



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



ACTIVITY1.3

TRAINING SESSIONS FOLLOWING THE FINDINGS FROM PREVIOUS ACTIVITIES

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SCOPE OF DOCUMENT

The purpose of this document is to provide a tool for the evaluation and report preparation process, allowing an AB under evaluation to present information, facts and figures about its performance and to provide a framework for the evaluation team to present confirmation of this information within the evaluation report. This document indicates where information is needed to provide a complete description and full picture of the operations of the AB. Thus, facts and the results of the implementation of policies should be reported, supported by evidence gathered by the evaluation process.





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4. ACCREDITATION BODY

4.1 Legal Responsibility

Governmental ABs shall describe the Ministries and/or Departments of which it is part, describe its legal status and structure as formally documented by government, and reference the Acts, Regulations or other statutory instruments that describe the authority under which the AB operates.

Non-Governmental ABs shall describe their legal status under the local laws; whether they are not-for-profit or profit-returning; who the owners are; and the documents that prescribe the authority under which they operate.

Non-Governmental ABs shall also describe their relationship with Government, such as any legal or contractual arrangements, memoranda of understanding, recognition by regulatory authorities, etc.





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In case the accreditation body is a separate legal entity within or owned by a larger body, the related bodies shall be identified (see 4.3.7). Multi-economy ABs (as defined in the S2-ILAC Rules) shall describe their relationship with the relevant economies' governments and where applicable, Regional Group.

4.2 Structure

4.2.1 A document (e.g. an organization chart) describing the AB structure and place within a larger entity, if applicable, shall be provided as Appendices. (See clause 4.2.8)

4.2.2 Authority and responsibility for decisions

4.2.3 Description of legal status (see section 4.1)

4.2.4 Document duties, responsibilities and authorities of top management





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4.2.5 Identification of Top Management

Names of top management shall be provided, i.e. who has overall authority and responsibility and who has been assigned day-to-day management responsibilities (for each of the items under 4.2.5 and 5.2.3, and where authorities and responsibilities may be held by more than one individual).

Evidences:

The AB must prove that the top management having overall authority and responsibility for each of the following:

- a) development of policies relating to the operation of the accreditation body;
- b) supervision of the implementation of the policies and procedures;
- c) supervision of the finances of the accreditation body;
- d) decisions on accreditation;
- e) contractual arrangements;
- f) delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management





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4.2.6 Access to Expertise for Advising the AB

The AB shall describe the mechanisms by which it accesses its expertise. This should be a description focused on the expertise to provide policy advice to the AB.

The AB shall describe how it identifies the need for technical expertise; how this expertise is recruited, and how it is managed and used in establishing accreditation criteria (for both existing and new accreditation programs) and advising the AB. The commentary should provide some indication of the expertise available to advise the AB in type, range and volume of the accreditation services offered.

If applicable, a list of the committees currently in place and a brief overview of the role that they play shall also be described.





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4.2.7 Rule for appointment, terms of reference and operation of committees

Evidences: eg: Regulation for the functioning of the Institutional Bodies, Statute, etc...

4.2.8 Entire structure documented, showing lines of authority and responsibility

Evidences:

Organization chart

4.3 Impartiality

4.3.1 Safeguard objectivity and impartiality

Evidences:

The safeguarding of objectivity and impartiality can be ensure through:

- risk analysis;
- economic independence;
- conditions for accreditation;
- performance of assessments;
- decisions on accreditation.





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4.3.2 Structure to provide opportunity for effective involvement by interested parties

The AB shall provide an explanation for why the structure is considered to provide effective involvement by interested parties in a balanced way.

Evidences:

Rules and duties of ACCREDITATION COUNCIL for MOLDAC.



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4.3.3 Non-discriminatory and accessible

4.3.4 Free from undue pressures

Evidences: the AB must prove to be commercially and financially independent from any external influence of any kind.

4.3.5 Competent accreditation decisions

Evidences: the AB must prove that each decisions on accreditation is taken by competent personnel and different from the persons who carried out the assessments.



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4.3.6 Provision of other services which affect impartiality

The AB shall provide a description of all other activities it is involved in outside of accreditation.

Evidences: the activities carried out by the AB in addition to accreditation must be analyzed in the document Risk Analysis ISO/IEC 17011, as follows:

- holding information meetings with CABs and assisting them in identifying opportunities for improvement during initial and surveillance assessments phases;
- issuing of technical publications to clarify specific topics and development of other cultural activities;
- arranging and participating as a lecturer in conferences, workshops, training /orientation/ educational courses, provided that these courses confine themselves to the provision of generic information and advice which is freely available in the public domain;
- dissemination of information on the European and International accreditation organizations and related activities;
- assisting other accreditation body on behalf of EA contract.





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4.3.7 Activities of related bodies and identification and analysis of relationship with related bodies

The AB shall identify the types of related bodies, the types of risk and how the AB has mitigated the potential for conflict of interest.

Evidences:

The AB in order to develop and maintain principles and policies to safeguard impartiality and objectivity, shall analyze its risks both within its structure and against behavior which may be adopted by Related Bodies.

Usually, two fundamental lines of action occur internally within a NAB:

- 1) the policy objectives of the NAB and subsequent verification of the implementation;*
- 2) the operative policy, whose final objective is the decision regarding accreditation, extension, renewal and the imposition of sanctions.*

***What is MOLDAC's approach with regard to these two lines of approach?
Regarding the safeguarding of impartiality and objectivity, which are the events and the risk levels identified by Moldac?***





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4.3.7 Activities of related bodies and identification and analysis of relationship with related bodies

The Risk Analysis developed by ACCREDIA considers the occurrences which could involve damages, regarding the aspects of impartiality and objectivity to be safeguarded, in particular:

Events unfavourable to objectivity;
Events unfavourable to impartiality;
Unfavourable events due to related bodies

The analysis allows assigning different levels of risks: **low risks** (anyway **under control**), **medium (to be control)**, high risk (**that require immediate intervention**). Situations with **high risks** are not envisaged in ACCREDIA risk analysis.





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4.4 Confidentiality

Evidences:

The AB shall demonstrate to have the adequate arrangements to safeguard the confidentiality of the information obtained in the accreditation process, for all personnel involved in the accreditation process including internal staff, committees and external organizations and/or individuals acting on its behalf.

4.5 Liability and Financing

4.5.1 Arrangements to cover liabilities

Evidences: the AB must prove to have an agreement with an insurance company on liability insurance for civil liability, for the legal protection for use in case of the disputes, and covering all internal and external personnel and the members of institutional Bodies, for all accreditation activities.

The criteria for the calculation of the ceiling are, for example as follows:

- The legal constraints imposed by the national laws;
- The number of accreditation schemes (eg: management systems, product, personnel, inspection, accreditation in the notified area, testing and calibration laboratories, etc.);
- The number of accredited CABs;
- The volume of activities and the revenue gained by the CABs.





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4.5.2 Adequate financial resources

The AB shall describe how it receives funds for undertaking its accreditation and other activities, and provide an overall indication of how these funds are allocated.

Evidences: *the AB must demonstrate what are its assets*





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4.6 Accreditation Activity

4.6.1/4.6.2 Normative documents, application and guidance documents

The information provided by the AB shall contain (but should not be limited to) the following:

- *The scopes of the Arrangement in which the AB accredits;*
- *The types of accreditation programs offered, i.e. the type of CAB activity it accredits, and when these programs were launched;*
- *Which accreditation activities (particularly fields) the AB considers to be part of the Arrangement, and which fields are not;*
- *Any economies outside of their own in which the AB provides accreditation and the number of the respective accreditations. A description of the AB's cross frontier accreditation policy shall be provided.*





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4.6.3 Extension of AB's activities

The AB shall give an overview of the policies and processes for extension of the described scope – both into the accreditation of new conformity assessment activities, and extending current programs into new fields of technology.

The description should include, where applicable:

- *Use of national and international guides for the operation of CABs;*
- *Co-operation with other ABs (e.g. by joint assessments, use of assessors);*
- *Conformance with international harmonized decisions on what may be accredited and what should not be accredited; and*
- *Examples of extension into new areas in the last four years.*

Evidences: The AB shall:

- describe its accreditation activities, referring to the relevant International Standards, Guides or other normative documents;
- establish procedures for setting up new accreditation schemes and for setting up the accreditation of new conformity assessment schemes.





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5. MANAGEMENT

5.1 General

5.1.1 Establishment of a management system

5.1.2 Documented procedures

5.2 Management System

5.2.1 Documented policies and procedure understood and implemented

5.2.2 Type, range and volume of work addressed; accessible

5.2.3 Management system representative appointed

5.3 Document control

5.4 Records

5.4.1 Procedures for record keeping

5.4.2 Procedures for retaining records

5.5 Nonconformities and corrective actions

5.6 Preventive Action





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5.7 Internal Audits

5.7.1 Procedure for internal audit

5.7.2/5.7.3 Internal audit schedule, process and results

The AB shall provide a summary of the internal audit program and the audit results for the last two years.

5.8 Management Reviews

5.8.1 Procedure for management review

5.8.2/5.8.3 Input and output to management review

The AB shall provide a summary of the management review process and the main outputs for the last two years.

5.9 Complaints

The AB shall provide a summary of the complaint process including numbers of total complaints, those considered valid and major reasons for the complaints.





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6. HUMAN RESOURCES

6.1 Personnel associated with the AB

6.1.1 Sufficient number of competent personnel

- *A brief overview of the role of each position having influence on the process of accreditation shall be provided.*
- *Staff- A summary of the level of competence of key managerial and supervisory staff, and the number of staff, including any staff changes since the last full evaluation, shall be provided.*

6.1.2 Sufficient number of assessors

The total number of currently qualified assessors and experts, broken down by accreditation programs and broken down by internal/own staff and external/contracted staff shall be provided.

6.1.3 Extent and limit of responsibilities for each person

6.1.4 Commitment to confidentiality, and conflict of interest avoidance





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6.2 Personnel involved in the accreditation process

6.2.1 Description of each accreditation activity

The AB shall provide a description of the mechanisms for ensuring the competence of each of the groups of personnel. Such mechanisms may include how individuals are selected and trained (both initially and on-going). Examples of such a commentary may include the following:

Staff

Training processes (initial and on-going) for operational staff involved in the accreditation process.

Committees

Where relevant, how committee members are recruited, trained (initially and on-going) and qualified.





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6.2.2 Procedures for recruiting, training, qualifying assessors and experts

- *How assessors are selected, trained and qualified, including the qualification for the technical scopes they are deemed competent to assess;*
- *An overview of assessors' technical and assessment qualifications, training and experience; and*
- *On-going training of assessors.*

Experts

- *As relevant, the same commentary as for Assessors; and*
- *The mechanisms for supervision of experts by qualified assessors during the assessment process*

6.2.3 Identifying competence of assessors by scope

6.2.4 Assessor familiarity with accreditation documents





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6.3 Monitoring

6.3.1 Procedure for monitoring competence of assessors, experts and decision makers

Particularly where committees and individuals are involved in the accreditation decision, the AB shall describe how they are monitored, and what actions are taken when training needs are identified.

6.3.2 Monitoring assessors

- *How assessors are systematically monitored, and what*
- *actions are taken when training needs are identified;*
- *Other forms of monitoring and feedback that ensure the*
- *on-going competencies of assessors.*

6.4 Personnel records

6.4.1 Record maintenance

6.4.2 Content of personnel records





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7. ACCREDITATION PROCESS

7.1 Accreditation criteria and information

7.1.1 General criteria

7.1.2 Publicly available information

7.2 Application for Accreditation

7.2.1 Application content

7.2.2 Other CAB information (CAB services; accreditation requested; quality manual)

7.2.3 AB review of adequacy of CAB information

7.3 Resource Review

7.3.1 Review of ability to carry out the assessment

7.3.2 Carry out in timely manner





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7.4 Subcontracting the Assessment

7.4.1 Subcontracting policy and agreements

7.4.2 Subcontracting process

The AB shall describe the conditions under which subcontracting takes place, and how it meets the requirements of this clause.

7.4.3 List of subcontractors

The AB shall provide the list of organizations with which it has a subcontract agreement

7.5 Preparation for Assessment

7.5.1 Preliminary visit

7.5.2 Selection of the assessment team

The AB shall provide information on the policies/mechanisms for deciding on the team composition.

7.5.3 Impartiality of the assessment team





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7.5.4 CAB objections to the assessment team

7.5.5 Defining the assignment for the assessment team

7.5.6 Sampling of the scope

The AB shall provide information on the policies for sampling of the scope for all assessment types (e.g. initial, surveillance and reassessment) and how the AB demonstrates fulfillment of these policies and ISO/IEC 17011.

7.5.7 Assessing key activities for initial assessments

7.5.8 Premises assessed in surveillance and reassessments

See section 7.11.

7.5.9 Setting the assessment date

7.5.10 Provisions for the assessors

7.6 Document and Record Review

7.6.1 Assessors' document review

7.6.2 Nonconformities reported to CAB





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7.7 On-site Assessment

7.7.1 Opening meeting

7.7.2 Conduct of the assessment

The AB shall provide a description of the steps of the on-site assessment and which criteria for selecting the CAB locations are used.

7.7.3 Witnessing the performance of conformity assessment activities

The AB shall provide the policies for determining the amount of conformity assessment services to witness.

7.8 Analysis of Findings and Assessment Report

7.8.1 The assessment team's analysis of documents and information

7.8.2 Assessment team's referral back to the AB

7.8.3 AB's reporting procedures





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7.8.4 AB retains responsibility for the assessment report

7.8.5 Resolution of the nonconformities

A description of the following shall be provided by the AB:

- *How findings are graded;*
- *How nonconformities with accreditation criteria are communicated to the assessed CAB;*
- *How these findings are to be addressed by the CAB and assessed and cleared by the AB, including any involvement by the assessment team;*
- *How such actions are used in the accreditation decision making; and*
- *What actions are taken on unsatisfactory resolution.*

7.8.6 Information provided for the AB's decision makers

7.9 Decision-Making and Granting Accreditation

7.9.1 Confirmation that requirements have been met





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7.9.2 The AB's decision

The accreditation decision-making process shall be described, including:

- *The effective separation of the assessment team and the decision maker(s);*
- *The use of proficiency testing in the decision making process (see 7.15.1); and*
- *The accreditation decision making process for surveillance activities and reassessments.*

7.9.3 Using results from assessment by another AB

7.9.4 Content of the accreditation certificate

7.9.5 Accreditation certificate content for different types of CABs





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7.10 Appeals

7.10.1 Procedure to address appeals

7.10.2 Details of the appeals process

The AB shall provide a summary of the appeals process including numbers of appeals and of appeals considered valid since the last full evaluation/4 years for initial evaluations.

7.11 Reassessment and Surveillance

7.11.1/7.11.2 *The AB shall describe its surveillance and reassessment program for its accredited CABs, including the term of accreditation, and whether or not expiry dates are used;*





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7.11.3 Surveillance and reassessment plans

The AB shall describe its surveillance and reassessment plan for its accredited CABs, including:

- *The reassessment frequency;*
- *The nature, frequency and scope of surveillance activities, with particular emphasis on on-site surveillance and the associated sampling of sites, personnel, and the scope of accreditation;*
- *The information on the policy for sampling premises from which one or more key activities are performed;*
- *How the AB responds to the operation of the CAB in more than one site or whether it operates cross-frontier; and*
- *Use of witnessing of testing, calibration, inspection and certification activities in surveillance and reassessment, if applicable.*





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7.11.4 Planning surveillances and taking account of other surveillance activities

The AB shall describe how it judges the proven stability that the services of the CAB have reached in its decision on the intervals for the surveillances and reassessments.

7.11.5 Corrective action time limits for surveillances and reassessments.

7.11.6 Continuation of accreditation based on surveillances and reassessments results

7.11.7 Conducting extraordinary assessments





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7.12 Extending Accreditation

7.13 Suspending, Withdrawing or Reducing Accreditation

7.13.1 *Procedure for suspension, withdrawal or reduced accreditation*

The AB shall detail the number of non-voluntary suspensions and withdrawals over the last four years.

7.13.2 *Decision to suspend or withdraw based on persistent failure by CABs in meeting requirements*

7.13.3 *Decision to reduce accreditation based on persistent failure by CABs in meeting requirements*

7.14 Records on CABs

7.14.1 Maintenance of records on CABs

7.14.2 Confidentiality of record keeping

7.14.3 Content of CAB records





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7.15 Proficiency Testing and Other Comparisons for Laboratories

7.15.1 Procedures for considering CAB's proficiency testing (PT) activities during assessment

7.15.2 List of PT programs (internal or external)

7.15.3 Laboratories participation in PT; corrective actions for PT (see also ILAC P9)

For ABs accrediting testing, calibration and inspection CABs, a description of the AB's implementation of ILAC P9 shall be provided. This description shall include any mandated PT programs and programs mandated and organized by the AB. The description shall cover the AB's fulfillment of any regional requirements including participation of its accredited CABs in PTs organized by Regional Groups.





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8. RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB

8.1 Obligations of the CAB

8.1.1 AB's requirements of the CAB

8.1.2 AB's requirements that the CAB report significant changes

8.2 Obligations of the AB

8.2.1 Information publicly available

8.2.2 Information on obtaining traceability of measurements

8.2.3 Information on international arrangements

8.2.4 Alerting CABS to changes in the AB's requirements

8.3 Reference to Accreditation and Use of Symbols

8.3.1 AB policy governing protection and use of the accreditation symbol

8.3.2 Measures to ensure CAB conforms with rules for claiming accreditation





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8.3.3 Action taken by AB

The AB shall describe the action taken in the case of misuse of the accreditation and/or the accreditation symbol

2.3 Other Arrangement Requirements to be Addressed (as detailed in italics below) IAF/ILAC A2

2.1 Standards

2.1.1 *Compliance with ISO/IEC 17011 and IAF/ILAC mandatory documents*

2.1.2 *Compliance with A2, section 2.2 (see below) and Regional requirements (see below)*

2.2 Supplemental requirements

2.2.1/2.2.1.1 *Experience in assessment/one accreditation in each scope*

2.2.1.2 *Access to expertise*





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2.2.1.3 Measurement Traceability (See also ILAC P10)

The AB (that accredits testing, calibration, and inspection CABs) shall describe:

- *Its policies for achieving satisfactory measurement traceability by its accredited CABs in compliance with ILAC P10;*
- *Access to international traceability and reference materials (RMs) by the accredited CABs (summary of the NMI status in relation to the CIPM MRA);*
- *Its specific policies and guidelines in areas where traceability is difficult to achieve;*
- *Its policies on the use of reference materials to achieve measurement traceability, where the concept applies; and*
- *Its policies on the estimation of measurement uncertainty shall also to be described, including how these are to be used in the traceability chain in compliance with ILAC P14.*





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2.2.1.4 PT requirements (see section 7.15 in Part 2.2)

2.2.1.5 Abide by requirements/obligations of region/international arrangements

2.2.1.6 Program to promote the arrangement

2.2.1.7 Contribute to peer evaluations

2.2.1.8 Cross frontier in accordance with IAF documents/taking into account ILAC G21 (see section 4.6 in Part 2)

