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1. INTRODUCTION

This guidance sets out the rules and standards to be followed for the license of certification bodies.

A certification body that applies for license shall submit information on its operations and personnel employed by it as well as its organizational chart to NBE.

To ensure that a Certification Body is objective, it is required to assess the structure established by it, assess its competence, review its certification scheme and applicable normative documents, assess the management system of its head office (including other locations, if any), assess the testing operations when applicable as well as witness assessment.

The purpose of assessment is to verify whether the product certification body has a system that complies with the requirements of ISO/IEC 17065 and applicable guidance documents.

The information provided by the certification body to the assessors and case officers of NBE shall be strictly kept confidential and shall not be disclosed to third parties before, during and after the assessment.

The license process of a certification body is carried out in accordance with the requirements of this document and PR-0-01 Procedure for the License of Conformity Assessment Bodies.

The general rules set out in the “PR-0-01 Procedure for the License of Conformity Assessment Bodies” shall be followed. This Guideline sets out the requirements to be met in addition to the Procedure No. PR-0-01.

Additionally, the requirements set out in the applicable NBE guidelines/documents relating to license for approval or to the applied sector/product group and in the applicable i-NAF/IAF/ILAC documents shall also be satisfied in addition to this Guideline.

2. TERMS AND DESCRIPTIONS

License: Certificate permit issued for NSO-NAP Series standards.

3. LICENSE SCHEME

The application of a Conformity Assessment Body that wishes to be licensed by NBE for license operations shall include the followings:

- Products, manufacture, etc. within a product certification program accepted by i-NAF (e.g., NSO-NAP 1 Natural Product or NSO-NAP 7 Vegan-Vegetarian or NSO-NAP 3 Eco Global Label).

A body that applies to NBE for the accreditation of product certification shall demonstrate which product certification scheme is used as a base for the certification.

A product certification body is responsible for sampling, testing, assessment of manufacture processes or management system, and surveillance of certified products. The product certification body shall comply with all the requirements set out in the standards and/or regulatory documents to be used for the certification (for example, all the tests to be performed on the product). The product certification body shall also follow the procedures on the method to be used for the certified products that have been modified.

4. APPLICATIONS

When an application is received from a product certification body that is operated according to ISO/IEC 17065, the Head of NBE License will appoint a case officer responsible for the license process. In addition to the assessment set out in the “PR-0-01 Procedure for the License of Conformity Assessment Bodies – 3.1.3 Taking and reviewing an application”, the Case Officer:

- a) (Contacts the organization) to confirm the NSO-NAP Series Standard(s) requested for license by the applicant product certification body.
- b) Assesses the scope of accreditation applied by the product certification body in terms of license.

It is required when applicable that Certification Body shall be currently operating in the scopes requested in the initial license application, except for the scopes where license is a precondition for authorization, and shall have completed a full certification process for such scopes.

NBE confirms the information on the different locations where certification service is rendered, and which of them are used to perform the key operations. The key operations are usually the processes that affect the competence of a CAB such as development of policies, procedures and/or processes, review of agreements when applicable, conformity assessment planning, reviewing the results of conformity assessment activities, approval of conformity assessment and decision on the conformity assessment.

Specifically, the key operations for the license approve of a Certification Body include:

- Formulation and approval of policies,
- Development and approval of processes and/or procedures,
- Initial assessment of competence, and approval of technical personnel and subcontractors,
- Control of monitoring process of competence of personnel and subcontractors and of outputs of this process,
- Contract review including technical review of applications.
- Decision on the certification including technical review of evaluation tasks.

5. ASSESSMENT PROCESS

At least, the following risk factors are considered for the license process of certification bodies and the license cycle programme and assessments are planned based on such risk factors.

- Types and number of locations where key operations are carried out,
- Type of scopes and risk level,
- Number of employees in the relevant scope and employee turnover,
- Frequency of certification of relevant scope and the number of produced reports/certificates,

- Non-conformities and observations identified during the previous assessment and/or the scopes suggested by the assessment team for assessment,
- Changes in locations and organizational changes,
- Subcontracting and change in the details of subcontractors,
- Revised standards within the CAB's scopes,
- Amendments to internal methods, legislation and legal requirements,
- Corrective/Preventive Actions taken by the CAB for non-conforming works, and feedbacks or complaints from the related parties.

In ANNEX A context, it shall be completed by the product certification body including the information for previous year and sent NBE no later than 1 month. The assessment team shall carry out an assessment based on such information and in accordance with the relevant clauses of assessment reports.

5.1 Initial License Assessment

The scope of assessment of the Certification Body's head office is determined by the case officer by communicating with the team leader, assessor and technical experts on the basis of risk factors and foreign activities and number of locations of the organization. In the initial license assessment, an office assessment is planned including all the scopes applied for. The witness assessment is planned to sufficiently sample all the scopes applied for. The requirements for a witness assessment are described in Clause 7 of this Guideline.

If the CAB operates in locations other than the head office, the initial license assessment will also include a visit to such locations. All the locations where the CAB performs the key operations are visited during the initial license assessment. The locations where other operations are performed are also sampled and visited based on the results of risk assessment to be conducted.

The certification body shall, prior to assessment, notify NBE of products/product group for which the current assessors are competent (competence matrix).

The competence criteria established by the certification body for the personnel involved in review and/or decision shall minimum include the criteria determined for the personnel that performs the assessment function for the relevant certification activity, and additional information and experience requirements, when required.

The product certification body shall employ all of its employees (full-time and part-time employees) in accordance with its management system. In any case, the labour contract for all employees shall be in writing and comply with the types of contracts described (full-time labour contract, part-time labour contract, etc.). For the types of works that are not required by the Labour Laws to be performed, a written contract shall be made between the organization and the relevant employee to set out the conditions such as work conditions.

A contract is made directly with the employee, recorded and made available to be demonstrated to the assessment team. The certification body semi-annually obtains the SSI (related Country Social Security Institution) service document with for the full-time employees appointed to managerial functions (technical manager, quality manager, etc.). The records that have been received maximum 1 week before the date of assessment shall be submitted to the assessment team during the NBE assessment.

The Product Certification Body shall prepare, in the electronic environment, a list of certifications for all the scopes requested for accreditation in accordance with the example table provided in Annex A and TABLE 1 to this Guidance, including the auditor, type of certification, certified product, name/code of customer, and location, and send this list to NBE.

It shall also notify the potential certification locations, if applicable, based on the current work program.

5.2 License Cycle

An license cycle program is planned to represent all of the activities included in the license scope with the management system. The risk assessments described in this Guideline are considered for planning of license cycle program. The scopes of surveillance assessment and re-license assessment are identified after the risk assessment to be carried out based on the risk factors and the assessment is planned accordingly.

The locations where the organization performs its key operations are prioritised on the basis of risk factors described in this Guideline and in accordance with a risk-based approach, and are visited minimum once per license cycle (48 months) in addition to initial license assessment. The locations where other operations are performed are also sampled and visited based on the results of risk assessment to be performed.

5.2.1 Surveillance Assessment

The Certification Body shall prepare, in the electronic environment, a list of all licensed certifications within the related country at the end of the year (the end of December) including the auditor, type of certification, certified product, name/code of customer, and location, and send this list to NBE.

This list will also be prepared for the foreign activities and sent to NBE in December of each year and 3 months prior to the date of routine surveillance assessment. The potential certification locations, if applicable, should also be notified based on the current work program.

Prior to assessment conducted annually, the certification body shall use this list to generate a current Personnel Authorization and Appointment Matrix including: available auditors are competent for which certification-fields (scope) and which types of certification, years of experience, profession, starting date of employment, and position and send this matrix to NBE no later than 45 days prior to the scheduled date of assessment.

The certification body is obliged to send the lists referred to in this section to NBE in the specified periods. When it is deemed necessary, NBE may require such lists from the certification body at any other time of the year.

If the certification body fails to provide such information in timely manner, NBE may impose sanctions such as suspension, non-extension of scope, non-renewal of license, or withdrawn of license.

The lists referred to in above are attached to this Guideline as an example.

5.2.2 Re-license Assessment

The scope of re-license assessment is determined as described in PR-0-01 Procedure for the License of Conformity Assessment Bodies and the assessment is planned accordingly.

The rules relating to the lists referred to in the section “surveillance assessment” shall also apply to re-license assessments.

5.3 Use of non-accredited own laboratory and/or the laboratory under control of the certification body

A certification body shall, prior to use of non-accredited own laboratory and/or the laboratory under control (if any), verify and assess the competency of laboratory to be used in accordance with the requirements of sections 6 and 7 of ISO/IEC 17025:2017 through the competent personnel appointed to relevant scope. The results of the assessment performed shall be documented, sent to NBE, kept up-to-date at all times, and submitted to the assessment team during the assessment. NBE includes in the assessment scheme witnessing operations of CAB performed in the non-accredited own laboratory and/or the laboratory under control of the body. CAB shall take action in this respect.

6. FIELDS WITH NO ACTIVITY

An accreditation and license is essential to identify the competency and availability of an organization as well as assessment of its independency and objectivity. In this context, it is not possible to make sure sustainability of competence of the certification body as it cannot submit any records as a proof of its competency with respect to main activity areas where the certification body does not operate for a certain period of time.

In this respect, it is suggested by the assessment team, as a result of surveillance or re-license assessments, to withdraw the licensed areas based on the fact that certification body does not operate in any of the main activity areas and/or has been unable to organize a witness assessment (a demo witness assessment is not acceptable) during an license cycle. The team leader/assessor reports the fields with no activity of certification body in the assessment report in accordance with the requirements of this section, and makes recommendations for the scope excluding such areas.

7. WITNESS ASSESSMENT PLANNING

A witness assessment measures the knowledge of audit team of certification body that operates on the basis of a certification scheme as well as determines whether they understand the certification scheme, including the competency of audited manufacturer to measure the effectiveness of inspections and tests performed by such manufacturer.

A witness assessment will include assessment of inspection operations and evaluation of management systems and testing.

A Certification Body that wished to be licensed by NBE shall submit a list of audits scheduled during the planning process of NBE license assessment and the details (background) of inspectors or auditors appointed to such audits to NBE. NBE's case officer and assessment team members determine the audits to be witnessed on the basis of this list and the risk factors described in this Guidance.

The number of witness assessments may be increased by the case officer based on the extent and complexity of scopes applied for and on the diversity of certification schemes and product groups in accordance with the opinion of the assessment team.

In selecting a certification audit to be witnessed, the initial certification audit is chosen. Alternatively, a full certificate renewal audit may be chosen. The surveillance audit may be witnessed where initial certification or re-certification audit is not possible.

In a witness assessment, the assessment team will minimum assess the followings and record their observations and comments in the “FR-7-01-62 Witnessed Assessment Report Used for Product Certification”:

- Competency of employee/employees involved in site assessment,
- Compliance of competency of certification personnel with competence criteria;
- Certification personnel is provided with all the required documented procedures, methods and equipment,
- Procedures that are up-to-date;
- Certification personnel completely and properly implements the procedures (for example, there are no personal practices that do not comply with the certification body's procedure)
- While on site, the records of all observations are kept as required by the procedure,
- The records clearly describe when the certification was performed using what methods and procedures, and what was certified,
- All the findings requiring immediate and mandatory action are being reported to the customer as required while on site,
- The reports comply with the requirements of certification body, applicable i-NAF, IAF, ILAC and NBE documents, requirements of ISO/IEC 17065, and applicable legal requirements (if any),
- Compliance of outsourcing,
- Conditions of agreement made with the customer are appropriate for the certification service provided.

If NBE assessment team identifies, during a certification audit witnessed by NBE, any non-conformity of Certification Body that requires monitoring, the witness audit shall be repeated.

The Assessment Team members will be appointed to witness audits based on the scope of application of certification body that applies for license. It is considered that NBE Assessment Team members are appointed on the basis of their expertise. If there are no assessors appointed in the assessment team for the area of expertise, the team will be supported by the technical expert.

The certification body is obliged to submit the documents relating to company to be witnessed, reports of previous audit if any, control forms and documents used for the audit, audit plan, and details of audit team (including background and labour contract) to NBE assessment team no later than 1 week prior to witness assessment.

During a witness assessment, the role of NBE assessment team is to observe the certification activity for assessment of performance and competence of certification personnel. NBE assessment team shall not deliver any comment or opinion on the organization or the product to be witnessed.

If possible, NBE assessment team is expected to participate in the audit to be conducted by the certification body to observe the whole audit process (from the opening meeting to the closing meeting).

A scheduled witness assessment will be performed for a certification body that is subject to initial license assessment of NBE. Also, periodic scheduled witness assessments will be performed for the surveillance, re-license or scope extension assessment of a certification body that is being accredited for the time being.

If there are any objective complaint/complaints about the certification body, NBE may conduct an unscheduled office and/or witness assessment to carry out the necessary examination in accordance with the PR-5-07 "Complaints and Appeals Procedure". The certification body is obliged to ensure organization of such unscheduled assessment immediately upon being notified.

If possible, at the end of witness assessment, NBE assessment team will share their findings with the auditors of certification body. If not possible, then the findings for the witness audit (non-conformities, observations, etc.) will be discussed at the closing meeting of license assessment.

The followings will be considered for selection of certification body's personnel to be observed during a witness assessment:

- New employment and authorization,
- Quality and experience;
- Location;
- Legal requirements;
- Total number of certification employees employed by the certification body,
- Number of audits conducted by the certification personnel
- Never observed before

The criteria above will be considered by the certification body for generating the Personnel Authorization and Appointment Matrix.

It is avoided to conduct a witness assessment on the same customer (witnessed before) of the certification body. If this is the case, the certification body shall inform NBE before the assessment is scheduled.

8. SCOPE EXTENSION

When possible, a care is taken to conduct the assessment for scope extension of a certification body simultaneously with the surveillance assessment or re-license assessment.

The certification body shall notify NBE of its request to conduct scope extension assessment together with the surveillance assessment minimum 2 months before the date of surveillance assessment.

For the scopes requested in the application for scope extension, Required Documents for Application shall be sent to NBE to the date of application.

In case of failure to send the required documents to NBE prior to the date of application, the application for scope extension shall not be considered until the required documents are sent to NBE.

It is required when applicable that Certification Body shall be currently operating in the scopes requested in the initial license application, except for the scopes where license is a precondition for authorization, and shall have completed a full certification process for such scopes.

Upon receipt of application for scope extension, NBE will decide whether there is a need for assessing the head office and/or for witness assessment of product certification. The following factors will be considered during the decision-making process.

- Scope of current licensed accreditation,
- Competence of auditor/technical expert within the scope;
- Extent of scope,
- Locations for which cope extension is requested,
- Risk factors

9. LICENSE SCOPES

The license scopes identify the product, product groups, standards applicable to products, mandatory documents and/or legal requirements if any, and certification schemes when required.

ANNEX A

EXAMPLE LIST OF CUSTOMERS/CERTIFICATIONS TO BE COMPLETED BY CAB FOR THE SCOPES IN LICENSE								
Product (Product) Intended Use	Group /	Standard applicable to certification	Assessment type	Date of audit/assessment	Date of certification decision	Name or code of certified company	City of certification	Name and Surname of CAB Auditor
Bitter Chocolate /Food		NSO-NAP 7	Initial Certification	2018, 7 JANUARY	2018, 9 MAY	X CORP.	SKOPJE	PERSONNEL X
....		Surveillance
....		Re-
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TABLE 1

FORM TO BE COMPLETED BY THE CAB FOR ALL SCOPES

(Please complete it in Excel format)

NBE LICNSE SCOPE <i>(to be completed based on the sub-scopes)</i>			NUMBER OF IMPLEMENTED CERTIFICATIONS <i>(to be completed for the last 2 years)</i>		DETAILS OF CAB PERSONNEL APPOINTED TO RELEVANT SCOPE <i>(to be completed for all employees that are currently employed and whose employment has been terminated)</i>						
Item No	Product	Standard	Date: .../.../...	Date: .../.../...	Name/ Surname	Profession	Position	Years of Experience	Date of Employment	Date of Authorization	Date of Termination of Employment
....

Note: If there are multiple sites, complete this form individually for each site.

DATE:

AUTHORIZED PERSON'S NAME SURNAME AND SIGNATURE: