

## **1 PURPOSE AND SCOPE**

The purpose of this procedure is to explain how license applications of Natural Conformity Assessment Bodies (NCABs) will be handled, evaluated, assessed and finalized by NBE according to the principles of NSO-NAP Series and international standards. It also informs the Natural Conformity Assessment Bodies about pre-assessment (when requested), initial license, and surveillance and re-license processes after license, and explains the obligations of the licensed organizations. It also describes the procedures and operations for the suspension, reduction, withdrawal and scope change of granted license 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, license assessment, follow-up assessment, license decision, surveillance and re-license 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suspension, reduction, withdrawal, lifting of suspension, scope change and re-application of organizations with withdrawn license related to the license of natural conformity assessment bodies licensed by NBE.

## **2 DEFINITIONS**

### **License**

It is an official recognition by a third party that a NCAB is in compliance (NSO-NAP Series and Accreditation Standards) with certain requirements and is competent to carry out the appropriate conformity assessment activities.

### **License Department**

License Department within working under the NBE Presidential.

### **License Cycle Program**

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

### **License Decision**

License decisions by NBE License Decision Board on granting license, maintaining, partial or full suspension, partial or full withdrawal, scope change or re- license of NCABs that applied for license or are already licensed.

### **License Scheme**

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

### **Expertise Committee**

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

### **Assessment**

NBE's process to assess a NCAB's competency according to certain standards (NSO-NAP Series and Accreditation Standards) and/or other normative documents and conducted within the scope of a specific license.

**Note:** Covers the evaluation of a NCAB's competency in all activities including the assessment of a NCAB's license competency; competency of NCAB'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 license & 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 license assessment. (An assessor can also be appointed as the team leader in the witness and follow-up assessments).

### **Flexible Scope**

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

### **Validation Audit**

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

## **Surveillance**

A series of activities including monitoring of the licensed NCAB to see if it continues to meet the license requirements, except for re-license

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

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

## **Appeal**

NCAB's request for re-evaluation of a negative decision concerning the desired license 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 NCAB'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 license activities on the performance, procedures, policies, personnel and experts working for NBE, NBE's activities, license assessment process carried out for NBE and any issue related to a NCAB's activities.

### **Witness Assessment**

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

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

NBE technical personnel, who are appointed by the relevant NBE License Departments, and are responsible for all kinds of technical and administrative communication, coordination and secretariat operations with the organization that applied for license or is already licensed, at every stage of the license 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.

### **Natural conformity assessment body**

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

### **Nonconformity**

Non-fulfilment of a requirement.

### **Remote Assessment**

Assessment of virtual or physical sites of a natural 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 license process is composed of the following main stages;

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

One of the following assessment techniques or a combination of several techniques is/are used in the license process. Which assessment technique is used at which stage of the license 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**

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

The documents to be submitted to our Agency for application are specified in detail in the forms of documents requested during application in the application forms.

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

The License application shall be filed by filling of "FR-0-01 Application Form" related to NCAB's engagement area, "FR-7-01-71 Accreditation Services, Natural conformity assessment body Authorized Person Notification Form" and 2 copies of "FR-0-02 License 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, license contract and Natural conformity assessment body Authorized Person Notification Form shall be signed by NCAB's top management or someone authorized by the top management.

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

### **3.1.2 License Scope**

The applying NCAB shall specify and clearly define the license scope relevant to the application. Prior to making the license application, NCAB shall clearly specify the license scope by obtaining support, when necessary, from the License Department.

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

The Head of License/Accreditation Department assigns the case officer who will carry out the processes related to the application. The assigned case officer shall send the NCAB's application data in NBE (NBE e-mail). A different file number is designated to each application and the all processes within the license 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 i-NAF, 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 NCAB requests license, and the existence of a mutual recognition agreement,
- f) NBE's cross-frontier license policy,
- g) Whether the application requirements that are defined by the scheme owner in the relevant license scheme are met.

When evaluating applications for initial license, 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 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 License 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 NCAB. 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 NCAB is involved in fraud, NCAB's intentionally submitting false information or hiding some information in the process of application evaluation or initial license assessment, license application is rejected and the process is terminated. For these reasons, re-application of a natural conformity assessment body for license, 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 license application. However, during the new license 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 NCAB with FR-7-01-13 Application Registration Form indicating that the file has been accepted as license application and the file number. NCAB shall by NBE to send the documents required in the application to in the NBE's e-mail.

When the installation of the required documents is completed, the case officer is informed by NCAB. The integrity and completeness of sent documents/records are checked by the case officer, and NCAB 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, NCAB 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 NCAB be informed accordingly.

NBE may re-evaluate an accepted application in the following stages of the license 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 license assessment cannot be carried out in a timely manner, NCAB 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 NCAB and is mutually agreed.

- b) Pre-assessment can be performed by a lead assessor, and by an assessor/technical expert when deemed necessary.
- c) NCAB'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 NCAB'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 NCAB 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, NCAB should communicate to NBE in writing its decision on whether it wants to continue with the license or not. If the decision is positive, the license 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 license 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 license 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 license process shall always consist of a lead assessor, one or more assessor depending on the scope to be licensed, 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 NCAB to be assessed.

Selection of the team leader in assessments may vary according to the assessment type (initial license, 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 NCAB.

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 NCAB along with FR-7-01-59 Assessment Team Proposal Form. If the applicant NCAB agrees with the Assessment Team Proposal, the assessment team shall commence reviewing NCAB's documents. In case of objection to the proposal, NCAB submits its application with reasons to NBE in writing according to "PR-5-07 Complaint and Appeal



Procedure".

If NCAB 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 NCAB.

I-7-01-13 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 NCAB, NCAB'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 NCAB File allocated to NCAB 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. NCAB 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 NCAB 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 license 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 NCAB 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, NCAB can reapply if so desires.

As a result of the document and record review process, assessment proposal should be submitted to NCAB within one month after reporting that it would be appropriate to carry out an on-site assessment. NCAB 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 NCAB are recorded.

### **3.3 LICENSE 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 NCAB 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 NCAB, which contains the assessment fee determined according to the assessment program and the appointed assessment team.

After the assessment proposal is confirmed by NCAB, 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 NCAB, 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 (i-NAF, EA, IAF, ILAC and NBE Guidelines, EU Directives, legal regulations, etc.) related to the license 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 NCAB documents, reviewing records, proficiency tests and performance review as a result of interlaboratory comparisons, interview etc. can be used.

If NCAB operates in other locations in addition to its head office, these locations are included in

the initial license assessment. All locations where NCAB carries out important activities are visited in the initial license 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 license 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-0-01, 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 NCAB 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-0-01, 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 license 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 license 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 licensed 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 conformity of its documented product/system.

Assessors and technical experts involved in the assessment of laboratories 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 license 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, i-NAF, 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 NCAB 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 NCAB is asked to put his/her signature that s/he accepts the nonconformities and suggestions by the assessment team. Where NCAB 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 NCAB 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 NCAB 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.

NCAB 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 NCAB to NBE.

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

## **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 NCAB 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 license is requested and/or NCAB precludes access to records and/or conditions are not present for the assessment team to collect objective evidence,
- e) NCAB 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; NCAB prevents access to records;
- g) NCAB 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 NCAB 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 NCAB. However, if the assessment is interrupted due to reasons such as NCAB 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 NCAB; and the assessment is finalized as unsuccessful.

If the interrupted assessment is an initial license 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 NCAB, 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 license 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 NCAB's File.

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

Since the assessment reports and other records relating to the assessment are accessible via NBE, these records shall not be sent to the NCAB 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 NCAB authorized person, case officer and assessment team.

### **3.3.5 Corrective Actions**

NCAB should submit the records of the corrective actions that it carried out in order to resolve nonconformities detected during the license assessment to NBE within 3 months at most. The corrective action records shall be sent by NCAB'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 NCAB 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 license 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 NCAB 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 license assessment before the expiry of one year from the application date in order to proceed with the license process.

Where there are differences in the findings stated in the closing meeting and the content of the assessment reports, NCAB 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 license assessment; however, its scope is limited in general with the reasons making the assessment necessary. The follow-up assessment shall be scheduled after NCAB 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 NCAB's license 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 NCAB's license is suspended partially or fully. However, if an additional assessment is needed when NCAB has no ongoing assessment, such assessment shall be treated as a surveillance assessment.

Where NCAB 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 NCAB's license partially or fully suspended due to NCAB'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 License Decision Board and finalize the suspension removal as quickly as possible. Where NCAB 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 NCAB'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 an non-finalized surveillance assessment, in case NCAB's license 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



license 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 LICENSE DECISION**

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

After the assessment team submits its final evaluation on the license assessment and its recommendation regarding license 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 license 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 license 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 license/accreditation department.

The License Department shall as a member of the License 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 (will be used for license decision review) Decision Review Form. If the License 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.

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

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

- a) Decisions on files about the initial license, re-license, scope extension, scope change, lifting suspension are made, after a technical review prior to decision, by the two people decision board consisting of the license department and assistant secretary general or secretary general by unanimous vote.
- b) Decisions on the suspension, scope reduction and withdrawal of license outside the request of Natural conformity assessment body (NCAB) are made, if necessary, after a technical review prior to decision, by the two people decision board consisting of the license



- 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 license 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 license with the current scope shall be made by the relevant head of license department after a technical review prior to decision.
  - e) In cases of preparing the license certificate and scope in a foreign language, scope reduction, withdrawal or suspension of license with the request of NCAB, address change, title change, writing changes in the scope, the decision recommendation is made by the case officer without requiring assessment. License decision is taken by the license department.

If a member of the Decision Board is involved in NCAB's assessment or s/he has conflict of interest with NCAB, 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 license area appointed by 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 license decisions be taken after an assessment. However, in cases where NCAB's license 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 license, NCAB is registered in the list of licensed organizations and its license status is published at the web page by stating the scopes for which it is licensed.

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

### **3.5.1 Preparation of the License Certificate**

NCAB assessed shall be informed by the case officer after the license decision has been made.

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

The addresses of all locations where NCAB carries out the conformity assessment activities within

the scope of its license, and information about the activities carried out at each location are clearly specified on the license certificates, on the scope attachments, or on the web page where the license information is published.

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

After all documents to be sent to the licensed organization are prepared, License Certificate and License Scope documents are sent along with the "License 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 license 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 NCAB, the license certificate and/or annexes shall be prepared in English, after submission of scope annexes in English prepared by NCAB, they are controlled then prepared and published on the NBE web page. Where changes are made to the original license certificate in Macedonian, the English version shall be updated if requested by NCAB; if not requested, the English version of the scope annexes are removed from the web page.

## 3.6. LICENSE CYCLE

The first license cycle begins on the date of initial license decision. The duration of the license cycle and the validity period of the certificate is 48 months from the date of initial license provided that the surveillance assessment and re-assessment are successful. In license 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 license.



Effective date of re-license decisions taken inside the license cycle period is the next day from the validity date of the certificate. If re-license decision is received within 4 months after the

expiration of the certificate's validity period (license 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 license.

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

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

### **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 NCAB's internal audits, etc.),
- j) Personnel competency and availability
- k) NCAB's legal personality and/or organizational structure (related to the coming changes, if any),
- l) NCAB's performance records,
- m) Witnessing some of the conformity assessment activities according to the planning in the license 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 license cycle program is prepared for each NCAB that will enable assessment in related locations in a way to represent all activities in the scope of license (scope in the annex to the license certificate) together with the management system throughout the cycle. When the cycle program is prepared, information on NCAB's management system, activities and performance is taken into account. The license cycle program is established after the initial license decision, and is updated prior to and after each assessment, and in necessary situations.

Within the framework of the license cycle program, the 1<sup>st</sup> surveillance assessment of the licensed 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 NCAB's activity area, changes in NCAB's structure, suspension of license 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 license cycle, this number may be increased for reasons mentioned below:

- \* Request for scope extension, complaint, changes in regulations and standards of NCAB's activity area, changes in NCAB's structure, suspension of license, etc.
- \* The requirements given in relevant license program and license 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 license cycle program.

The license cycle program (including surveillance assessments and reassessment) is planned to represent all activities found in the license scope (scope in the annex to the license certificate) together with the management system. The details of this planning are specified in the relevant NBE documents for each license program (I-7-01-12, I-7-01-13, G-0-01, G-1-10, G-2-09, 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 license 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-0-01, G-1-10, G-2-09, 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 license cycle (48 months) in addition to the initial license assessment. The locations where other activities are carried out are also visited by sampling according to the results of risk assessment.

NCAB should also continuously meet the license criteria for conformity assessment activities for which it is licensed 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 license assessment. Unlike the initial license 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 NCAB with the Document and Record Review Form. Corrective action and reporting periods defined in the initial license assessment also

apply to the surveillance assessment.

If a major finding which inhibits maintaining the license 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 license 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.

NCAB shall send the records of corrective actions to the NBE in the NCAB file for NCAB 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 NCAB during the specified period, the process for partial or full suspension of license 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 License Decision Board.

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

### **3.6.2 Re-assessment**

In case, the licensed NCAB requests the renewal of the License Certificate, it applies to NBE in written form at least 12 months before the end of the validity of its license certificate.

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

Re-assessment is planned, performed and reported similar to the initial license assessment. Unlike the initial license 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 NCAB with the Document and Record Review Form. Corrective action and reporting periods defined in the initial license assessment also apply to the re-assessment.

The re-assessment shall be carried out to confirm NCAB's competency and to cover all requirements of the standard for which the natural conformity assessment body has been licensed. When planning re-assessment to confirm NCAB's competency, information on the personnel and other resources for NCAB'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-0-01, 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-license, the case officer shall confirm that NCAB has no re-license 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 license period, the name of NCAB is deleted from NBE website.

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

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

Licensed natural conformity assessment body informs NBE of its request for license's suspension/withdrawal/scope reduction by a letter signed by the NCAB official. The request for suspension/withdrawal/scope reduction shall be evaluated by the relevant case officer and submitted to the License Decision Board for decision via NBE.

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

#### **3.7.2. Suspension, Withdrawal and Extension of NCAB's License by NBE:**

##### **3.7.2.1 Suspension of license**

NCAB's license 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 NCAB no longer has competency,
- b) If it is determined by objective evidence such as assessments or complaints that NCAB's structure or activities violate the impartiality requirements in the relevant license standards,
- c) If there are personnel, settlement, equipment and management changes affecting NCAB's licensed activities and NBE evaluates these changes as potential risks,
- d) If NCAB has not notified NBE of the following changes within the period specified in the license 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 license activities and the ability to meet license 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 NCAB fails to fulfil its obligations in the agreements signed with NBE,
- h) If NCAB fails to comply with new license 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 NCAB uses its license certificate and license mark in a misleading way,
- k) If the assessment is interrupted due to reasons arising from NCAB or NCAB employees during the assessment,
- l) In case, NCAB appoints people who were proven by objective evidence to have been involved in confidence shaking activities in license 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 NCAB'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 NCAB's partners or if they take part in the conformity assessment activities as managers,
- n) If NCAB has not demonstrated the minimum practices specified in the relevant guidelines within the license cycle in scopes for which it is licensed, has not organized witness assessments, or has not carried out its licensed conformity assessment activity within the period specified in related documents,
- o) If NCAB is involved in activities such as issuing certification, license, recognition or competency within the scope of ISO/IEC 17065, ISO/IEC 17025, ISO/IEC 17021-1 and similar standards, which NBE uses as the basis for its license activities,
- p) If there are other conditions specifically mentioned in the relevant license program that require suspension.

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

### **3.7.2.2 Withdrawal of license**

NCAB's license is withdrawn under the following conditions:

- a) If the reasons for the suspension of license cannot be resolved in time or if the corrective actions are found to be insufficient,
- b) If there exists objective evidence of fraud in NCAB's conformity assessment activities and/or if it is determined that NCAB prepares false record/report/certificate and has severe and intentional negligence,

- c) If NCAB deliberately misinforms NBE, deliberately conceals information or submits false record or evidence to NBE,
- d) If NCAB deliberately violates license rules,
- e) If NCAB intentionally uses NBE license mark or i-NAF mark in scopes or areas for which it is not licensed,
- f) If NBE unilaterally cancels license agreements due to conditions such as security issues, natural disaster etc.; due to conditions that arise in a specific sector/country/region/license area that will weaken the confidence in license; due to changes in international license rules and policies or the requirements arising from the sanctions of i-NAF, IAF, ILAC,
- g) If NCAB is involved in declarations and behaviours that damage the prestige and reputation of its license or NBE,
- h) If the confidence in license disappears due to NCAB losing its competency or impartiality in conformity assessment activities,
- i) If there are other conditions specifically mentioned in the relevant license 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 license 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 license is taken by the License 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 natural 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 NCAB's address. The obligation of NCAB 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 license mark document issued from the decision date to the notification date, these documents should be withdrawn by NCAB as they are not in the license scope.

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

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

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

In the event that NCAB is faced with license suspension, reduction or withdrawal sanctions, NCAB



shall inform the affected customers about the said sanctions and their consequences without any delay. NCAB may be required to withdraw documents or reports bearing its license mark due to the suspension, reduction or withdrawal of its license.

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

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

The current information on the license of NCAB whose license is suspended, is published on NBE website under "Accredited Bodies / Categories" page. If the license 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 "license is withdrawn", if partially withdrawn then it is published as "the scope is reduced". If the withdrawal/suspension is due to the NCAB'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 licensed scopes of conformity assessment bodies, whose license scopes have been suspended, withdrawn or reduced, will be published on the NBE web page.

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

The license application of a natural conformity assessment body whose license 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 license application. However, in the new license process, the reasons for withdrawal and the previous period records are taken into consideration.

The license application of a NCAB whose license 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 natural conformity assessment body whose license 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 license certificates.

For license application of a natural conformity assessment body whose license 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.

License suspension is continued for a maximum period of 6 months. Within this period, NCAB 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 NCAB, NCAB's license is withdrawn or its scope is reduced.

After a natural conformity assessment body with suspended license 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 license/reduce its scope.

### **3.7.5 Extending License Scope**

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

Applications for extending the license scope are made similar to the initial license applications. The scope extension application is assessed similar to the initial license 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 NCAB 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 licensed 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, i-NAF, 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 NCAB 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 license scope extension request is planned, carried out and finalized in accordance with this procedure.

Since the previously signed "FR-0-02 License Agreement" with the organization is valid, a new License Agreement is not concluded.

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

##### **4.1. NCAB's OBLIGATIONS**

NCABs shall fulfil the following obligations:

- Comply with the relevant license standard, the relevant requirements in the documents published by NBE for NCABs (communiqué, regulations, guidelines, procedures, policies etc.) and the license rules set by i-NAF.
- Limit their license declaration only to the scope for which they are licensed. They should establish and implement procedures to help customers distinguish between the conformity assessment services they provide; the scope being licensed and the activity areas outside of the license scope.
- Not use its license 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 license is suspended or withdrawn, they cannot use promotional materials containing information on license and shall return all documents requested by NBE related to license.
- If the license is suspended or withdrawn, they shall immediately stop using the material showing their license status, and discontinue advertisements indicating their status as an licensed organization.
- NCAB, whose license is withdrawn or scope is reduced, shall inform its customers about the withdrawal/reduction of its license and about its consequences. It shall submit to NBE records of its activities performed for this matter.

- Prevent the use of license 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 license 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 license 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 license 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 license activities and its ability to meet license requirements
  - Changes related to the scope, representation, address and people regarding its abroad activities
- Obligated to pay the fees charged for the license in accordance with the stated time and requirements specified in "G-0-02 Service Fees Guide".
- Have an adequate professional liability insurance covering the conformity assessment activities for which they are licensed (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 licensed NCAB customers within the provisions of the relevant standard for which they are licensed 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 NCAB does not prevent NCAB 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 license belongs to the Natural conformity assessment body.
- Issuing follow the criteria of NBE in your certificates.
- Keep records of its activities performed within the scope of its license 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 license directed by NBE.
- Inform the affected customers about the suspension, reduction or withdrawal of their license 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 NCAB in order to evaluate the service provided by NCAB.

Moreover, NCABs are obliged to fulfil all obligations in the FR-0-02 License Agreement signed with NBE.

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

### **4.2.1 Licensed Subcontractor Use**

- NCAB shall learn whether the subcontractor that it intends to use in conformity assessment services is licensed and the validity period of its license, and document this information. The Natural conformity assessment body shall present these documents to NBE when necessary.
- NCAB shall clearly state the results of test, measurement or certification performed by the subcontractor in any document, report or certificate issued. NCAB is responsible for the test, measurement or certification results obtained from the subcontractor.

### **4.2.2 Non-Licensed Subcontractor Use**

- The use of a non-licensed subcontractor is only available in special cases. Before using a subcontractor, NCAB shall check and evaluate the competency of the subcontractor to be used according to the requirements of the relevant standard for which it is licensed. 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 NCAB to observe the activities performed by subcontractor. NCAB shall take measures related to this situation.

## **5 OTHER MATTERS**

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

When a special case, not defined in NBE documents, at any stage or on any subject related to the license process is encountered, the necessary evaluations are made about the matter, and the final decision is recorded with the signature of a head of license (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	NCAB	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 License 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 License Decision Draft		C	IM			
18	License Decision	D	D	C		I	
19	Preparation of the License Cycle Program	D	D	IM	C	C	
20	Signing of License Documents	IM	I	C			
21	Delivery of License Documents		I	IM		I	
22	Archiving the File		I	IM		I	

**Abbreviations:** NCAB: Natural conformity assessment body,

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

**AD: License Department**

**CO: Case Officer**

**AT: Assessment Team**

**C: Cooperation**

**RU: Records Unit**

**D: Decision**

**IM: Implementation**

**I: Information**

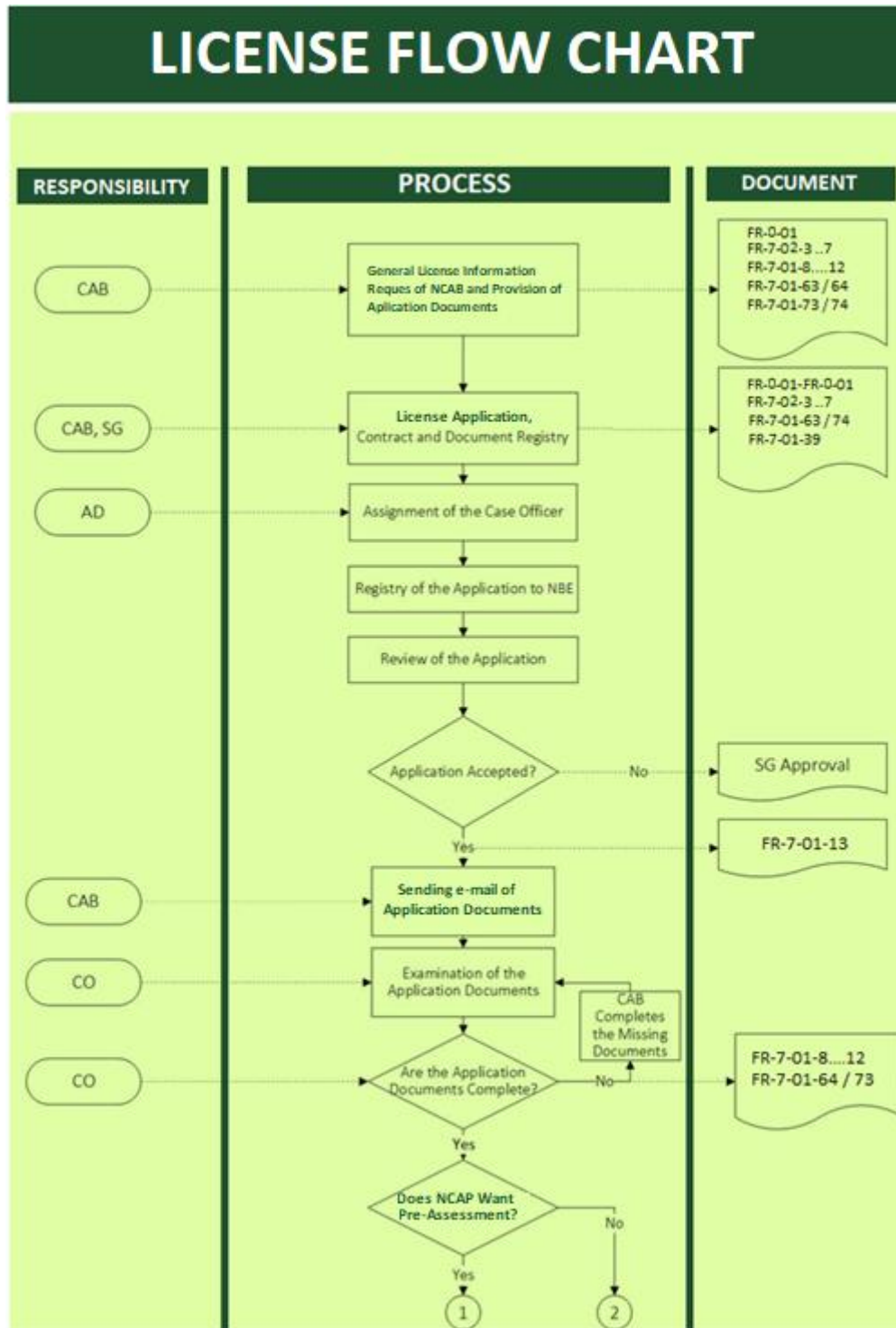
## 7 RELATED DOCUMENTS

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

### REVISION HISTORY:

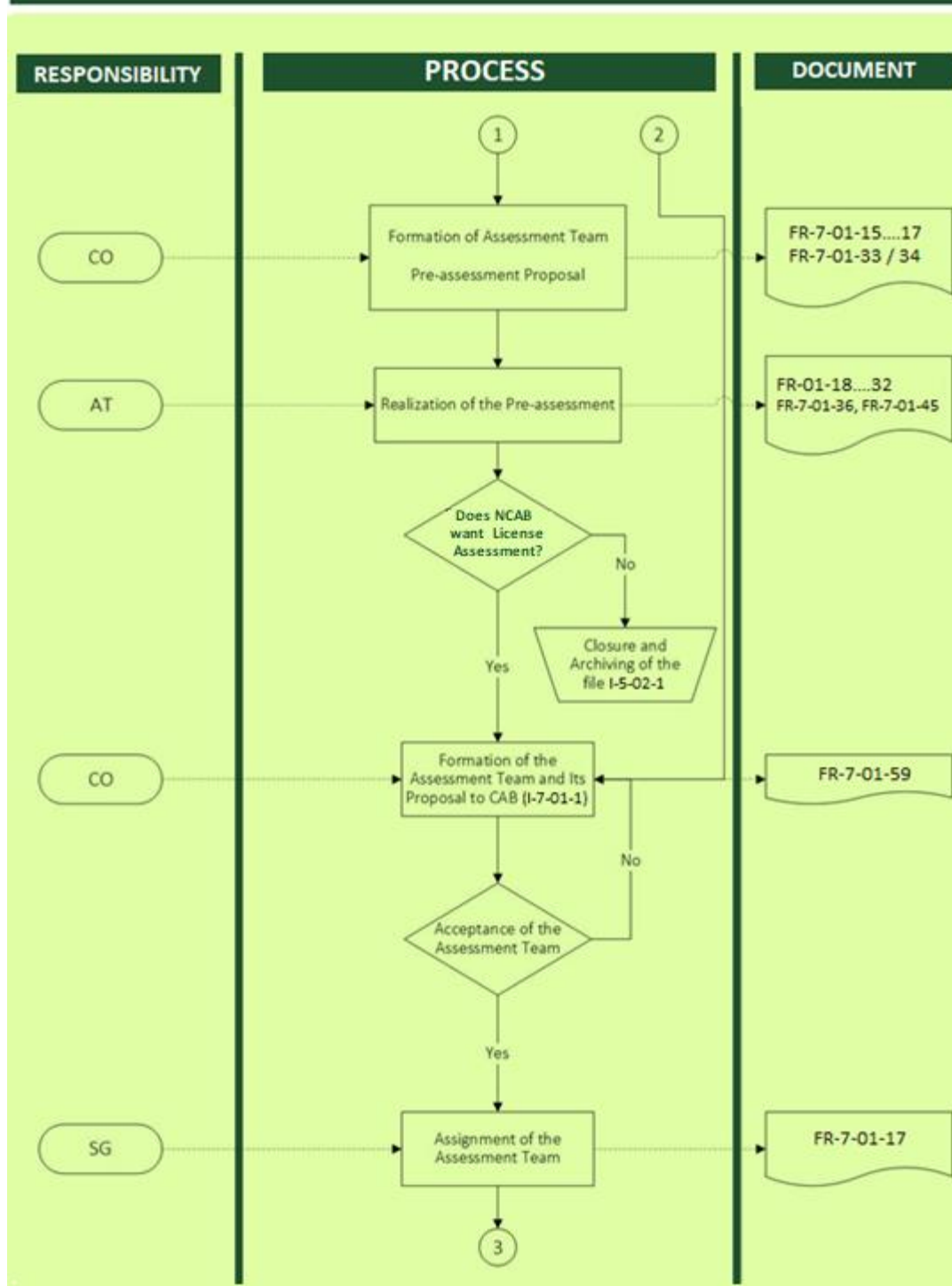
PAGE NO:	REVISION NO:	CAUSE FOR REVISION:

ANNEX A: LICENSE FLOW CHART FOR INFORMATIVE



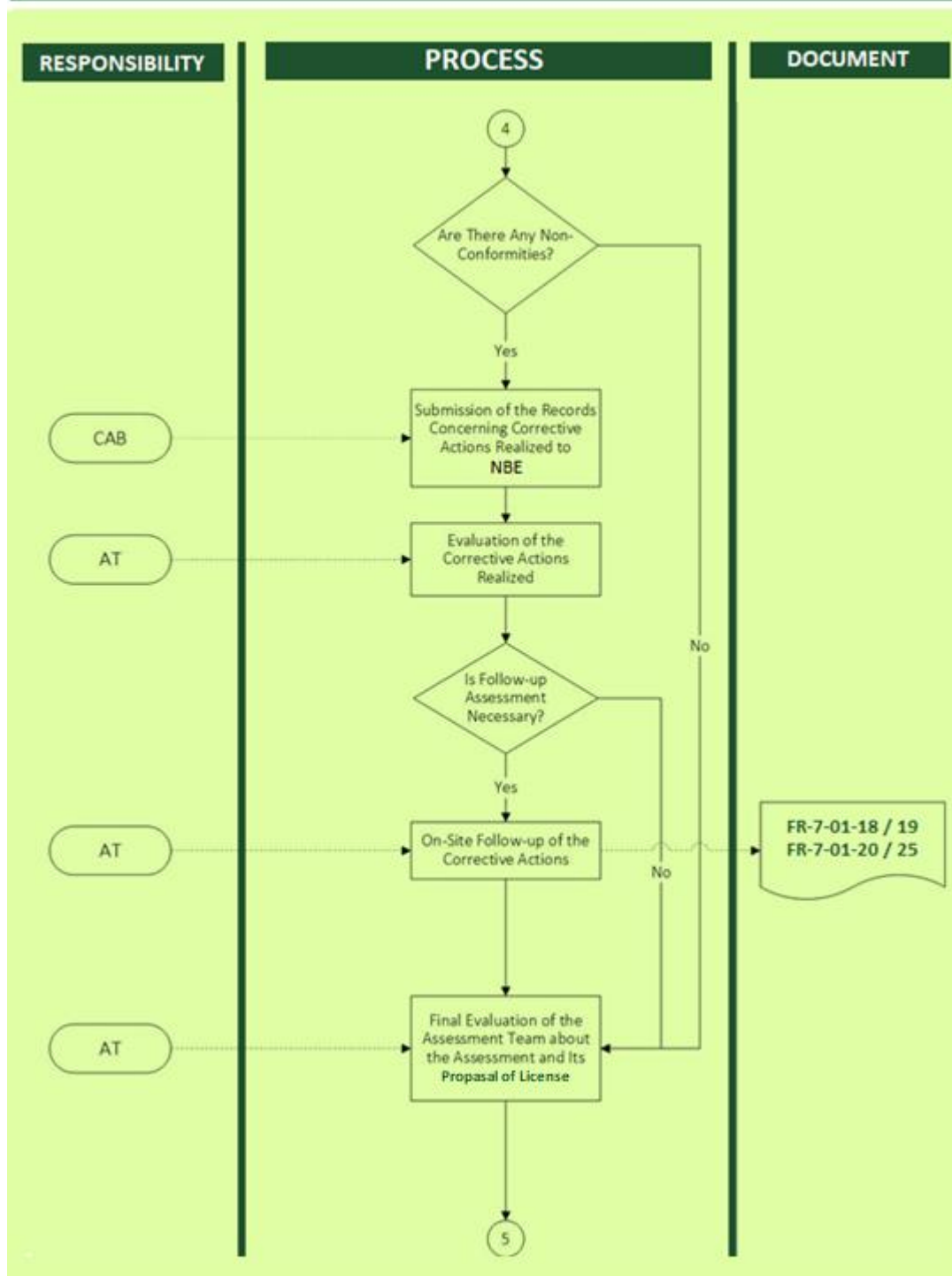


## LICENSE FLOW CHART





## LICENSE FLOW CHART



## LICENSE FLOW CHART

