

**National Accreditation
Agency of Ukraine**

Approved
by NAAU Decree
dated 27.12.2019 № 274-Я

NAAU MANAGEMENT SYSTEM

NAAU Cross Border Accreditation Policy

*(Approved and recommended for application by online ballot voting of the
Accreditation Council members dated 27.12.2019)*

NAAU Cross Border Accreditation Policy

1 General

1.1 This document outlines NAAU policy on accreditation rules of conformity assessment bodies (CABs) performing accredited activity outside Ukraine. The policy rules are based on the Regulation (EC) No 765/2008 (hereinafter – Regulation), documents EA-2/13 «EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members», IAF MD 12 “Accreditation assessment of conformity assessment bodies with activities in multiple countries” and ILAC-G21:09 «Cross-frontier accreditation – principles for cooperation».

1.2 The purpose of this policy is to support single accreditation principles and single conformity assessment. They are also intended to support identical terms for CABs accredited by NAAU and for CABs accredited by other partners in EA, IAF and ILAC. In addition, the policy aims at providing consistent approach for accreditation applications submitted by CABs from different countries.

1.3 This policy is applied to all CAB types with a main office located outside Ukraine and CABs with a main office in Ukraine performing conformity assessment activity in other countries.

1.4 The policy rules within the EA region and outside this region are different.

2 Terms and definitions

For the purpose of this document the following definitions apply.

2.1 EA region - the geographical region covered by countries where national accreditation bodies are EA members according to EA Articles of Association.

2.2 Local accreditation body (LAB) – the national accreditation body of the country where the accredited conformity assessment body is established. The term also refers to the accreditation body of a country where there is a site included in an accreditation granted by an accreditation body in another country.

2.3 National accreditation body (NAB) - accreditation body in a country legally appointed by the government of that country.

3 Cross border accreditation within the EA region

NAAU cross border accreditation policy within the EA region implies the following:

3.1 NAAU does not grant accreditation and does not offer accreditation services for CABs outside Ukraine in the EA region.

3.2 Exceptions from this policy include situations when Article 7 Clause 1 of the Regulation is applied. NAAU may accept application for accreditation from a CAB in the EA region, outside its own country, in any of the following situations:

(a) where the member country in which the CAB is established has decided not to establish a NAB and has not had recourse to the NAB of another country following the decision on inexpediency to maintain its NAB or to provide certain accreditation services;

(b) where NAB in the member country where CAB is established does not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;

(c) where NAB in the member country where the conformity assessment body is established has not undergone peer evaluation in respect of accreditation activities for which application for accreditation is submitted and is not an EA MLA signatory in relevant fields.

Before accepting an application for accreditation from a CAB located in another country of the EA region, NAAU shall contact LAB to confirm that conditions described in (b) and (c), apply and inform about its intentions and actions.

In case NAAU granted accreditation in another country of the EA region due to the lack of existing LAB competence to accredit the requested activity or due to the fact that LAB is not a signatory to the relevant EA MLA / BLA, NAAU informs the CAB that NAAU shall transfer accreditation of this CAB to the LAB upon change in these conditions.

3.3 In the event that LAB becomes a signatory to the EA MLA / BLA after NAAU has granted accreditation to a CAB in that country, NAAU shall take steps to transfer the accreditation to that LAB.

NAAU does not start a new accreditation cycle or does not proceed with accreditation after the LAB becomes an MLA / BLA signatory.

In the transfer process, NAAU provides the LAB with information on the scope of CAB accreditation, the last CAB assessment report, and report on complaints, if any.

3.4 Where NAAU reviews an application for accreditation submitted by a CAB with head office and sites located in different countries of the EA region, requirements to accreditation of CABs with sites situated in different countries of the EA region shall apply. This procedure is given in Chapter 5 of EA-2/13.

3.5 During accreditation of Ukrainian and foreign CABs with sites situated in different countries of the EA region, requirements to accreditation of CABs with sites situated in more than one country of the EA region given in Chapter 5 of EA-2/13 shall apply.

3.6 Cooperation between NAAU and other EA members on cross-border, multisite accreditation is carried out according to Chapter 6 of EA-2/13.

3.7 With the aim of assessing critical sites of Ukrainian CABs located in the EA region NAAU will subcontract relevant LAB provided this body is a signatory to EA MLA/BLA.

4 Cross border accreditation outside the EA region

NAAU cross border accreditation policy within the EA region implies the following:

4.1 NAAU may accept application for accreditation from a foreign CAB outside the EA region in the following cases:

- (a) There is no LAB established in the country where CAB is located;
- (b) The NAB of the country where CAB is located does not offer accreditation of conformity assessment activities specified in the application for accreditation.
- (c) The NAB of a country where CAB is located is not a signatory to the ILAC MRA or IAF MLA for the declared activities;
- (d) The CAB is part of a group who wants all their CABs to be accredited by the same NAB.

4.2 Where one or more NABs that are ILAC MRA or IAF MLA signatories for the requested scope of accreditation exist in the country (economy) of the applicant, and the applicant still elects to apply for accreditation from NAAU, NAAU takes the following steps before accepting the application:

- a) enquire if the applicant is aware of the NAB established in its country;
- b) inform the applicant of the fact that accreditation provided by a domestic accreditation body would better take account of local factors and conditions, where relevant;
- c) inform about the equivalence of the NAB's accreditations as demonstrated through the ILAC MRA or IAF MLA.
- d) inform the LAB about the receipt of application for accreditation and the scope of accreditation requested by the CAB.

NAAU accepts the application from the CAB only if the applicant persists in requiring accreditation by NAAU.

Where possible, NAAU may involve LAB representatives as assessors and / or technical experts in its assessment team. NAAU will also consult with the LAB to

take into account any accreditation requirements established in accordance with local conditions.

4.3 Where LAB is not a signatory to the relevant ILAC MRA or IAF MLA agreements or its scope does not cover the activities for which application for accreditation is submitted, NAAU will seek cooperation with the LAB in accordance with the principles and rules of cooperation in the field of cross border accreditation set out in relevant ILAC and IAF documents in order to provide LAB with the opportunity to gain experience to apply for relevant MLA/MRA signatory status.

After accepting an application for accreditation from CABs in countries where LABs are not signatories to the relevant ILAC MRA or IAF MLA, NAAU will notify the local AB about the receipt of application for accreditation. NAAU will also inform the local AB about the scope of accreditation requested by the CAB.

4.4 For accreditation of CABs located in countries without established LABs, NAAU will proceed with such applications for accreditation without additional cross border rules.

4.5 NAAU may subcontract a LAB for the assessment of CABs located in other countries and witnessing of their activities in case this LAB is signatory to ILAC MRA or IAF MLA for relevant activities. In case this LAB is not a signatory to relevant agreements, NAAU performs the assessment, where possible, in cooperation with the LAB. Assessment of a new site added to the list of critical CAB locations is performed by the NAAU assessment team with possible involvement of local assessors and experts.

4.6 NAAU pays particular attention to the situation when a CAB was accredited before by the LAB or other AB or submitted its application for such accreditation, but did not get such accreditation

4.7 While considering the possibility of granting accreditation to a CAB outside Ukraine and EA region, NAAU takes into account general security conditions in a country where CAB is located with regard to official recommendations of the Ministry of Foreign Affairs of Ukraine.

5 Accreditation of conformity assessment bodies with sites performing activities in more than one country

5.1 At least once a year CABs accredited by NAAU shall inform NAAU about countries where they perform conformity assessment activity accredited by NAAU. NAAU registers such countries for each CAB.

5.2 For witnessing of activities carried out by Ukrainian CABs outside Ukraine within the EA region NAAU involves, where possible, relevant LAB by subcontract in the case this LAB is a signatory to EA MLA/BLA with relevant scope.

5.3 For Ukrainian CABs, which perform activities on sites situated in other countries and seek accreditation to cover the activities for all of its sites, NAAU fulfils the requirements of EA2/13 and meets the following conditions:

- 1) Multisite accreditation is possible only provided all activities are within the responsibility of one legal entity.
- 2) The information on accreditation of Ukrainian CABs provided by NAAU contains only the name of the legal entity responsible for accredited conformity assessment activities carried out at all sites of this CAB.
- 3) All sites covered by the CAB accreditation shall operate under the same management and the same quality management system.
- 4) The registered legal entity of the CAB shall demonstrate its responsibility for the activities performed by the local sites that forms part of the scope of accreditation, control and monitor the activities in all its sites.
- 5) The local CAB sites may offer conformity assessment activities to the local market only on behalf of the accredited CAB. The certificates and reports issued under the accreditation granted by NAAU shall contain the name and address of the accredited legal entity without reference to the name or logo of any local CAB.
- 6) The principles of multisite cross border accreditation of CABs require the conformity assessment body and the sites included in the multisite accreditation to abide by the following:
 - 7) The CAB shall fully cooperate with NAAU;
 - 8) Local sites cannot reject the participation of the LAB in the assessment, reassessment and surveillance processes in case this was determined by NAAU.
 - 9) NAAU may subcontract LABs for an assessment of CAB sites located in other countries and witnessing of their activities, if it is a signatory to EA MLA, ILAC MRA or IAF MLA for the relevant activities. However, assessment of new site, which is added to the list of critical CAB locations, will be carried out by NAAU assessment team with the possible involvement of local assessors and experts. The assessment of sites located in other countries is carried out with regard to the requirements of clauses 3.2-3.4 of IAF MD12.
 - 10) Where a site is removed from the list of sites covered by accreditation, it is necessary to determine the impact on the status of the entire scope of accreditation.

1.1 11) NAAU develops a CAB assessment program that covers the activities, locations, and personnel to be assessed, taking into account the risk associated with CAB activities. Where necessary, NAAU undertakes review of the risk with input from the LAB(s), utilizing their knowledge and expertise of their respective markets and regulations. Specific considerations to take into account when establishing the approach include, but are not limited to:

- local regulations;
- knowledge of the local market;
- volume of work carried out by the CAB at different locations;
- impact of the CAB activities conducted under NAAU accreditation on the local CAB market;

- history of assessment results of the conformity assessment activity and/or location;
- level of control and monitoring demonstrated by the CAB for each given location
- whether or not the local office holds accreditation from the LAB for the same or different scope and/or utilises the same or different conformity assessment processes and/or operated the same or different management system
- where location holds accreditation by the LAB, the cycle/frequency of the LAB assessment shall be utilised as far as possible

6 Subcontracting and cooperation with other accreditation bodies

6.1. When NAAU provides accreditation services in another country, it provides the required competence to carry out accreditation taking into account factors such as language, local laws and regulations, culture, etc. in addition to common technical competence requirements. NAAU cooperates with the LAB to obtain the required information.

6.2. If another AB performs accreditation in Ukraine, NAAU will provide maximum assistance in providing access to information and competency resources at the request of another AB. If NAAU does not participate in the assessment carried out by another AB, it may observe the assessment carried out by another AB.

6.3. Where NAAU performs the assessment in another country, the LAB may witness the assessment by NAAU. If the CAB does not object, NAAU will support it.

6.4. NAAU shall ensure availability of documented arrangements with customers that allow the use of relevant LABs to assess conformity assessment activities performed in their countries, provided these LABs are signatories to relevant EA MLA and grant accreditation for the relevant conformity assessment activities.

6.5 Within cross-border accreditation NAAU may involve accreditation personnel from other NABs to the assessment teams. In case these NABs are not signatories to relevant recognition arrangements NAAU is responsible for teaching, training and monitoring of this accreditation personnel. assessors or experts. In case ABs are signatories to relevant recognition arrangements, NAAU determines certain tasks for such persons on the basis of their competence according to the information submitted by other ABs.

6.6 NAAU may subcontract other NAB to perform part of CAB assessment.

In the case of subcontracting the following rules are applied:

1. In case NAAU subcontracts the assessment to the local AB and uses its assessment results, NAAU shall have confidence in the fact that this AB performed works according to the requirements of ISO/IEC 17011.
2. If NAAU addresses other AB to perform the assessment on behalf of NAAU on the subcontract basis, the AB uses its own procedures, systems and reports

for the assessment and will not be obliged to use NAAU assessment procedures.

3. NAAU has a right to point out specific areas or assessment aspects which it requires other AB to check during the assessment and reporting. Other AB shall provide compliance with the specified NAAU requirements. NAAU provides the other AB with all necessary information to ensure efficient assessment.
4. Language to be used during the assessment shall be agreed in advance. The reporting language for NAAU may be English or Ukrainian.
5. The subcontracting agreement with the other AB will be concluded to determine terms and conditions in detail.

6.7 In case NAAU withdraws or suspends accreditation of CAB, which is also accredited by the LAB, NAAU will inform the LAB about it.

6.8 Every time when NAAU is informed by the other NAB about withdrawal or suspension of accreditation for the CAB, which is also accredited by NAAU, NAAU performs review. The purpose of this review is to decide in which way such withdrawal or suspension affects accreditation granted by NAAU. NAAU informs the other NAB about results of this review.

The validity period of this policy is not limited.

This policy is revised when necessary.