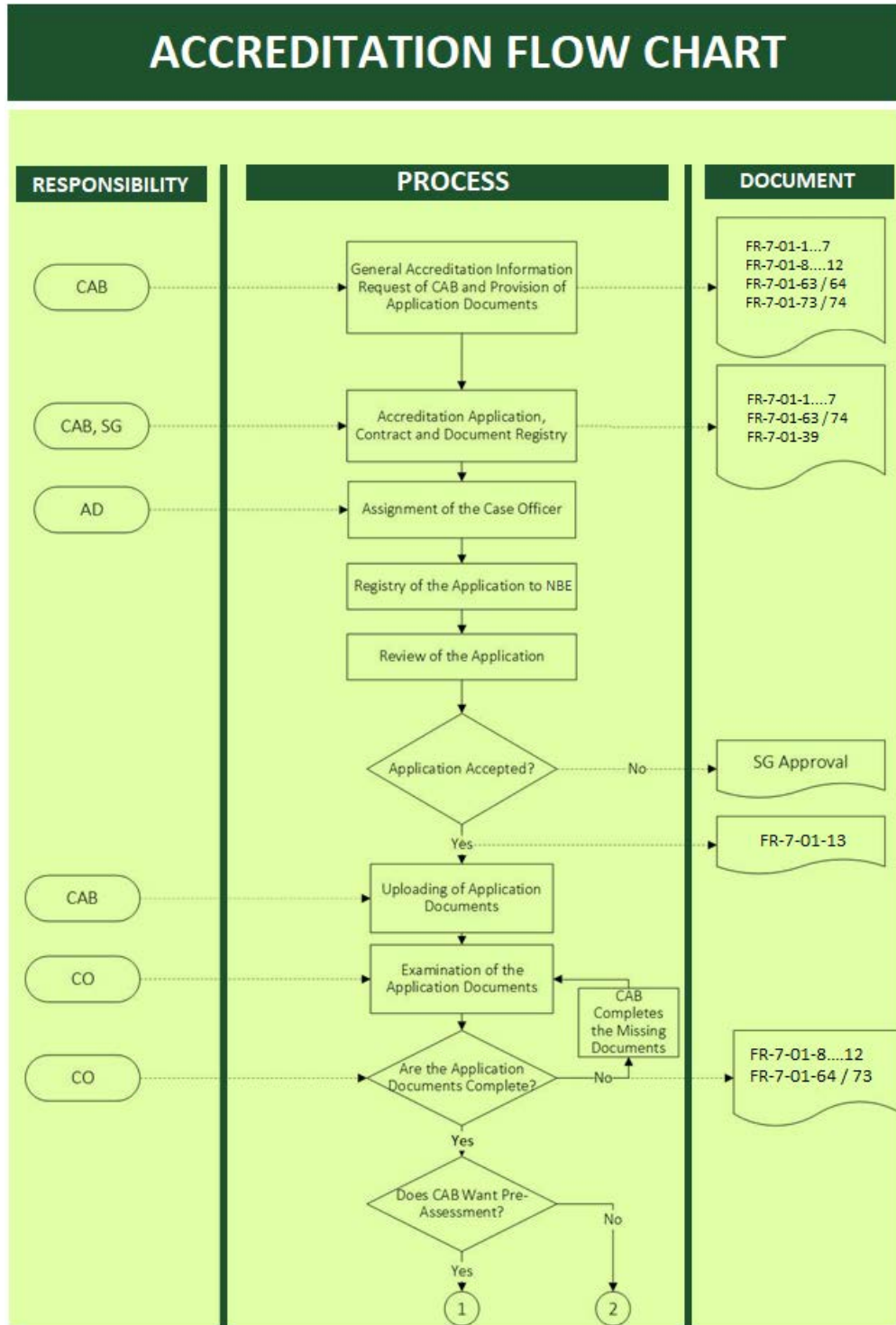
## 7 RELATED DOCUMENTS

Documents related to this Procedure are given in LS-7-1-1 'PR-7-1 Procedure Related Documents List'.

### REVISION HISTORY:

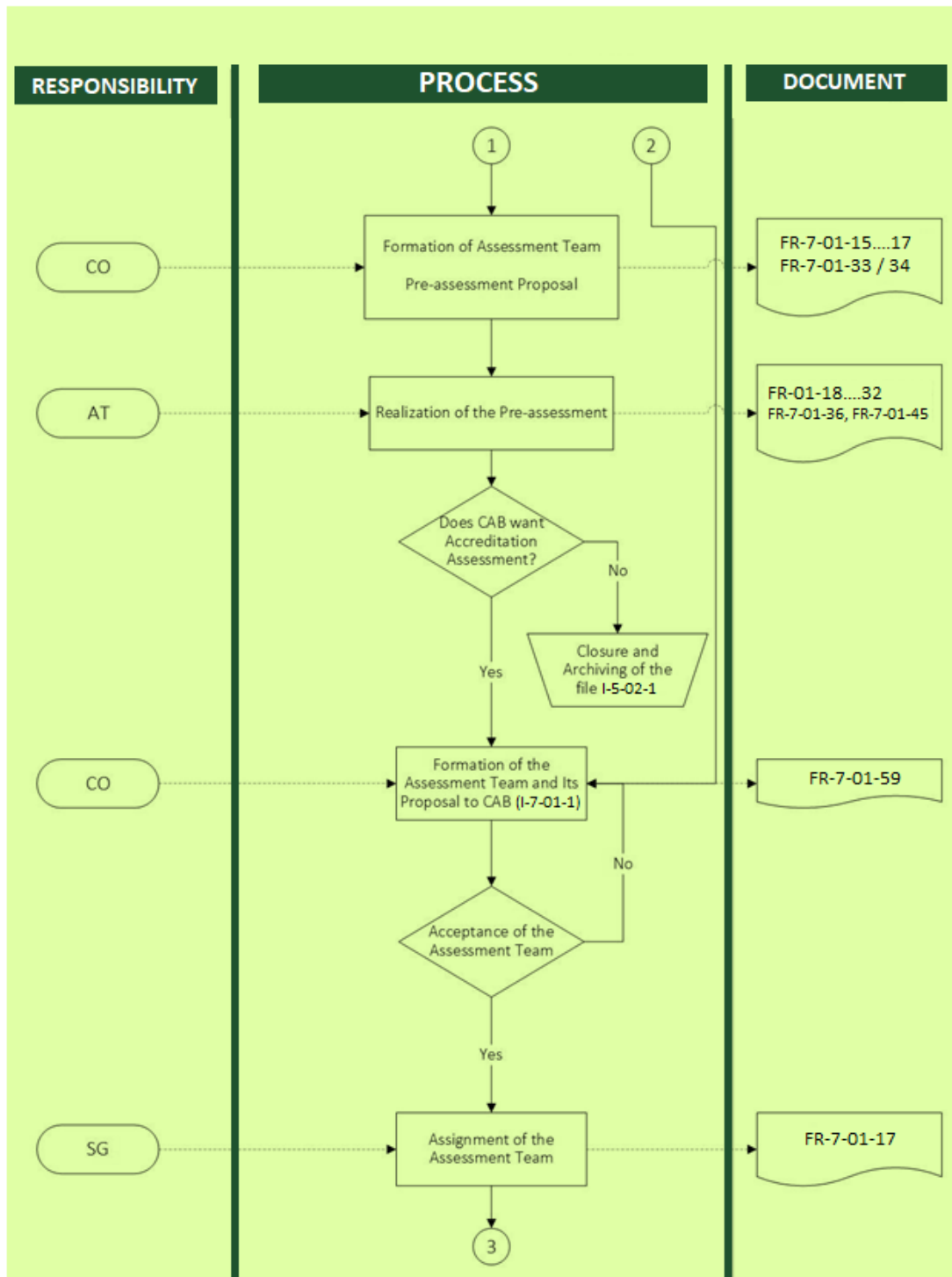
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**ANNEX A: ACCREDITATION FLOW CHART FOR INFORMATIVE**

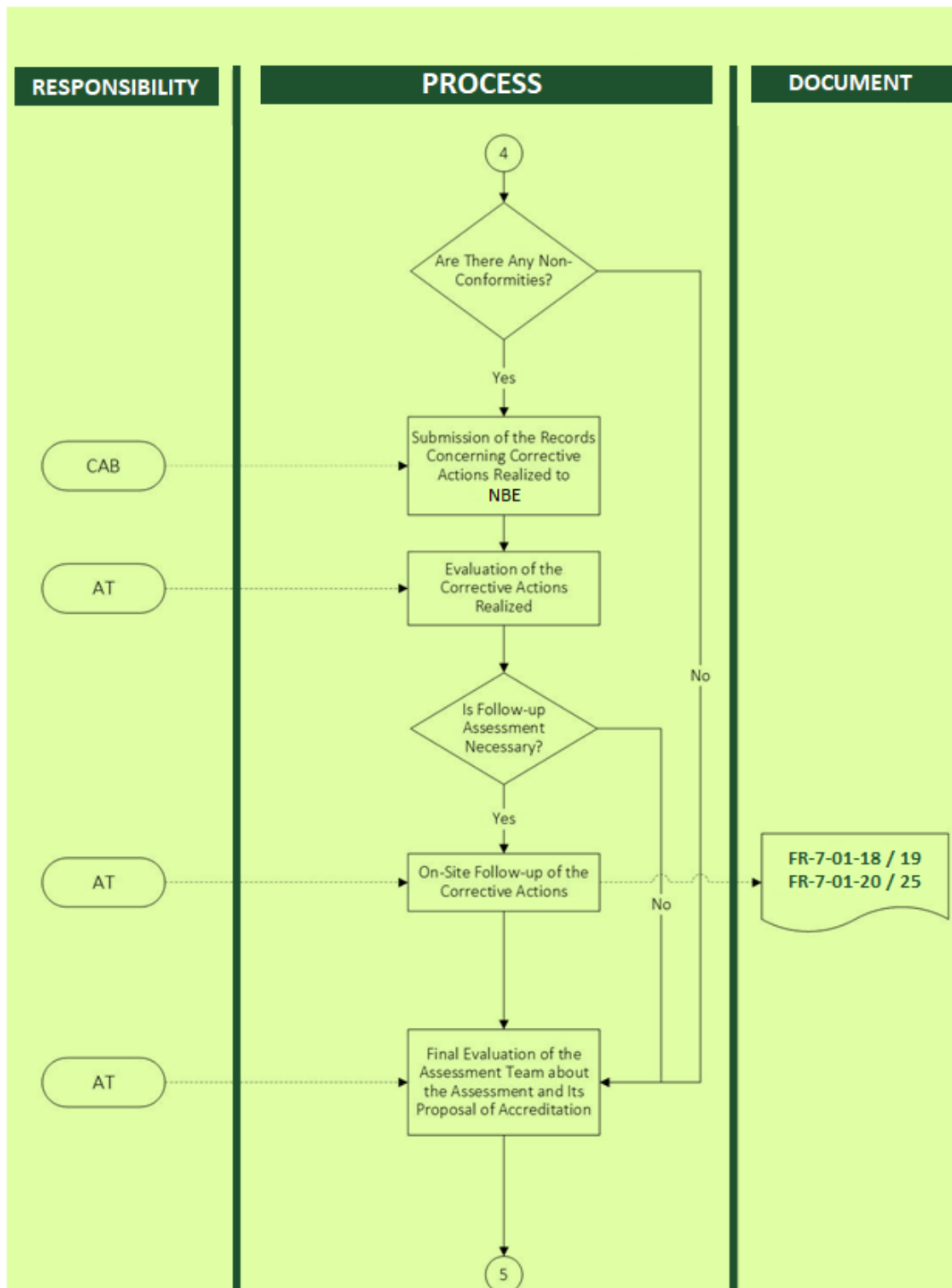




## ACCREDITATION FLOW CHART



## ACCREDITATION FLOW CHART



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