



Support for the National Accreditation Centre MOLDAC
to successfully undergo the EA peer evaluation process
Twinning Project MD14/ENPI/TR/20



ACTIVITY 1.4

TRAININGS OF MOLDAC PERSONNEL INVOLVED IN
ACCREDITATION PROCESS INCLUDING THE ISSUE REGARDING THE
REQUIREMENTS OF THE NEW VERSIONS OF THE EA, IAF, ILAC
DOCUMENTS

EA-2/13 M: 2012

Giulia SURIANI



This project is funded by
The European Union

Slide 1 of XX





EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

TERMINOLOGY

1.1 EA region: The geographical region covered by countries of the EA members, the countries which have been formally identified by the EU or EFTA as candidate countries for membership in the EU or EFTA and countries of accreditation bodies with which EA has signed a bilateral agreement is referred to as the “EA region”.

1.2 Foreign accreditation body (FAB): “Foreign Accreditation Body” refers to an Accreditation Body when it accredits a conformity assessment body which has sites with key activities in another country than the country of the accreditation body accrediting it.





EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

TERMINOLOGY

1.3 Local accreditation body (LAB): The term “Local Accreditation Body” refers to 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.

1.4 National accreditation body (NAB): The term “National Accreditation Body” refers to the **accreditation body in a country legally appointed by the government of that country**.

[Example of a Cross Frontier multisite where FAB is ACCREDIA and LABs are ENAC and UKAS](#)





EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§2.SCOPE

2.1 This document describes **EA's policy** and procedures for cooperation between national accreditation bodies **when accreditation is provided by a national accreditation body, to a conformity assessment body which has sites in another country** (also called multisite accreditation) **in the EA region** or has key activities in another country in the EA region. This document also describes the procedures to be followed by EA members concerning accreditation in another country **under the conditions of European Regulation (EC) 765/2008 article 6 part 3 (also called cross border accreditation).**





Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§3. General Policy

3.1 It is EA Policy that an **EA member shall not promote or market its accreditation services in the country of another accreditation body in the EA region.**

3.2 EA members shall not compete with other EA members in the EA region

3.3 EA members shall only consider providing accreditation services to conformity assessment bodies in countries or economies of other EA members **in the cases defined in the European Regulation (EC) 765/2008 article 6 part 3.** This shall also apply to countries of accreditation bodies with which EA has a bilateral agreement.

3.4 This policy **does not address conformity assessment body operations in foreign countries when the activity is not classified as a key activity.**

3.5 [...] when a national accreditation body accredits a conformity assessment body in its own country for a foreign national regulation, **the accrediting national accreditation body shall ask for assessment support from the national accreditation body of the country issuing the regulation in order to make sure that it has full information on the implementation of that regulation.**



This project is funded by
The European Union

Slide 5 of XX





EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation Between EA Members

§4. Cooperation Requirements for Cross Border Accreditation

4.1 Where it is permissible and an EA member is going to accredit a conformity assessment body in a foreign country for whatever reason, whether this is in or outside the EA region, **it shall inform the Local Accreditation Body of its intentions and keep it informed of its actions.** The **Foreign Accreditation Body** shall take all necessary steps to **cooperate as much as possible with the Local Accreditation Body.**



This project is funded by
The European Union

Slide 6 of XX





EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation Between EA Members

§4. Cooperation Requirements for Cross Border Accreditation

FAB shall inform LAB of its intentions and keep it informed of its actions. **COOPERATION!**

Examples of emails exchange among ACCREDIA (FAB) and CYS-CYSAB (LAB) in 2011

- [ACCREDIA informs CYS-CYSAB about the on-site assessment](#)
- [CYS-CYSAB confirms his participation](#)
- [ACCREDIA informs the Laboratory about the participation of the LAB](#)
- [The Laboratory accepts members of LAB as Observer](#)





Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



ACCREDIA Policy: PG-12 - *Procedure for the application of "Cross Frontier" accreditation -*

4.1 Initial examination of geographical area

It is necessary to evaluate carefully, during **examination of the application for accreditation and initial contacts**, factors **regarding the geographical area of the Body asking for information for accreditation**. This regards both the registered **head office of the CAB** (which, independently of its legal nature, has the responsibility for all certifications) **and also the position of local or branch locations**

[ACCREDIA's application form DA-00 rev.07](#)



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation Between EA Members

§4. Cooperation Requirements for Cross Border Accreditation

4.2 An EA member National Accreditation Body is permitted to provide accreditation to conformity assessment bodies in the EA region, outside its own country, **only in the following situations:**

- (a) where the country in which the conformity assessment body is established has decided **not to establish a national accreditation body** and **has not had recourse to the national accreditation body of another country;**
- (b) where the **national accreditation body in the country** where the conformity assessment body is established **does not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;**
- (c) where the national accreditation body in the country where the conformity assessment body is established has **not successfully undergone peer evaluation** in respect of the conformity assessment activities for which accreditation is sought. -> **This was the case of the previous example; in 2011 CYS-CYSAB was not yet signatory for EA MLA nor ILAC MRA for Calibration** <http://ilac.org/signatory-search/>



This project is funded by
The European Union

Slide 9 of XX





Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation Between EA Members

§4. Cooperation Requirements for Cross Border Accreditation

4.4 Outside the EA region, each EA member may have its own policy concerning accreditation in other countries.

4.5 Before accepting an application within the conditions described in 4.2 (b) and (c), the **Foreign AB shall confirm with the Local AB that one of these conditions apply.**

4.6 When an EA member, in the situations described in 4.2 and 4.3, is requested to provide accreditation services in another country in the EA region, it should pay most attention to **using the specific competence needed, taking into account factors such as language, local laws and regulations, culture, etc. in addition to the normal technical competence requirements.** [...] The Local AB shall facilitate the access of the Foreign AB to this information and to competence resources if and when available. **The preferred EA approach to ensure access to relevant competence is to use resources of the Local AB as much as possible.**

4.7 When the conditions under 4.2 or 4.3 have changed and at each re-assessment the Foreign AB shall **confirm that previously accepted justifications and conditions for providing cross border accreditation still apply.** **The records of these justifications shall be retained and be subject to evaluation during EA Peer Evaluations.**



This project is funded by
The European Union

Slide 10 of XX





Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§4. Cooperation Requirements for Cross Border Accreditation

4.8 In the exceptional case where the Local AB and the Foreign AB have **not been able to establish cooperation** according to EA procedures, **they will both keep records of the reason why they have not been able to cooperate**. This information shall be documented, retained and provided on request.

4.9 An EA member shall ensure that the **contracts with its clients, include clauses that enable the Local ABs to be used for assessments of conformity assessment activities performed in other countries without the need for prior approval or communication, if the Local AB is a signatory of the relevant EA MLA and provides accreditation for the relevant conformity assessment activity**. Such a clause shall also make sure that the Foreign AB and the Local AB can share information with each other concerning the conformity assessment body.

*ACCREDIA-DT Policy is described in **RG-13 rev.5**:*

“If ACCREDIA-DT receives an application from a Laboratory operating abroad, Regulation (EC) 765/2008 and ACCREDIA document PG-12 “Policy for the application of Cross Frontier accreditation” become applicable, as well as the relevant EA and ILAC documents”.



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§5. Cooperation Requirements for multisite accreditation for CABs with sites in more than one country in the EA region

5.1 Where a conformity assessment body with a **Head Office established in one country** also **has local sites situated in other countries of the EA region**, it may seek an accreditation to cover the activities for all of its sites (also called multisite accreditation in this document), **with the AB of the country where its head office is established.**

[Example of ACCREDIA's multisite in more than one country in the EA region](#)

Interpretation of terminology used in clause 5.1 and Guidelines to assessment focus are given in **EA-2/13 M S1: 2013**



This project is funded by
The European Union

Slide 12 of XX





Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§5. Cooperation Requirements for multisite accreditation for CABs with sites in more than one country in the EA region

5.2 The principles of multisite cross border accreditation require the conformity assessment
body and the sites included in the multisite accreditation to abide by the following.

- 1. The multisite conformity assessment body shall fully cooperate with the NABs involved.**
- 2. Local sites cannot reject the participation of the Local AB in the assessment, reassessment
and surveillance processes.**

When accepting applications EA members shall make sure that the applicant is made aware of
and accepts these conditions.

5.3 [...] The NAB shall require that the conformity assessment body shall state that **the head
office takes full operational, financial and legal responsibility for activities performed by the
local site, in its contracts with its customers**



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§5. Cooperation Requirements for multisite accreditation for CABs with sites in more than one country in the EA region

ACCREDIA Policy for the application of Cross Frontier accreditation PG-12 rev.2:

In case b) (CAB with head office, legally recognised in Italy with
secondary sites in various geographical areas)

If a location to be audited is abroad **it will be necessary to collaborate with the local AB / NAB, either directly or subcontracting the activity to such Body as long as it has MLA recognition, or with the presence of a local expert** if deemed necessary depending upon the accreditation scheme, (e.g. EMS).



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation Between EA Members

§5. Cooperation Requirements for multisite accreditation for CABs with sites in more than one country in the EA region

5.4 If a local site, as referred to in 5.1.6 **is removed** from the list of local sites on the accreditation certificate, for lack of fulfilment of requirements, **the impact on the status of the full scope of accreditation shall be determined**. In this regard particular consideration shall be given to the requirements on the head office for controlling activities (5.1.3) and for taking responsibility for performed activities (5.1.5).

5.5 A site where key activities are performed **shall** during initial assessment **be visited and assessed, before it can be covered under the multisite accreditation**.

5.6 The programme for follow-up assessment (surveillance and reassessment) of sites where key activities are performed **shall normally take place at the same frequency as at an equivalent single site conformity assessment body**. The frequency of surveillance visits may be reduced or increased based upon a risk assessment undertaken by the accrediting EA member. Justifications for a reduction or increase in frequency shall be recorded for each case by the EA members and be subject to evaluation during EA Peer Evaluations.



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation Between EA Members

§6. Cooperation procedure between EA members on cross border, multisite accreditation

In all circumstances where a Foreign AB knows that it will need the cooperation of a Local AB for performing assessments, it shall report this as soon as possible. **The Foreign AB shall inform the Local AB of its needs in the coming calendar year at the latest three months before the beginning of the calendar year.** At this stage, the exact scope of the assessment may not be clear but such early information is essential to allow for resource planning by the Local AB. The scope of the assessment will have to be reported to the Local AB at the latest three months before the due date of the assessment. If these general rules are followed regularly, any exceptions will be easier for the Local AB to handle.

[ACCREDIA case study1: information to the local AB](#)

6.1 Cooperation between Local and Foreign AB can only function efficiently if both parties are committed to responding to all requests in a **timely manner and announce at an early stage any difficulties they may encounter.**



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§6. Cooperation procedure between EA members on cross border, multisite accreditation

6.2 When an EA member performs assessments for another EA member, **ISO/IEC 17011 clause 7.4.1 applies.** [..]

ISO/IEC 17011

7.4.1 [..] The accreditation body shall not subcontract the decision-making. If the accreditation body subcontracts assessments, it shall have a policy describing the conditions under which subcontracting may take place. A properly documented agreement covering the arrangements, including confidentiality and conflict of interest, shall be drawn up.

- [Example of Memorandum of Understanding \(Model\) \(ACCREDIA PG-12 Annex 1\)](#)
- [Example of BILATERAL AGREEMENT Model FOR SUBCONTRACTING \(ACCREDIA PG-12 Annex 2\)](#)

ACCREDIA case study: bilateral agreement for subcontracting assessments



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§6. Cooperation procedure between EA members on cross border, multisite accreditation

6.3 When a Local Accreditation Body agrees to undertake assessments on behalf of a Foreign Accreditation Body, **the Local Accreditation Body may use its own accreditation assessment procedures, systems and reports and shall not be required to use the assessment procedures, systems or reports of the Foreign Accreditation Body.** The report shall, in any case, contain sufficient information about the findings and supporting **evidence to ensure that a sound decision can be taken by the Foreign Accreditation Body.** The Foreign Accreditation Body shall specify the scope of the requested assessment in such detail that the risk for misunderstanding is minimized. The Local Accreditation Body shall ensure that it follows the instructions of the Foreign Accreditation Body in such matters. The Foreign Accreditation Body shall provide the Local Accreditation Body with all information needed to ensure effective assessment within the agreed time frame according to the agreement signed. **The Foreign Accreditation Body shall inform the Local Accreditation Body of the outcome of the accreditation decision when it is made.**

[ACCREDIA case study1: example of local AB reports accepted by ACCREDIA](#)



This project is funded by
The European Union

Slide 18 of XX





Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§6. Cooperation procedure between EA members on cross border, multisite accreditation

6.4 The language to be used during the assessment and in reports **shall be agreed** between the accreditation bodies involved and the conformity assessment body in advance of the assessment. **The default language shall be English.**

6.5 The approach to the cooperation between the Local Accreditation Body and the Foreign Accreditation Body will differ depending on the specific circumstances of the conformity assessment body. **For cross border multisite accreditation, there are 3 possible cases:**

- 1-** The accredited conformity assessment body has a site with key activities in a country where the site is itself a CAB accredited by the Local AB for an identical scope
- 2-** The accredited conformity assessment body has a site with key activities in a country where the site is itself a CAB accredited by the Local AB for a different scope
- 3-** The accredited conformity assessment body has a site with key activities in a country where the site is not at all accredited as a CAB by the Local AB



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§6. Cooperation procedure between EA members on cross border, multisite accreditation

ACCREDIA Policy for the application of Cross Frontier accreditation PG-12 rev.2:

The following situations are likely to occur:

- a) **CAB with head office, legally recognized abroad with secondary sites, if such exist, in various geographical areas, amongst which Italy.**
- b) **CAB with head office, legally recognized in Italy, with secondary sites in various geographical areas. -> Study Case 1**
- c) **Secondary site in Italy of an accredited CAB already accredited by a different accreditation Body in another state. -> Study Case 2**



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§6. Cooperation procedure between EA members on cross border, multisite accreditation

6.6 The FAB shall notify the LAB of its decision to suspend or terminate an accredited activity performed in the foreign site.

Equally the LAB shall notify the FAB of its decision to suspend or terminate an accredited activity of a site if that site holds an independent local accreditation through the LAB

It is important that this information is communicated immediately after the decision has been taken and that each EA member considers if the suspension/termination affects any accreditations it provides.

6.7 The FAB and the LAB shall **exchange any valid and relevant information**, such as outcomes of assessments, complaints, market feedback, etc, concerning conformity assessment bodies where they are both involved.

6.8 EA member accreditation bodies shall appoint at least one contact point for communications concerning cross border activities.

ACCREDIA Contact person for cross frontier accreditation is Sara Vitali s.vitali@accredia.it



This project is funded by
The European Union



Support for the National Accreditation Centre MOLDAC to successfully undergo the EA peer evaluation process

Twinning Project MD14/ENPI/TR/20



EA 2/13 M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation
Between EA Members

§7. Transfer to the local accreditation body

7.3 If a FAB has granted accreditations in another country in the EA region due to the lack of competence of the LAB or due to the fact that the LAB is not a signatory of the relevant MLA agreement, **conformity assessment bodies will be informed of the fact that they shall have to change to the LAB as soon as these conditions change.** In these situations the principles of this document apply. **The Foreign Accreditation Body shall not renew such an accreditation or extend the accreditation after the Local Accreditation Body enters the MLA.**

[Example1 of transfer of accreditation](#)

[Example 2 of transfer of accreditation](#)



This project is funded by
The European Union



CASE STUDIES

CASE STUDY 1: Cooperation between ACCREDIA (FAB) and UKAS (LAB) and ENAC (LAB) on cross border multisite accreditation

CASE STUDY 2: Cooperation between ACCREDIA (LAB) and DAkkS (FAB) on cross border multisite accreditation

