



**NATIONAL ACCREDITATION CENTRE**

# **MOLDAC POLICIES**

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## CONTENT

<b>P-01 POLICY REGARDING MOLDACs COMPETENCE AND COHERENCE OF FUNCTIONALITY</b> .....	<b>3</b>
<b>P-02 POLICY ON USE OF PROFICIENCY TESTINGS AND OF OTHER INTERLABORATORY COMPARISONS IN ACCREDITATION PROCESS according to ILAC P9</b> .....	<b>5</b>
<b>P-03 POLICY ON MEASUREMENT OF TRACEABILITY based on ILAC P10</b> .....	<b>10</b>
<b>P-04 POLICY ON HANDLING THE NONCONFORMITIES</b> .....	<b>14</b>
<b>P-05 POLICY ON CROSS-BORDER ACCREDITATION according to the provisions of Regulation (CE) 765/2008, EA-2/13, ILAC G21</b> .....	<b>17</b>
<b>P-06 POLICY ON OUTSOURCING OF ASSESSMENT according to EA-2/13</b> .....	<b>19</b>
<b>P-07 POLICY ON TREATING THE OBJECTIONS OF CABs REGARDING ASSESSMENT TEAM MEMBERS AND OBSERVERS</b> .....	<b>21</b>
<b>P-08 POLICY AND RULES ON THE USE OF ACCREDITATION SYMBOLS, OF ILAC-MRA COMBINED MARK, OF IAF-MLA COMBINED MARK AND REFERENCES TO ACCREDITATION according to EA-1/19, EA-3/01 and ILAC P8 and IAF ML2, IAF PL8</b> .....	<b>22</b>
<b>P-09 POLICY ON IMPARTIALITY, MANAGING CONFLICTS OF INTEREST AND ENSURING OBJECTIVITY IN ACCREDITATION ACTIVITY</b> .....	<b>29</b>
<b>SYNTHESIS OF CHANGES</b> .....	<b>32</b>

Note: The present document represents the English version of the Romanian document. In case of conflict the Romanian version will prevail.

## **P-01 POLICY REGARDING MOLDACs COMPETENCE AND COHERENCE OF FUNCTIONALITY**

Accreditation provides confidence in competence and integrity of conformity assessment activities, which can be used as support in implementation of government policies and regulations, which have impact on health, wellness, safety and environment.

Quality of accreditation services builds the trust provided by the accreditation system to regulators, the business area and the beneficiaries of accreditation.

National Accreditation Centre's top management established as its main objective to maintain the status of EA BLA, ILAC-MRA and IAF MLA signatory, by ongoing fulfillment of requirements of Regulation (CE) 765/2008, Law no.235/2011, as well as requirements of EN ISO/IEC 17011:2017 standard, and of applicable EA, ILAC, IAF documents, by improvement of the accreditation service quality provided through:

- defining undertaken activities/ processes;
- defining the parameters and their monitoring mechanisms;
- developing and implementing of tools to improve the management system;
- setting goals to improve the accreditation activities;
- compliance with general and specific criteria of impartiality and independence in the evaluation process and decision making;
- evaluation and ongoing training of personnel involved in the accreditation process;
- identifying needs and requirements of direct and indirect accreditation customers, assessment and insurance of their satisfaction level;
- identification of expertise sources outside the territory of Republic of Moldova.

In order to maintain its status of EA BLA, ILAC-MRA and IAF MLA signatory, MOLDAC established the following:

- permanent consulting of all interested parties: authorities, consumers, accredited conformity assessment bodies, for prompt identification for needs of accreditation development;
- permanent collaboration with national authorities regarding identification of directions for development for national and/or European legislation, in order to ensure the necessary accreditation schemes in the regulated areas;
- systematic participation in the activities of committees, specialized groups of the European Commission;
- cooperation with other national accreditation bodies and with regional or international associations.
- Implementation of measures, as appropriate, to maintain the safety and security of EA / ILAC / IAF members during their stay on the territory of Republic of Moldova.

MOLDAC ensures and improves permanently the competence of personnel involved in accreditation process, by implementation and maintenance of some mechanisms and tools of competence evaluation as follows:

- insures the optimal number of suitable staff, related to the workload;

- insures participation in programs for training and maintenance for continuous improvement;
- provides documentary resources - standards and guides;
- provides technical support in the evaluated field including communication with technical committees, access to the database;
- collaboration and exchange of experience with regional and international organizations in the field, and use of obtained information during the participation of their representatives in EA, ILAC and IAF committees, to harmonize its practices with those of accreditation bodies which are EA, ILAC and IAF members;
- implementation and maintenance of a Feedback system for improvement of personnel competence.

MOLDAC has proposed to continuously improve the performance of accreditation activities in order to develop the conformity assessment activities as a whole, thus making an important contribution to the evolution of the national economy.

Whenever there are changes of the EA BLA Agreement requirements, MOLDAC ensures compliance with the provisions of the EA General Assembly resolutions.

MOLDACs field of activity is suited to the needs of the country's economy and to the economic requirements of the domestic market. In addition, MOLDAC meets the requirements of the domestic economy by developing new schemes/ areas to support the fulfillment of the European Union legislation's requirements in the field of free movement of products, protection of life, health and safety of persons, environmental protection and consumer protection.

## **P-02 POLICY ON USE OF PROFICIENCY TESTINGS AND OF OTHER INTERLABORATORY COMPARISONS IN ACCREDITATION PROCESS according to ILAC P9**

### **Introduction / Purpose of the document**

Proficiency testing/ inter-laboratory comparisons represent one of the reliable and efficient mechanisms to prove competence of the laboratory/ inspection body (when testing activities that directly affect or determine the inspection result, or when they are asked by law or authorities, are available and justified).

Participation in PT schemes provides information on performance of measurement systems/ activities (equipment, methods, personnel, etc.) and highlights other aspects of the management system (application review, sample receiving and preparing, data processing, results reporting etc.) which represents the risk managements suitability and identification of the training needs of laboratory/ inspection body staff.

For calibration laboratories the positive results of participation in PT/ILC are used by MOLDAC to confirm calibration and measurement capabilities (CMC).

### **Terms and definitions:**

**Proficiency Testing (PT):** evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons (**ISO/IEC 17043**).

**Interlaboratory Comparison (ILC):** organization, performance and evaluation of measurements or testing on the same or similar items by two or more laboratories according to predetermined conditions (**ISO/IEC 17043**).

**Measurement Technique:** the process of testing/ calibrating/ identification of property, including any pre-treatment required to present the sample, as received by the laboratory, to the measuring device. (e.g. ICP-MS, Rockwell Hardness, PCR, Microscopy, Force Measurement) (**EA-4/18**).

**Property:** represents the quantity being measured (e.g. length, hardness, force, concentration of arsenic in soil) (**EA-4/18**).

**Product:** the item that the measurement technique is being applied. (e.g. Soil, Vegetables, Serum, Polystyrene, Concrete) (**EA-4/18**).

**Level of Participation:** the number of sub-disciplines that an organization identifies within its scope, and therefore the number of specific proficiency testing that shall be considered for participation (**EA-4/18**).

**Frequency of Participation:** represents how often a laboratory determines that it needs to participate in PT for a given sub-discipline; this may vary from sub-discipline to sub-discipline within a laboratory and between laboratories with the same sub-disciplines (**EA-4/18**).

**Sub-discipline:** an area of technical competence defined by a minimum of one Measurement Technique, Property and Product, which are related. (e.g. determination of arsenic in soil by ICP-MS) (**EA-4/18**).

**Metrological sub-domain** - domain of metrological competence defined at least by one of the measuring technique in metrological calibration/ verification.

**Small interlaboratory comparisons (small ILC)** - interlaboratory comparisons organized by a maximum of seven or fewer laboratories (**EA-4/21 INF**).

### **Accepted PT/ILC**

MOLDAC recognizes the PT/ILCs results issued by:

- PT/ILC providers accredited according to ISO/IEC 17043 requirements by accreditation bodies that are signatories to EA MLA and ILAC MRA agreements;
- PT/ILC providers within EA and APLAC or from other regional or international cooperation;
- National Metrological Institutes within the regional metrological organization;
- providers within national, regional, international companies, for specific areas, only if upon declaration of working according to ISO/IEC 17043;
- European Reference Laboratories (EURL);
- national PT/ILC providers, which declare that they are acting according to ISO/IEC 17043, which files regarding competence, are accepted by MOLDAC according to following criteria: accredited laboratories, positive results in PT/ILC participations at European and international levels, experience in PT/ILC organization at national level and appointed by regulators;
- the results of scientific projects that provide information similar to those obtained from ordinary ILCs could be considered as alternatives to PT.
  - the results of participation in "small ILC", which meets the requirements of document EA-4/21 INF.

The list of PT/ILC providers accepted by MOLDAC is published on WEB-site [www.acreditare.md](http://www.acreditare.md).

### **General provisions for all types of laboratories**

When proficiency tests/ inter-laboratory comparisons are organized by EA or regional and international bodies, for example within bilateral/ multilateral recognition agreements, accredited laboratories named by MOLDAC are obliged to participate.

Laboratories and, where relevant, inspection bodies which seek accreditation/ extension shall present satisfactory results at least for one participation at PT/ILC at national, European or international levels for each sub-discipline and for each metrological sub-domain (LE, LVM).

During the on-site assessment, the laboratory must present the results of PT/ILC participation to the MOLDAC team (performance data, test type, method used, and organizer evaluation). If the results are not satisfactory, the laboratory must provide evidence of corrective actions.

If PT/ILCs are not available for specific areas, laboratories/ inspection bodies must provide evidence an analysis that demonstrates that they do not exist.

If the PT / ILC are not available for the field of competence, the laboratory / inspection body may, inadvertently, initiate participation in "small ILC" with other accredited entities. These "small ILCs" can be organized according to the three possibilities described in the document EA-4/21 INF.

The laboratories/ inspection bodies can request MOLDAC to carry out the measurement audit activities. Responsible for organizing and conducting the "*Measurement Audit*" process is **only** the laboratory/ inspection body that selects the subject of the measurement audit (e.g. subject to calibration, reference material), performs the data analysis and evaluates the results of participation. MOLDAC analyses **only** the way in which the "*Measurement Audit*" was performed, and takes into consideration its results.

In cases when the results of "*Measurement Audit*" are unsatisfactory, MOLDAC requires from CAB actions, similar to those described in sub-chapter "*Comparisons which indicate unsatisfactory performance*" of this Policy."

Participations in PT / ILC cannot be systematically replaced with participation in "small ILC" as well as "Measurement Audit".

After analyzing the impossibility of checking the validity of the results of the work of the laboratory / inspection body through external activities, they must ensure the validity of its results through internal activities as indicated in section 7.7.1 of ISO / IEC 17025 and point 5.6.4 ISO 15189.

### **Comparisons showing unsatisfactory performance**

Laboratories/ inspection bodies shall have appropriate criteria of results acceptability from participations in PT/ILCs. In case of unsatisfactory, aberrant results or in situation in which PT results indicate a potential problem, the laboratory/ inspection bodies shall determine the causes and analyze possible effects. Based on this analysis, the laboratory shall make corrective actions and if necessary, to cease the work, to ask from the customers reports/ certificates with the invalid results, implement corrective actions to allow ensuring of the quality of results. MOLDAC will check the adequacy and effectiveness of the actions undertaken during the next assessment. If it is found that corrective actions were not effective, MOLDAC will take the decision to immediately suspend those activities for which unsatisfactory results have been obtained.

### **Additional provisions for calibration laboratories**

For accredited calibration laboratories, for each **metrological sub-domain**, must be identified the calibration range, the metrological traceability chain, the subject to calibration, physical size/ feature, similar calibration methods, for example:

- for masses: weights with metrological classes and different nominal values,
- for temperature: thermocouples of different metrological classes at temperatures up to 1600°C.

Examples of **metrological sub-domains** that have different procedures and methods of calibration/ metrological verification are included in [Annex PM-A-1.1](#) to this document.

Within one accreditation cycle, CABs have to obtain satisfactory results in PT/ILC at least once for each sub-domain prior requesting re-evaluation. The requirements apply to all locations under accreditation.

For calibration, the measurement audit consists of calibration of one measuring equipment or a standard whose calibration parameters are known to the assessment team and the calibration is performed entirely by the laboratory and only in the presence of a technical assessor during the one-site assessment.

In case of measurement audit, the performance of the laboratory will be recorded by technical assessor in the witness template.

Bilateral comparison for calibrations is accepted as an alternative to PT/ILCs, when one or more measurement devices are calibrated both by the assessed laboratory and the reference laboratory for suitable reference values. Reference laboratory can be National Metrological Institute, or a laboratory accredited by EA MLA or ILAC MRA signatory according to ISO/IEC 17025, characterized by an uncertainty significantly better than that requested by the assessed laboratory.

### **Additional provisions for testing/ medical laboratories and inspection bodies conducting measurements**

MOLDAC requires that all testing/ medical laboratories and inspection bodies to have their own participation policy in PT/ILCs, which depends on the type and size of the accreditation scope, adequate to cover the entire accreditation scope within one accreditation cycle, but participations could be more frequent, depending on common approaches in specific disciplines, legal requirements, etc.

Accredited laboratories/ inspection bodies must participate in PT/ILCs at least once with satisfactory results for each sub-discipline, for each metrological sub-domain ([VM](#)), [group of medical devices](#), listed in [Annex PM-A-1.2 \(P-02\)](#) according to the plan documented by the CAB and evaluated/accepted by MOLDAC. The requirements apply to all locations under accreditation.

For the preparation and revision of the plan, the laboratory shall consider for each domain/ discipline at least the following factors:

- the results obtained from previous participation at PT/ILCs;
- the frequency and the entity of actions deriving from internal controls of the management system of technical activities, in particular those permitting identification, quantification and monitoring of any systematic deviation (such as nonconformities, corrective actions, preventive actions deriving from testing, calibration and metrological confirmation);
- the results of assessment by second or third parties;
- circumstances or factors of the laboratory which could justify a modification to the usual frequency of participation;
- analysis of risk level (see EA-4/18)
- the availability of PT/ILC providers.



Guidelines on the level and frequency of participation in proficiency testing are documented in ILAC P9, EA-4/18. The laboratory shall ensure participation of each employee and to present evidences, that the samples for participation in PT/ILCs are treated in ordinary working mode. The planning for participation in PT/ILCs shall be analyzed annually by the laboratories, and revised if appropriate to maintain the suitability. Non-participation in available schemes shall be justified by the laboratory and accepted by MOLDAC.

To organize measurement audits for testing there are 2 possible options:

- assessment team have the control sample/ certified reference material. Those can be submitted to laboratories during the on-site assessment, or submitted before assessment.
- assessment team do not have the control sample/ certified reference material. In this case assessment team may subcontract provision of necessary materials, and the laboratory shall pay the cost for these services.

The results obtained in the test/ analysis/ measurement are compared with the target values of the control sample or with the value indicated in the certificate of the reference material.

In case of measurement audit, the performance of the laboratory will be recorded by technical assessor in the witness template.

The bilateral comparison for testing between accredited laboratories according to ISO/IEC 17025 is acceptable, when other PT/ILCs are not available, under predetermined conditions. In these cases, due to the fact that the statistical analysis of data is not possible, and that these data are few and not representative, the results are assessed as little significant.

[Annex PM-A-1.1 \(P-02\) - Metrological subdomains for calibration / metrological verification laboratories.](#)

[Annex PM-A-1.2 \(P-02\) - Sub-disciplines \(groups\) of medical devices for inspection bodies](#)

## **P-03 POLICY ON MEASUREMENT OF TRACEABILITY based on ILAC P10**

*If this document refers to laboratories without further specification, they should be read as calibration laboratories, testing laboratories, medical laboratories and inspection or verification bodies that carry out measurements or testing.*

Policy is based on mandatory requirement that, before being put into service, all laboratory equipment, used for testing/ calibration/ metrological verification/ medical analyses/ inspection activities, which have significant effect on the accuracy or validity of the results of testing/ calibration/ metrological verification/ medical analyses/ inspection activities, shall be calibrated, using reference standards whose metrological traceability to the international system of measurement units (SI) is ensured.

Laboratories shall have appropriate policies and procedures, in accordance with ILAC-G24 recommendations, for setting and adjusting intervals between two successive calibrations of measurement equipment.

### **For calibration**

For measurement equipment and reference standards which have a significant effect on accuracy or validity of testing, calibration or sampling results, according to point 5.6.1 of ISO/IEC 17025:2005 and to point 6.4.6 of ISO/IEC 17025:2017, which shall be calibrated, in order to meet the requirements of 5.6.2.1.1 and 5.6.3.1 of ISO/IEC 17025:2005 and 6.5 of ISO/IEC 17025:2017, MOLDAC policy is that these have to be calibrated by:

1. A National Metrology Institute/ a Designated Institute whose service is suitable for the intended purpose and is covered by CIPM MRA Arrangement. The services covered by the CIPM MRA are specified in Annex C of BIPM KCDB which includes the scope and measurement uncertainty for each listed service; they can be indicated by including the BIMP CIPM MRA logo on the calibration certificates. In the case of non-application of logo, the applicant of service shall verify the CMC cover by consulting the web site of BIPM  
<http://www.bipm.org/en/cipmmra/participation/signatories.html>

or

2. An accredited calibration laboratory whose services are suitable for the intended purpose (i.e. the accreditation scope covers a certain specific calibration) and the Accreditation Body is covered by ILAC Arrangements (ILAC-MRA) or by ILAC recognized Regional Arrangements.

or

- 3a. A National Metrological Institute whose services are adequate for the intended scope but is not covered by CIPM MRA. MOLDAC recognizes calibration services offered by a National Metrological Institute for which in CIPM MRA does not exist categories of Measurement and Calibration Capabilities, but which participate in relevant CIPM MRA comparisons and for which there are evidences of technical competence (evidence of participation in additional comparisons published in the KCDB database, bilateral comparisons between NMIs), for at least one related CMC.

or

3b. A calibration laboratory whose work is suitable for the intended purpose, but is not covered by the ILAC Arrangement or Regional Arrangements recognized by ILAC. In this situation, the applicant laboratory shall provide the selection criteria as well as appropriate evidence for ensuring traceability and estimation of measurement uncertainty.

The evaluation of calibration services provider is performed by CAB according to ISO/IEC 17025 requirements. In this case, MOLDAC shall assist as an observer at the on-site evaluation of the provider. The assessment of service provider performed by CAB is assessed by MOLDAC.

The choice of traceability routes 3a and 3b is applicable to the types of calibration for which the routes presented in case 1 and 2 are not possible. For a specific type of calibration, if only routes 3a and 3b are available, route 3a is selected.

Certification of the company's management system does not in itself demonstrate the supplier's competence.

The evidence of metrological traceability accepted by MOLDAC is limited only to specific procedures and sizes subject to assessment and does not refer to competence for other sizes or other services provided by the supplier (in cases 3a and 3b).

Adequate evidence of technical competence and metrological traceability of the calibration supplier laboratory may include, but not necessarily be limited to: (*reference points to ISO/IEC 17025:2005*)/ (*reference points to ISO/IEC 17025:2017*)

- Records of results from participation in ILC within CIPM MRA or organized on regional level (5.9/7.7);
- Records of results from participation in ILC performed with another NMI or ID (Designate Institutes);
- Ensuring metrological traceability on SI or on reference materials by participation in PT/ILC organized at the regional level (e.g. COOMET, EURAMET etc.) or covered by accreditation (5.9/7.7);
- Records on validation of calibration method (scientific publications, technical reports etc.) (5.4.5/7.2.2);
- Procedures for uncertainty estimation and metrological capacity (5.4.6/7.6);
- Documentation on insurance of results on measurements traceability (5.6/6.5);
- Documentation on insurance of validity of the calibration results quality (5.9/7.7);
- Evidence on capability of personnel involved in calibration (5.2/6.2);
- Documentation on adaptation and environmental conditions under which the calibrations were performed (5.3/6.3);
- Records on Calibration Laboratory Audit (4.6.4,4.14)6.6 /8.8);

For calibrations which cannot be made strictly in SI units, MOLDAC policy for meeting requirement 5.6.2.1.2 of ISO/IEC 17025:2005 and 6.5.3 requirement of ISO/IEC 17025:2017 is:

4. The requirement 5.6.2.1.2 of ISO/IEC 17025:2005 and requirement 6.5.3 of ISO/IEC 17025:2017 can be applicable if the laboratory has demonstrated that points 1-3 of this policy cannot be reasonably met. It is the responsibility of the laboratory to choose a way to meet the requirements 5.6.2.1.2 and 6.5.3 from ISO/IEC 17025:2017 and provide evidence that this is fulfilled. Such evidence shall be documented and the documentation will be evaluated and accepted by MOLDAC.

## **For testing/ medical analysis**

For testing laboratories accredited according to ISO/IEC 17025 as well as for medical laboratories accredited according to ISO 15189, MOLDAC policy is:

5. If calibration of the equipment used in testing/ analyses contributes significantly (critical equipment) to the result or to measurement uncertainty, for meeting requirement 5.6.2.2.1 of ISO/IEC 17025:2005 and of requirement 6.5 of ISO/IEC 17025:2017, respectively requirement 5.3.1.4 of ISO 15189, the same policy as for calibration (points 1-4) is applied.
6. If the calibration equipment used in testing/ analyses do not contribute significantly to the results, the laboratory shall provide evidences to demonstrate this. Therefore, the traceability does not need to be demonstrated. For meeting the requirement 5.6.2.2.2 of ISO/IEC 17025:2005 and of requirement 6.5.3 of ISO/IEC 17025:2017, respectively the requirement 5.3.1.4 of ISO 15189, the same policy as that specified in point 4 is applied.

## **If traceability is provided by reference materials**

For requirements included in the ISO/IEC 17025:2005 (5.6.3.2), ISO/IEC 17025:2017 (6.5.2 b, 6.5.3a) on the use of reference materials MOLDAC policy is:

7. Assigned values of Certified Reference Materials (MRC) produced by a National Metrology Institute/ Designated Institute and included in the KCDB database of BIPM, or produced by a Reference Materials Producer (RMP), accredited according to ISO/IEC 17034 "General Requirements for the Competence of Reference Material Producers", shall be deemed to have established a valid traceability.
8. Assigned values of Certified Reference Materials covered by the entries in the database of the Joint Committee for Traceability in Medical Laboratories (JCTLM) are considered to have established valid traceability.
9. Most of reference materials and of Certified Reference Materials are produced by manufacturers of Reference materials. These can be considered as critical consumables and laboratory shall demonstrate that each reference material or certified reference material is suitable for its intended use, as required by point 4.6.2 of ISO/IEC 17025:2005 and by point 6.6.2 c of ISO/IEC 17025:2017, and point 4.6 ISO 15189.
10. If traceability of reference materials according to options 7 or 8 is not feasible, the following alternative methods may be accepted:
  - a) gravimetric preparation of the standard solution made of pure substances;
  - b) reference materials which are not produced accordingly to ISO 17034 may be accepted, if this laboratory also obtains a similar reference material from another independent manufacturer and has a satisfactory cross reference;
  - c) MRCs provided by PT providers with characteristics based on proven properties during proficiency tests, etc.

## For inspection bodies

MOLDAC policy is:

11. If the verification/ inspection body perform measurements during the verification/ inspection activities, used measurement equipment shall comply with ISO/IEC 17025 requirements. Additional instructions regarding this subject can be provided by ISO 10012.
12. If the equipment used for inspections significantly contributes on results (critical equipments) or on measurement, the same policy is applied as for calibrations (points 1-4).
13. If the calibration equipment used in inspection does not significantly contribute to the results, the inspection body shall provide quantitative evidences to demonstrate this. Therefore the traceability does not need to be demonstrated.

## Cooperation between MOLDAC and NMI regarding traceability of measurements results

Dissemination of units from national standards as well as of measurement capability, from NMI to accredited laboratories, is essential in obtaining client's trust in a national measurement system.

A coherent relationship is established between NMI and MOOLDAC, for use, by MOLDAC, of metrological expertise offered by NMI for providing of necessary input information.

## Annexes

Annex PM-A-1 (P-03) – Metrological sub-domains for calibration laboratories.

## **P-04 POLICY ON HANDLING THE NONCONFORMITIES**

### **1. The way of treatment of non-conformities**

In the accreditation process, MOLDAC assessment team may detect non-conformities during its assessments, if the requirements for accreditation are not met by the conformity assessment body.

Established non-conformities are recorded in Report of the raised non-conformities at the analysis of documented information or in non-conformities reports in case on assessments, at the moment of their finding.

According to ILAC G3 Annex A the non-conformities identified during the assessment are classified by the lead assessor and are officially presented to the legal representative of conformity assessment body, who sign for acknowledgment.

MOLDAC verifies the Reports on non-conformities presented to CAB at the closing meeting by the lead assessor/ team leader and, where appropriate, modifies the wording of non-conformities, without changing their meaning, according to the results of the findings analysis from assessment team and the requirements of the reference standard. Within 5 working days after on-site assessment lead assessor/ team leader sends modified Nonconformities Reports to CAB, for signing them by the CABs.

If the CAB does not agree with certain non-conformities recorded by the assessment team, it has the possibility to address to the MOLDAC Professional College.

According to their impact on management system and the credibility of the accreditation scheme, MOLDAC grades non-conformities as follows:

- ✓ **Critical** nonconformity – nonconformity which, through the generated effects, significantly affects the credibility of the CAB's competence;
- ✓ **Major** non-conformity – absence of implementation or failure to implement/ maintain specified accreditation requirement(s), which has/have direct negative effects on the quality of the results of the conformity assessment body or the existence of a situation in which, based on objective observations, doubts are posed on the quality of activities performed by the CAB;
- ✓ **Minor** non-conformity – failure to implement/ maintain one/ several specified accreditation requirement(s), which has/have no direct negative effects on the quality of the results of the conformity assessment body or the existence of a situation in which, based on objective observations, generates the premises of major nonconformities occurrence.

MOLDAC can issue a critical non-conformity only during surveillances, reassessments and extraordinary assessments. If the CAB, within 5 working days, fails to provide evidence of the removal of the critical nonconformity (corrections) and the plan of the

corrective actions planned for removal, the activity affected by the critical nonconformity will be suspended.

For all categories of non-conformities found by MOLDAC and for all types of assessments, CAB should establish for each non-conformity the following:

- the root cause of non-conformities,
- the amplitude of non-conformities,
- specific actions to be taken for elimination of non-conformities:
  - o corrections,
  - o corrective actions,

and, subsequently, to undertake analysis of the effectiveness of corrective actions.

If the lead assessor considers that the cause analysis, corrections and corrective actions are inadequate, he will require from CAB restoring of the non-conformity analysis, but not more than one more time.

CAB has to treat non-conformities and to present evidences of their elimination within terms indicated in Annex 1 to RA.

If the lead assessor considers that the evidence on closing of the non-conformities is not sufficient, he/she must request additional information from the CAB but at most once again.

If MOLDAC identifies a risk associated with the use of a supporting document incorrectly issued under CAB accreditation (eg certificates, test reports, analysis bulletins, verification bulletins, and others) and/or a risk to the consumer of the product/service evaluated by the CAB, then the document in question issued under accreditation, must be withdrawn from the CAB client by the CAB in a limited period, resulting from the associated risk, but not more than 3 months.

The CAB must notify its client, that the withdrawn document is invalid and that it must stop using it or, if necessary, re-examine its decisions made on its basis.

Before taking decision all identified non-conformity at CAB shall be closed.

During the assessment activities, MOLDAC assessment team can issue observations.

**Observation** - is a proposal from assessment team regarding areas which could be improved.

## **2. Verification of the implementation of effectiveness of corrective actions**

### **2.1. Analysis of documented information**

The found non-conformities during the analysis of documented information will be sent to the conformity assessment body, in writing, after carrying out the analysis. CAB must present revised documentation in terms indicated in Annex 1 to RA.

Verification of corrections and corrective actions implementation carried out by CAB is made by the MOLDAC assessment team during the on-site assessment.

## **2.2. On-site assessment**

For the minor/ major non-conformities raised during on-site assessment (premises), CABs should submit, in terms indicated in RA Annex 1, the following:

- the root cause of non-conformities,
- the amplitude of non-conformities,
- specific actions to be taken for elimination of non-conformities:
  - o corrections,
  - o corrective actions,

and, subsequently, to undertake analysis of the effectiveness of corrective actions.

For identified observations on areas which could be improved, in case of acceptance, CAB could elaborate an Improvement Plan and present it to MOLDAC.

CAB must present evidences on elimination of non-conformities in terms indicated in RA Annex 1.

## **2.3. Witness assessment**

The non-conformities found during witness assessment are recorded in Reports of non-conformities and, depending on the assessment conditions, the lead assessor/ technical assessor presents them to the witnessed person for acknowledgment, after what send them to the CAB, by fax, to be signed by the head of it.

CAB shall present evidences of elimination of non-conformities in terms indicated in RA Annex 1.

The lead assessor/ technical assessor analyze the causes, corrections and corrective actions submitted by the conformity assessment body and if they are appropriate, accept them. If the lead assessor considers that the cause analysis, corrective actions and corrections are inadequate, s/he requires from conformity assessment body modification of the non-conformity analysis, but at most once.

## **2.4. Analysis of evidences of closing of non-conformities**

After submitting the evidences of closing of non-conformities by CAB to the MOLDAC secretariat, the Lead Assessor, or a team member (by case), examines them and decides the place of carrying out the analysis, which can be at MOLDAC premises, CAB premises, or CABs client's premises.

CAB shall present evidences of closing of non-conformities within terms indicated in RA Annex 1.

## **2.5. Assessment of the effectiveness of corrective actions**

Effectiveness of the implemented corrective actions by CAB for the closing of found non-conformities at the previous assessment will be verified at the following assessment and reported to CAB. In cases when assessment team will find that non-conformities from the previous assessment systematically repeat, those will be classified in higher grade (for example from minor to major).



## **P-05 POLICY ON CROSS-BORDER ACCREDITATION according to the provisions of Regulation (CE) 765/2008, EA-2/13, ILAC G21**

### **1. MOLDAC cooperation with EA members regarding cross-border accreditation**

MOLDAC may accept the application for accreditation from a conformity assessment body from EA member countries only in one of the following situations:

- a) when the member state 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 member state;
- b) when the national accreditation body in the country where the conformity assessment body is established does not perform accreditation towards the conformity assessment activities for which accreditation is sought;
- c) when the national accreditation body from the country in which is located the CAB, was not successfully peer evaluated, regarding conformity assessment activities for which accreditation is requested.

If MOLDAC receives an application under paragraph 1 b) or c) it shall inform the national accreditation body of the member state where the conformity assessment body is established about the received application.

MOLDAC may request national accreditation body of the member state where the applicant CAB is established to participate in the assessment as observer.

MOLDAC may request another national accreditation body to conduct a part of assessment activities. In this case, the accreditation certificate is issued by MOLDAC.

### **2. MOLDAC cooperation with EA members on cross-border accreditation for CAB with multiple locations in several countries within EA region**

MOLDAC accepts the application for accreditation from a conformity assessment body which has its headquarters in Moldova and with multiple legal locations established in other countries. In these cases MOLDAC can subcontract the assessment of locations by the national accreditation bodies from the countries where those are established, with the condition that national accreditation bodies that are subcontracted by MOLDAC are EA MLA/ EA BLA or IAF-MLA/ ILAC-MRA signatories.

MOLDAC informs the Accreditation Body on its needs in the next calendar year, no later than three months before the beginning of the calendar year.

### **3. Conformity assessment bodies from non-EU member states seeking accreditation**

MOLDAC may accept the application for accreditation from CAB established outside EA member countries in one of the following situations:

- a) There is no local accreditation body operating in the respective country;
- b) The local accreditation body does not provide entirely the requested accreditation scope (including standards and specific schemes);
- c) For reasons based on trade preferences or other businesses of the applicant CAB;
- d) Customers of the conformity assessment body require a specific accreditation and can not be persuaded to accept the accreditation of the local accreditation body;
- e) The conformity assessment body is part of a group that wants all its conformity assessment bodies to be accredited by the same accreditation body.

In this case, MOLDAC shall:

- a) inform whether the applicant conformity assessment body knows about the existence of a local accreditation body;
- b) explain to the requesting conformity assessment body that accreditation by the local accreditation body would better take into account local factors and conditions when appropriate;
- c) point out that if the request for accreditation is accepted, MOLDAC may involve the local accreditation body in the accreditation process;
- d) inform the local accreditation body regarding the acceptance of the request.

#### **4. Taking over the accreditation by MOLDAC from other Accreditation Body**

Taking over the accreditation of a conformity assessment body established on the territory of the Republic of Moldova, accredited by an European accreditation body, signatory of EA MLA/ EA BLA, IAF MLA or ILAC MRA, is made during the validity period of the existing accreditation certificate, so that:

- conformity assessment body submits to MOLDAC an application for initial accreditation;
- MOLDAC can take into consideration the information on previous accreditation, if those are made available (eg. the accreditation scope, the last assessment report, complaints, etc.) by the applicant for accreditation or by accreditation body that had accredited it;
- accreditation process is undertaken as in the case of initial accreditation, according to Accreditation Rules (code RA);
- accreditation certificate issued by MOLDAC has a validity period of 4 years from the date of its issue.

MOLDAC informs the accreditation body from Europe, signatory to EA MLA/ EA BLA, from which has taken the accreditation, on CAB' obtaining of MOLDAC's accreditation.

## **P-06 POLICY ON OUTSOURCING OF ASSESSMENT according to EA-2/13**

This policy establishes the way of outsourcing by MOLDC of an assessment or of a part of it, by other accreditation bodies which are EA MLA/ IAF MLA/ ILAC-MRA signatory, located outside Moldova's territory.

In the same time, it is established the way of subcontracting of MOLDAC by other accreditation body signatory to EA MLA, IAF MLA of ILAC-MRA.

### **1. Outsourcing of accreditation activities by MOLDAC.**

MOLDAC can outsource its activities to other accreditation bodies from Europe or outside the Europe.

If outsourcing is necessary, MOLDAC shall outsource only assessment activity.

MOLDAC do not outsource decision-making.

MOLDAC shall outsource only accreditation bodies which are signatory of EA MLA, respectively IAF MLA or ILAC MRA.

MOLDAC shall have competence to make decisions and remains responsible for outsourced activities and for made decisions.

Whenever MOLDAC outsource the assessment to another accreditation body, this must be done under the following conditions:

- assessment activities are conducted under a contract with the respective body, which shall contain arrangements, including those relating to confidentiality and conflicts of interests;
- to obtain written consent of the CAB to use a particular subcontractor;
- to use procedures and documents of the subcontracted body;
- the language used is mutually agreed with the subcontracted body;
- decision on accreditation is made by MOLDAC, which will inform the local accreditation body on the taken decision;
- costs are agreed between parts.

### **2. MOLDACs subcontracting by other AB**

In cases in which MOLDAC can be subcontracted by an accreditation body from outside Moldova's territory, for assessment of one location of one CAB established on Moldova's territory:

- activities are performed based on a contract or on a command. The template for the contract can be the one provided by EA secretariat, if applicable;
- MOLDAC rates are used according to calculation scheme for provided accreditation services, approved and annexed to Law nr.235 of 01.12.2011 (Annex nr.1);

- MOLDACs applicable documents are used, if there is no other arrangements made with the accreditation body which subcontracted MOLDAC;
- used language for assessment on Moldova's territory is, normally, Romanian language;
- assessment report is drafted in English;
- decision upon accreditation is taken by the accreditation body which subcontracted MOLDAC.

MOLDAC

## **P-07 POLICY ON TREATING THE OBJECTIONS OF CABs REGARDING ASSESSMENT TEAM MEMBERS AND OBSERVERS**

MOLDAC shall inform the conformity assessment body on the composition of the assessment team that will perform the assessment.

The conformity assessment body has the right to refuse one or more members of the assessment team, as well as the observers.

The conformity assessment body may object on designation of one or more members of the assessment team and observers with a justification such as:

- existing conflicts of interest that can be proven;
- it may be proven that they are not impartial;
- a previous incorrect behavior can be proven.

The conformity assessment body may refuse one or more members of the assessment team only in writing accordingly with article 16, align (2), point c) from Law 235/2011 with subsequent amendments.

MOLDAC analyzes each objected case and, when the objection is founded, appropriate measures are taken.

MOLDAC reserves the right to use, if necessary, assessors from foreign accreditation bodies. In this case, the costs are recalculated and are communicated in addition to CAB. MOLDAC implements the necessary measures to maintain the safety and security of foreign assessors during their stay on the territory of Republic of Moldova, as appropriate.

When in Communication Sheets on evaluation team members are included MOLDAC monitors, observers which include persons from the regulators, assessors from regional and international accreditation bodies, interpreters, CAB is obliged to accept their participation.

## **P-08 POLICY AND RULES ON THE USE OF ACCREDITATION SYMBOLS, OF ILAC-MRA COMBINED MARK, OF IAF-MLA COMBINED MARK AND REFERENCES TO ACCREDITATION according to EA-1/19, EA-3/01 and ILAC P8 and IAF ML2, IAF PL8**

### **1. National Accreditation Mark**

The National Accreditation Centre from Republic of Moldova (MOLDAC) is the owner of the National Accreditation Mark of Republic of Moldova under the Law no. 235/2011 with subsequent amendments.

National Accreditation Mark is a component of accreditation symbol and is described in annex 2 of Law no.235/2011.



If the mark has to be increased or decreased, it is necessary to respect the proportions given in Law no.235/2011.

MOLDAC use the National Accreditation Symbol on the accreditation certificates that it issues, according to Law no.235/2011 with subsequent amendments.

### **2. Accreditation Symbol**

MOLDAC accreditation symbol indicates that CAB is accredited and attests that this body has necessary competence to perform activities specified in accreditation certificate.

#### **2.1. Description on accreditation symbol**

Accreditation symbol consists of the following elements:

- national accreditation mark;
- reference standard;
- type of the CAB:
  - Testing Laboratory – LI
  - Calibration Laboratory – LE
  - Metrological Verifications Laboratory – LVM (OI)
  - Medical Laboratory –LM
  - Products Certification Body – OCpr
  - Quality Management Systems Certification Body – OCsms,
  - Food Safety Management Systems Certification Body – Ocsmsa
  - Inspection Body - OI;
- number of accreditation certificate.

Accreditation symbols for different types of CABs are included in Annex 2 to this document.

## 2.2. Use of national accreditation symbol

The National Accreditation Symbol applies only on:

- testing reports,
- calibration certificates,
- inspection reports/ certificates,
- medical examinations bulletins,
- metrological verifications bulletins,
- periodical checks bulletins,
- products conformity certificates,
- management systems conformity certificates.

The accreditation symbol shall be used by accredited conformity assessment bodies only for activities covered by the accreditation.

The accreditation symbol should not be ambiguous and in detriment to the MOLDAC image.

Thus:

- conformity assessment body shall not use the accreditation symbol together with other symbols (e.g. reference to ISO 9001 etc.);
- if the report or certificate issued by conformity assessment body include both accredited and non-accredited activities, then it must mandatory identify which are the activities covered by accreditation (e.g. "testing identified in the report with \* are accredited"). Therewith, those activities which are not covered by accreditation should not exceed 1/3 of all CAB activities indicated in report/ certificate.

The appliance of accreditation symbol is prohibited on:

- testing/ calibrations reports, medical analysis bulletins, metrological verifications bulletins, inspections/ conformity certificates if those are issued only to non-accredited conformity assessment activities;
- business cards, on promotional items (pens, diaries, calendars, etc.);
- website;
- products and packaging (excluding reference materials, tested samples, calibrated instruments and other reference materials);
- reports and certificates of CABs which have not yet received the accreditation, even if they are in the accreditation process;
- any other documents besides reports and certificates (accredited entity's letterhead, correspondence, invoices, quotations, advertising support, business or communication documents, other documents with technical, commercial or advertising character).

Symbols applied on reports/ bulletins/ certificates issued by CAB can be used in the original colors or black/white. The format for the application symbol on the document must be \*.jpg. The symbol should not be rotated. The symbol must be always used on a background that will not affect legibility and visibility.

In accordance with art.13 (7) of Law no. 235 of 01.12.2011 regarding the accreditation and conformity assessment activities, the accredited conformity assessment bodies are obliged to use on the issued documents the accreditation symbol for the services provided according to the accreditation field.

Accredited conformity assessment bodies are responsible for the way in which they use accreditation symbol, otherwise sanctions are applicable as set at point 7 of this policy.

### 3. Reference to accreditation status

The accredited entity whose MOLDAC gave the right to use accreditation symbol, through the Agreement on the use of accreditation symbols (code PR-04-F-52), may refer to accredited status, only for the scope for which accreditation was granted.

On any other documents, accredited entity can use reference to accreditation status through a text, like:

*"CAB is accredited according to the standard ....., for ..... (testing/ calibration/ metrological verification/ medical analysis/ products certification/ management systems certification/ inspection)".*

It is forbidden to use references to accreditation status (namely the phrase indicated above) on documents listed in chap.2.2 from above (for example conformity certificates, testing reports etc.).

The entity must state unambiguously the activity covered by accreditation.

Accredited conformity assessment bodies are responsible for the way in which they use the reference to accreditation status, otherwise sanctions are applicable as set at point 7 of this policy.

### 4. Reference to MOLDACs status of EA BLA or ILAC-MRA signatory or IAF-MLA

As signatory of EA Bilateral Agreement (EA BLA), of ILAC Mutual Recognition Agreement (ILAC-MRA) and of IAF Multilateral Recognition Arrangement (IAF MLA), MOLDAC indicates the information on its status on the Accreditation Certificate, as follows:

- MOLDAC National Accreditation Mark is combined with tagline – ***"MOLDAC is EA BLA signatory for ... (examples: testing, calibration, medical analysis, inspections, product certification, management systems certification)"***.
- Next to the MOLDAC National Accreditation Mark, it is applied **ILAC MRA Mark** for ***testing, calibration, medical analysis and inspection*** activities, according to ILAC R7.
- Next to the MOLDAC National Accreditation Mark, it is applied **IAF MLA Mark** for ***product certification, management systems certification***, according to IAF ML2.



## **5. The use by the accredited CAB of the reference to MOLDAC signatory status**

### **5.1. Use by the accredited CAB of the ILAC MRA combined Mark**

CABs, accredited by MOLDAC for calibration, testing, medical analysis and inspection activities, can use ILAC-MRA Combined Mark, which consists of: MOLDAC accreditation symbol together with ILAC-MRA mark. This combined mark must be accompanied by unique identification of accredited CAB.

An example in this respect is presented in Annex 3.

ILAC-MRA combined mark can be used by accredited CAB if the following conditions are met cumulatively:

- CAB is accredited by MOLDAC in the scope in which MOLDAC is ILAC-MRA signatory;
- CAB signs an agreement with MOLDAC regarding the use of ILAC-MRA combined mark.

After the agreement for use of ILAC-MRA combined mark is signed, MOLDAC gives to CAB the ILAC-MRA combined accreditation mark.

It is forbidden to use ILAC-MRA combined mark unaccompanied by the respective accreditation symbol.

ILAC-MRA combined mark shall be placed only on documents listed in chap.2.2 from above (for example inspection reports/ certificates, testing reports etc.), at the top of the document, near the CABs mark/ symbol.

It is forbidden for CAB to place ILAC-MRA combined mark on the top of the documents listed in chap.2.2 from above, near other symbols (for example the logo of certification body which certified CAB, symbols/ marks of other associations/ entities from which CAB is part of, etc.), except CABs mark/ logo.

It is forbidden for CAB to use ILAC-MRA combined mark during suspension period, after accreditation was withdrawn, after the expiration of the accreditation certificate or after the validity of the accreditation certificate has ceased following the cancellation of the accreditation standard.

Accredited conformity assessment bodies are responsible for the way in which they use the reference to accreditation status, otherwise sanctions are applicable as set at point 7 of this policy.

An example of ILAC MRA is shown in the Appendix to this document, PM-A-3 (P-08).

### **5.2. The use by the accredited CAB of the reference to MOLDAC status as signatory EA BLA**

Accredited CABs may only use the EA BLA signatory status of MOLDAC if the following conditions are met cumulatively:

- CAB is accredited by MOLDAC in the field for which MOLDAC is signatory of the EA BLA agreement;
- CAB signs an agreement with MOLDAC for the use of the statement referring to EA BLA signatory status of MOLDAC.

Accredited CABs may indicate on their supporting documents a reference to EA BLA signatory status of MOLDAC by including the statement "*MOLDAC is the signatory of EA-BLA for ... (Examples: tests, calibrations, medical analyzes, inspections, product certification, management systems certification*", as set out in the Annex to this document PM-A-3 (P-08).

MOLDAC allows the use of the references described in points 5.1 and 5.2 of this document by signing with the accredited entity the "Agreement on reference to MOLDAC signatory status" (code PR-04-F-52/1).

### **5.3. Use by the accredited CAB of the IAF MLA combined Mark**

CABs, accredited by MOLDAC for product certification, management systems certification, can use IAF-MLA Combined Mark, which consists of: MOLDAC accreditation symbol together with IAF-MLA mark. This combined mark must be accompanied by unique identification of accredited CAB.

An example in this respect is presented in Annex 3.

Accredited CAB can use IAF-MLA combined mark if the following conditions are met cumulatively:

- CAB is accredited by MOLDAC in the scope in which MOLDAC is IAF-MLA signatory;
- CAB signs an agreement with MOLDAC regarding the use of IAF-MLA combined mark.

After the agreement for use of IAF-MLA combined mark is signed, MOLDAC gives to CAB the IAF-MLA combined accreditation mark.

It is forbidden to use IAF-MLA combined mark unaccompanied by the respective accreditation symbol.

IAF-MLA combined mark shall be placed only on documents listed in chap.2.2 from above (for example inspection reports/ certificates, testing reports etc.), at the top of the document, near the CAB's mark/ symbol.

It is forbidden for CAB to place IAF-MLA combined mark on the top of the documents listed in chap.2.2 from above, near other symbols (for example the logo of certification body which certified CAB, symbols/ marks of other associations/ entities from which CAB is part of, etc.), except CABs mark/ logo.

It is forbidden for CAB to use IAF-MLA combined mark during suspension period, after accreditation was withdrawn, after the expiration of the accreditation certificate or after the validity of the accreditation certificate has ceased following the cancellation of the accreditation standard.

Accredited conformity assessment bodies are responsible for the way in which they use the reference to accreditation status, otherwise sanctions are applicable as set at point 7 of this policy.

An example of IAF-MLA is shown in the Appendix to this document, PM-A-3 (P-08).

## **6. Use of the EA, ILAC, IAF logo by MOLDAC**

According to the provisions of EA-1/19 document, MOLDAC may use EA logo only in the case when it has requested and obtained the written consent from the EA secretariat.

According to the provision of ILAC-R4 document MOLDAC may use ILAC logo only in the case when it has requested and obtained the written consent from the ILAC secretariat.

According to IAF PL8, MOLDAC may use IAF logo only in the case when it has requested and obtained the written consent from the IAF secretariat.

## **7. Sanctions imposed to conformity assessment bodies for misuse of the mark/ accreditation status**

MOLDAC can immediately suspend accreditation of CABs, for respective field, in case is ascertained the abusive use of accreditation symbol or of the reference to accredited status by it.

During the suspension, CAB has no right to use the neither accreditation symbol nor reference to accreditation status. Otherwise, MOLDAC will withdraw accreditation.

In the period between two assessments, if MOLDAC ascertains or is informed by various means about the abusive use of accreditation symbol or of reference to accreditation status by the conformity assessment body, it may perform an extraordinary assessment, focused on this aspect.

The conformity assessment body has no right to transfer the right to use the accreditation symbol granted by MOLDAC to other accredited conformity assessment body or to his client.

The accreditation body takes effective measures to ensure that accredited conformity assessment body:

- fully comply with MOLDACs requirements regarding its status of accredited conformity assessment body, when referring to its accreditation in mass-media and other means of communication such as the internet, documents, brochures or advertising, etc.
- uses the accreditation symbols exclusively for conformity assessment body's locations that are explicitly included in the accredited scope;
- makes no statements on its accreditation, which MOLDAC could consider misleading or not permitted;
- ensures that any justifying document issued by CAB or parts thereof are not used in a misleading manner;

- at the moment of suspension or withdrawal of accreditation (for whatever reason), discontinue its use in all advertising materials containing references to accredited body status;
- does not allow accreditation to be used to imply the fact that a product, process, system or person is approved by MOLDAC;
- inform affected customers of the suspension, restriction or withdrawal of accreditation and associated consequences.

MOLDAC shall take appropriate action to treat the incorrect references to accredited body status, or misuse of accreditation symbols in advertisements, catalogues etc., thus:

- require corrective actions,
- suspend accreditation and publication of it,
- withdraw the accreditation and publication of it,
- take legal actions.

### **Annexes**

Annex PM-A-2 (P-08) – Accreditation symbols for different types of CABs

Annex PM-A-3 (P-08) – Example of ILAC-MRA and IAF-MLA combined marks for CAB.

## **P-09 POLICY ON IMPARTIALITY, MANAGING CONFLICTS OF INTEREST AND ENSURING OBJECTIVITY IN ACCREDITATION ACTIVITY**

National Accreditation Center (MOLDAC) is designated as unique, national accreditation body, which does not subordinate to any public authority, and has an experience since 2004 in accreditation of conformity assessment services.

MOLDAC has strengthened its position and obtained the status of signatory to EA BLA, ILAC-MRA and IAF MLA, which demonstrates its competence, impartiality, independence, credibility and transparency of the accreditation services provided according to Regulation (CE) 765/2008 and Law no.235/2011 requirements, as well as requirements of EN ISO/IEC 17011:2017 standard, and of applicable EA, ILAC, IAF documents.

MOLDAC provides accreditation services, which conform to clients' needs, for competence recognition for performed conformity assessment services, as well as for issued certificates and reports, by creating an open collaboration environment with accredited applicants and stakeholders.

MOLDAC is responsible for impartiality of its accreditation activities, and does not permit any commercial, financial or other kind of pressures to compromise its impartiality.

Entire personnel and all members of committees of MOLDAC, which can influence accreditation process, acts in an objective manner and is not subjected to any kind of commercial, financial or other kind of unjustified pressure, which could lead to compromise impartiality. MOLDAC assures itself, by signing of Commitment to impartiality statement, that entire personnel and all members of committees reveal any kind of potential conflict of interests, whenever it may appear.

MOLDAC operates its activity based on fundamental principle that the accreditation service must provide confidence to all interested parties and relevant market players the representatives of which are involved in Accreditation Council and in Technical Committees.

MOLDAC ensures a balanced representation of interested parties in the committees, without predomination on one interest.

Ensuring impartiality and credibility of issued accreditations lean also on transparency regarding access of interested parties to adequate information which should be made publicly available such as: "Insufficient control mechanisms" information, namely:

- publicly available documents regarding accreditation process (policies, criteria, rules, etc.);
- application opportunities for accreditation which comply with activity and declared competence, without taking into account the CABs size, membership of an association or group, number of CABs already accredited;
- identical contractual conditions for all clients;
- accreditation costs according to "Calculation Scheme for payments and accreditation services", provided by Annex 1 of Law no.235/2011;
- process requests according to the approved procedure;
- Register of accredited CABs with their accreditation scopes.

MOLDAC makes available to the public through publications, electronic means (MOLDACs website, Twitter, Facebook etc.) or other means, and updates at appropriate intervals information regarding its activity, as well as regarding modification of accreditation requirements.

MOLDAC services are accessible to all applicants whose applications for accreditation fall within the scope of its accreditation activities as defined in its policies and rules. The policies, processes and procedures of the accreditation body are non-discriminatory and applied in a non-discriminatory manner.

MOLDAC ensures impartiality in decision-making as well. Taking into consideration of the proposal of the assessment team members and on the Commission's opinion on Recommendation of Accreditation, the decision is made based on all information related to assessment, without being influenced in any way. The decisions regarding accreditation are taken by persons who are not involved in the evaluation process.

Within MOLDAC has been established a process of identifying, analyzing, evaluating, treating, monitoring and documenting of risks that could affect the impartiality of the entire accreditation activity, including any conflicts arising from its relationships; this process was implemented, maintained and further improved. Where there are threats to impartiality, it is documented how these risks are eliminated or minimized and any residual risk documented. Management at the highest level analyzes any residual risk to determine whether it is at the acceptable risk level. If there is a risk of impartiality that cannot be minimized or eliminated, accreditation may not be granted or may be withdrawn.

MOLDAC regularly presents to the Accreditation Council the outputs of risk analysis that has been conducted, including relations with related bodies (through joint ownership). Impartiality in this case is ensured by observing the following principles: total separation and independence of MOLDAC from any other body, including top leadership, decision-makers and technical personnel, effective mechanisms to prevent any influence on the outcome of any accreditation activity, as well as the use of distinct names, logos and symbols.

MOLDAC does not provide consultancy services to its clients or conformity assessment services which are subjected to accreditation, to avoid an unacceptable risk of impartiality. MOLDAC does not suggest to any CABs that accreditation would be simpler, easier, faster or less expensive if certain consultancy or specific advice were used by the applicant.

## THE COMMITMENT OF TOP MANAGEMENT TO IMPARTIALITY

Aware of the importance of impartiality in carrying out the accreditation activities of the National Accreditation Center from Republic of Moldova (MOLDAC), we are committed to ensuring the accreditation body's impartiality for carrying out an impartial accreditation process by complying with the policies and procedures of the accreditation body.

MOLDAC Director

Eugenia SPOIALĂ

MOLDAC Deputy Director

Larisa NOVAC

## SYNTHESIS OF CHANGES

This document was revised in order to be aligned with EN ISO/IEC 17011:2017 requirements.

Modifications are indicated in text with blue font.

Changes included on the pages: [1](#), [8](#), [9](#), [24](#), [32](#).