

1. PURPOSE AND SCOPE

The purpose of this document is to explain the accreditation processes of the Conformity Assessment Bodies, which operate abroad with the accreditation offered by the NBE -New Business Education Foundation(NBE) and which applied to NBE for accreditation from abroad, in accordance with “ i-NAF, IAF and ILAC “cross-frontier accreditation policies”. This document includes all Conformity Assessment Bodies accredited in the country and currently rendering service also in other countries or the Conformity Assessment Bodies applied for the accreditation from abroad.

2. DESCRIPTIONS AND ABBREVIATIONS

2.1 CAB: Conformity Assessment Bodies

2.2 i-NAF: International Natural Accreditation Forum

2.3 IAF: International Accreditation Forum

2.4 ILAC: International Laboratory Accreditation Cooperation

2.5 Important Activity: In general processes affecting the competence of the CAB, such as policy formulation, processes and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments.

In particular the processes that can be considered as important activity are classified according to accreditation field and given below

For the accreditation of inspection bodies, important activities include:

- policy formulation;
- process and/or procedure development;
- process of initial selection of inspectors and, as appropriate;
- contract review;
- planning conformity assessments;
- Review and approval of conformity assessments.

For the accreditation of product & natural product certification bodies, important activities include:

- policy formulation and approval;
- process and/or procedure development and approval;

- initial assessment of competence, and approval of technical personnel and subcontractors;
- control of the monitoring process of competence of personnel and subcontractors and its outcomes;
- contract review including technical review of applications and determining the technical requirements for certification activity in new technical areas or areas of limited sporadic activity;
- Decision on certification including technical review of evaluation tasks (see IAF GD5 - G.4.2.26).

For the accreditation of management system certification bodies, important activities include:

- policy formulation;
- process and/or procedure development;
- initial approval of auditing personnel, or control of their training;
- on-going monitoring of auditing personnel;
- application review;
- assignment of auditing personnel;
- control of surveillance or recertification audits;
- Final report review or certification decision or approval.

For the accreditation of personnel certification bodies, important activities include:

- policy formulation and approval;
- development and approval of processes and procedures necessary for the operation of the certification of persons systems, including requirements for selection and appointment of examiners;
- subcontracting a part of certification process, or replacing the approved subcontractor
- review of applications and of contractual arrangements associated with the assessment and certification of persons;
- development, evaluation and maintenance of the examination(s) and of re- certification;
- decision on certification of persons, including signing or authorization of certificates;

- development and approval of policies, processes and procedures for the resolution of appeals and complaints received from applicants, candidates, certified persons and their employers and other parties about the certification process and criteria;

- Final decision on appeals and complaints.

2.6 Local Site: Whatever the relationship with the CAB and irrespective of where it is located, the site that performs conformity assessment activities and/or those activities are managed on behalf of CAB.

2.7 Critical Locations (Site): the physical locations, whatever the composition (office, person etc) or legal relationship (contractor, franchisee etc) of such location with certification body where important activities mentioned in Clause 2.6 are conducted or controlled.

2.8 Other Activities: Certification functions not mentioned in Clause 2.6

2.9 Remote Personnel: The individuals, who may be internal or external that perform certification activities for a CAB and do not work at a fixed office location.

Descriptions placed in ISO/IEC 17000 standard are valid in addition to the above-mentioned ones.

3. PRACTICE

3.1 General Policy

NBE offers accreditation services without any commercial concerns and profit motives to satisfy the needs of national economy. It offers accreditation services in line with i-NAF Cross-Frontier Accreditation Policies and does not enter into competition with other members of i-NAF.

NBE offers accreditation services abroad on condition that:

- a country has not established an Accreditation Agency and formally instructed the NBE for the required accreditation services,
- a country does not have an Accreditation Agency and have not instructed any other Accreditation Agency for the accreditation services,
- Accreditation Agency of the related country does not offer accreditation services regarding the field for which accreditation service is demanded,
- Accreditation Agency of the related country does not have international recognition regarding the field for which the accreditation service is demanded,

Unless rejected, NBE conducts all abroad accreditation activities with the cooperation of the Local Accreditation Agencies of the countries in which the activities are conducted. Such cooperation may be put into practice as assigning assessment team members from

the country in which conformity assessment activities are conducted, carrying out joint assessment or giving permission for the observers of Local Accreditation Agency during the assessment process. In this cooperation, NBE intends to promote the MLA/MRA Agreements, support Local Accreditation Agencies of the countries, develop cooperation, and support Accreditation Agencies which have not signed MLA/MRA agreement to sign the agreement or to extend their MLA/MRA scopes.

3.2 Cross-Border Accreditation Applications

Upon receiving an accreditation application, NBE examines whether the application is in line with the cross-border accreditation conditions of the Agency. In cases where an Accreditation Agency, which is a signatory of MLA/MRA Agreement, is available in the country to which the application is made, NBE highlights the importance of MLA/MRA agreements and directs the applicant organization to apply Local Accreditation agency. If the application is in line with the conditions of offering cross-border accreditation service, NBE carries on the process. The Agency repeats such examination during surveillance and reassessment and recourse the CAB to apply Local Accreditation Agency, when possible.

NBE accepts the applications when it provides accreditation services in the applied accreditation field and the application is in line with NBE's cross frontier rules. The agency manages the process by taking the special competencies such as language, local legislation and culture into consideration, as well as the technical competence required. And for this reason, the Agency tries to develop the most appropriate approach, by taking the competences of the personnel or assessors of the local Accreditation Agency into consideration, when offering accreditation service and performing assessment.

However, in cross-border accreditation activities, NBE does not totally transfer the initial assessment and the reassessment of CAB's head office, regardless of its location, to Local Accreditation Agencies and participates in these assessments in all cases.

If a Local Accreditation Agency acquires international recognition by signing MLA/MRA Agreement during the accreditation process, NBE directs the CAB to Local Accreditation Agency to be accredited. In cases where this forwarding is not an option or cannot be realized, the process continues until accreditation renewal process. During this period, surveillance assessments are requested from Local Accreditation Agency competent within the scope of the application and recognized inter-nationally. In cases where these requests are rejected, NBE performs surveillance assessments with its own assessment teams and informs and Local Accreditation Agency about the situation.

If the local Accreditation Agency competent within the scope of the application and recognized inter-nationally accepts to perform surveillance assessments, the process is managed in line with the Clause 6.4 of TS EN ISO/IEC 17011:2017, with Local Accreditation Agency. NBE informs Local Accreditation Agency about the important points required to be concerned during the assessment process and offers all kinds of necessary information to local Accreditation Agency to ensure an efficient implementation of the assessment. Assessment process is managed by using the assessment procedures, system and reporting

process of the Local Accreditation Agency. The language used in the assessment process is determined upon the negotiation held between NBE, Local Accreditation Agency and the CAB.

The Reports are drawn up in English.

Local Accreditation Agency is informed about the accreditation decision taken by NBE regarding the assessment.

NBE informs all the parties in cases of suspension, withdrawal and termination of the accreditation regarding the accreditations abroad, by publishing the situation on web site. The Agency also informs Local Accreditation Agency about the complaints regarding the CAB in question.

NBE assesses the critical locations in other countries of accredited foreign CABs definitely before including the local site into the scope of accreditation and goes on performing the assessment every year. Assessment procedure is implemented by NBE or a Local Accreditation Agency competent within the scope of the application and recognized internationally. Assessment procedures for the locations not considered as critical location (other activities or remote personnel) are implemented in line with the principles set out in Article 3.3.

NBE performs the assessments of foreign laboratories and inspection bodies that are operating in more than one location according to the principles set out in Clause 3.3.

3.3 Accredited Activities of CABs (Accredited by NBE) in Other Countries

In the event that a CAB either Macedonia-based or where head office of CAB is in different country, already accredited or to be accredited by NBE intends to provide or is already providing conformity assessment services abroad or in a country other than where its head office is located, the following processes are implemented;

- CAB shall inform NBE within no later than 30 days, about the activity it will carry out abroad. CAB, which applies for accreditation, reports the necessary information given in the FR-5-11-3 and its responsibilities due to the accreditation during the application for the activities it will carry out abroad.
- NBE accredited CABs, before 31st of December every year, shall report the information regarding the activities carried out abroad by filing out F511-003 and uploading it into relevant field of NBE Corporate Service Portal. Having considered the information received, CAB's assessment is planned by taking into account the principles given in the ANNEX I of this guidance.
- Whether the abroad activities of certification bodies are "critical locations" is determined according to that information received. If the certification body's activity is a critical location, then the abroad local site is assessed before being included in the scope and once every year. However, the frequency of assessment of the critical locations in the accreditation cycle may be reduced or increased based upon the

principles given in the ANNEX I. The justification for this determination shall be recorded by case officer.

- The head office (in Macedonia) and all of the local sites to be included under the NBE accreditation shall operate under the same management system.
- CABs shall have all the mechanisms to substantially control the activities of local sites
- The local sites shall not offer accredited services to the local market under their own name and logo within the NBE accreditation.
- Issued certificates/reports by the local sites of NBE accredited CAB, must contain the information (name and address) of CAB's head office. Only contact information of local site can be given in abovementioned certificates/reports.
- Total responsibility lies within the accredited CAB for the conformity assessment activities performed by the local sites.
- NBE identifies the addresses of critical locations of CABs in its accreditation certifications and/or scope annexes
- If the abroad activity of certification bodies is not considered as an important activity (other activities or usage of remote personnel, conformity assessment activities in abroad conducted by personnel from head office), then based upon the number of issued certificated at least one assessment is performed in accreditation cycle and offices in those particular countries are visited.

The thresholds for performing accreditation assessment to abroad activity are given below,

For Management System Certification Bodies;

- If number of issued certificates is equal or more than 40 in one country where CAB is active then the activities are witnessed and local offices are visited in that country
- If total number of issued certificated for all countries where CAB is active in several countries, then NBE selects the country that is visited and office is assessed. NBE also may decide to visit or assess more than one country depending on the number of issued certificates,

For Product Certification Bodies;

- If number of issued certificates is equal or more than 20 for one product group in a country where CAB is active, then the activities of CAB's are witnessed and local offices in that country are visited,
- If number of issued certificates is equal or more than 40 in total in a country

where CAB is active, then the activities of CAB's are witnessed and local offices in that country are visited,

- If number of issued certificates is equal or less than 20 for one product group or below 40 in total for countries where CAB is active, then NBE may select one of a country to witness the activity of CAB and visit the local offices in accordance with ANNEX I of this guidance. NBE also may decide to witness the activities performed in more than one country,

For Certification Bodies of Persons;

- If number of issued certificates is equal or more than 200 in a country where CAB is active, then the activities of CAB's are witnessed and local offices in that country are visited,
- If number of issued certificates is less than 200 in one country, and exceeds it in total over the countries where CAB is active, NBE selects one of a country where CAB is active, then the activities are witnessed and local offices are visited. NBE may select one of a country to witness the activity of CAB and visit the local offices in accordance with ANNEX I of this guidance. NBE also may decide to witness the activities performed in more than one country,
- When the thresholds are exceeded, the CAB informs NBE in advance within a reasonable time of the next certification activity, and arrange the logistics for NBE witness assessment.

The number of withdrawn certificates are included in calculation of the thresholds and added to the number of valid issued certificates. When a CAB meets the thresholds mentioned above anytime in accreditation cycle, it would be sufficient for NBE to witness the activities of CAB in that country at least one time, and visit the local offices where exist.

- Where the abroad activity of an inspection body and a laboratory is classified as an important activity then this location performing important activity is assessed every year. However, the frequency of assessment of the critical locations in the accreditation cycle may be reduced or increased based upon the principles given in the ANNEX I. The justification for this determination shall be recorded by case officer.
- If the activity of an, inspection Bodies and a laboratory is not determined as an important activity, then multisite accreditation rules (NBE G-2-09) are applied. They are assessed at least once during the accreditation cycle.

NBE, for the purpose of assessment of abroad accredited activities of CABs defined in Clause 3.3, requests support from Local Accreditation Agency where the activities are performed, providing that it is a signatory of MLA/MRA agreements and competent within the scope of accreditation.

If this request accepted then assessment process is implemented in line with the Clause 3.2 of this guidance.

If this request mentioned above is not accepted or responded by Local Accreditation Agency then NBE performs the assessment of local sites by its own assessment team and Local Accreditation Agency accordingly.

ANNEX I

ASSESSMENT PROGRAM (INFORMATIVE DOCUMENT)

NBE develops an assessment program, covering the current accreditation period that enables it to confirm the CAB's conformity with the requirements of the relevant conformity assessment standard, within the CAB's scope of accreditation, irrespective of where certification activities are performed.

Assessment program is developed by including the activities performed by CABs and whether they are important activities or not, determination of locations where these activities are performed, information regarding remote personnel in it, by taking into consideration of following:

- a) The relationship between CAB's head office and its local sites
- b) Means of mechanisms to control the activities of local sites by head office
- c) Whether the CAB holds accreditation from the local AB,
- d) The number of local sites, undertaking certification activities, in each country,
- e) The number of remote personnel, undertaking certification activities, in each country,
- f) Where important activities are performed and managed or from where remote personnel performing important activities are managed,
- g) The range of certification activities performed, where they are performed and from where remote personnel are managed,
- h) The effectiveness of the CAB's management controls of its certification activities,
- i) The accessibility of the CAB's records,
- j) The availability of selected CAB personnel (internal and external) for interview,
- k) The number of certificates and/or reports issued through a particular local site,
- l) Schemes for which certification is granted through a particular local site,
- m) Where a local site manages other local sites or remote personnel outside of their national boundaries,
- n) Information regarding countries covered by remote personnel and how they are managed,
- o) Risk analysis involving the activities (important, other activities and remote personnel) and local sites,
- p) Complaints submitted to CAB and/or NBE,
- q) Evidences of malpractice activities.