



NATIONAL ACCREDITATION CENTRE

ACCREDITATION RULES

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

1 PURPOSE

This document described rules for accreditation of Conformity Assessment Bodies.

2 SCOPE

This document applies to all conformity assessment bodies, both to those seeking accreditation, and to those accredited.

3 REFERENCE DOCUMENTS

- Regulation (EC) 765/2008 of the European Parliament and of the Council of 09.07.2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93
- Law no. 235 of 01.12.2011 on accreditation and conformity assessment activities with subsequent amendments.
- Government Decision from 77 of 25 January 2013 on the reorganization of the State Enterprise "Centre of Accreditation in the field of Products Conformity Assessment" with subsequent amendments.
- SM EN ISO/CEI 17011:2017 - Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies
- Applicable EA, ILAC, IAF documents, according to General Criteria for Accreditation code CA.
- Internal documents of MOLDAC Management System.

4 DEFINITIONS AND ABBREVIATIONS

4.1 Definitions

This document uses definitions from:

- Law no. 235 of 01.12.2011 on accreditation and conformity assessment activities with subsequent amendments.
- SM SR EN ISO/CEI 17000:2006 - Conformity assessment. Vocabulary and general principles.
- SM EN ISO/CEI 17011:2017 - Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies
- SM SR EN ISO 9000:2016 – Quality Management Systems. Basic principles and vocabulary.

4.2 Abbreviations

ONA	National Accreditation Body
CAB	Conformity Assessment Body
SM	Management System
LÎ	Test Laboratory
LE	Calibration Laboratory
LVM	Metrological Verification Laboratory
LM	Medical Laboratory
OI	Inspection Body

OCpr	Product Certification Body
OCprec	Ecologic products Certification Body
OCsmc	Quality Management Systems Certification Body
OCsmsa	Food Safety Management Systems Certification Body
OCsmm	Environmental Management Systems Certification Body
OCsi	Information Security Management Systems Certification Body
OCso	Occupational Safety Management Systems Certification Body
OCp	Personnel Certification Body
OPT	Proficiency Testing and Inter - Laboratory Comparison Organizer
PT	Proficiency Testing
ILC	Inter-Laboratory Comparison
ŞDA	Head of the Accreditation Department
EvŞ	Lead Assessor
ŞE	Team leader
CRA	Commission for Recommendation of Accreditation

5 MOLDAC – SHORT HISTORY

5.1 General information about MOLDAC

Name:	National Accreditation Center (MOLDAC)
Fiscal code:	1003600086372
Address:	1 Vasile Alecsandri str., mun. Chişinău
IBAN:	MD36MO2224ASV67245277100
Bank:	BC Mobiasbancă – Groupe Societe Generale SA, c/b MOBBMD22
Phone number/ fax:	+373 22 210 316
E- mail:	acreditare@moldac.gov.md

National Accreditation Body is a legal entity, based on its governmental status. Initially was created by Law no.186-XV of 24.04.2003 regarding conformity assessment of products, as well as by Government Decision no.1646 of 31.12.2003 regarding creation of accreditation system in the conformity assessment of products' area. State Enterprise "Accreditation Center in the Field of Products Conformity Assessment" (CAECP) was designate as Unique Accreditation Body. CAECPs statute was approved according to the Decision no.38 of 28.06.2004 issued by the Ministry of Economy and Trade.

By Law no.235 of 01.12.2011 regarding accreditation and conformity assessment activities, National Accreditation Center, with the acronym MOLDAC, was designate as unique accreditation body.

According to the Law no.235 of 01.12.2011 regarding accreditation and conformity assessment activities with subsequent amendments – MOLDAC is a public institution, monitored by the Ministry of Economy and Infrastructure, non-commercial and acts in a non-profit way. Accreditation activity its an activity of public authority, officially recognized, and is done by MOLDAC.

Trough GD no.77 of 25.01.2013, State Enterprise "Accreditation Center in the Field of Products Conformity Assessment" was re-organized by changing in Public Institution "National Accreditation Center from Republic of Moldova" (MOLDAC) and was approved the Regulation on organization and function of National Accreditation Center.

5.2 International recognitions

In order to demonstrate compliance with criteria established in ISO/IEC 17011 standard, MOLDAC is subject to Peer Evaluations, organized by European Cooperation for Accreditation (EA), which is recognized by European Commission as European infrastructure of accreditation, according to the article no.14 of Regulation (CE) no.765/2008 of the European Parliament and of the Council of 09.07.2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, after consultation with the Member States.

MOLDAC is the signatory to the Bilateral Agreement with EA (EA BLA) for the following schemes:

- Testing, including medical testing,
- Calibration,
- Inspection,
- Certification of products,
- Certification of management systems.

MOLDAC is signatory to Mutual Recognition Arrangement ILAC-MRA for the following schemes:

- Testing,
- Calibration,
- Medical examinations,
- Inspections.

6 ACCREDITATION CRITERIA

MOLDAC provides accreditation services to CABs according to the General Accreditation Criteria code CA, which are mandatory for CABs.

The General Accreditation Criteria, code CA, are those presented in the relevant normative documents for the CABs operation, reference standards, European and International Organizations EA, IAF, ILAC documents and the provisions of this document.

MOLDAC accredits:

Table no. 1

CAB	CAB Code	Accreditation Scheme	Referential for accreditation
Laboratories	LI	Testing Laboratories	ISO/CEI 17025
	LE	Calibration Laboratories	ISO/CEI 17025
	LM	Medical Laboratories	ISO 15189
Inspection Bodies	OI	Inspection Bodies: <ul style="list-style-type: none">- Inspection bodies- Metrological verification laboratories (type A)	ISO/IEC 17020

CAB	CAB Code	Accreditation Scheme	Referential for accreditation
Certification Bodies	OCpr	Product Certification Bodies	ISO/CEI 17065, National legislation
	OCprec	Ecologic products Certification Bodies	ISO/CEI 17065, National legislation in the field of ecologic products
	OCsmc	Quality Management System Certification Bodies	ISO/CEI 17021-1, ISO/CEI 17021-3
	OCmsa	Food Safety Management Systems Certification Bodies	ISO/CEI 17021-1, ISO/TS 22003

If one of the accreditation reference documents is reviewed or a new accreditation reference document is issued, MOLDAC automatically adopts changes to its criteria and gives customers a reasonable time for transition, according to the Informative Documents published on the website www.acreditare.md.

Adoption of the new conditions for accreditation is made by MOLDAC in consultation with stakeholders.

MOLDAC informs all stakeholders on the following:

- Establishment of changes in the accreditation conditions;
- The complexity of changes occurred;
- Justification of changes occurred;
- MOLDAC policy on transition to the new conditions;
- Way of action for achievement of transition;
- Transition periods decided by MOLDAC.

MOLDAC ensures the necessary human resources for the transition to the new accreditation conditions. Already accredited CABs will be able to upgrade to new versions of the standards on surveillance assessment, to reassessment or additional assessment, according to provisions set out in the Informative Documents, published on the website of MOLDAC.

Already accredited CABs will send to MOLDAC transition plans to new versions of standards for being analyzed by Lead Assessors and if necessary to identify those elements of the standard, which have been interpreted insufficiently by CABs, to establish jointly on deadlines for the transition process, not exceeding the limits established at European and international level.

MOLDAC may decide to extend its field of competence to other accreditation schemes in accordance with international standards included in the list of reference standards approved by the Ministry of Economy and published on the MOLDAC website.

MOLDAC policy and procedures for the extension with new schemes, new specific sectorial standards, new sector schemes, new schemes of conformity assessment, new standards or normative documents used by the CAB are described in General Criteria for Accreditation (code CA) as well as in procedure Establishment of Accreditation schemes (code PR-06).

7 REQUIREMENTS FOR THE PROCESS

7.1 Accreditation requirements

Applicants for accreditation must obey continuously criteria defined in reference standards for accreditation, in EA, IAF, ILAC documents, in national legislation, in the MOLDACs management system's documents applicable for the area for which accreditation is requested, of for which it was granted.

Customization of accreditation criteria is made by MOLDAC within General Criteria for Accreditation document (code CA), which is available on MOLDACs web-page.

If there are some explanations requested regarding documents mentioned above, for a specific accreditation scheme, those are formulated by MOLDACs personnel which have necessary competence.

CAB, upon request from their clients, can request for accreditation of conformity assessment activities (testing, inspection and certification of product) which is developed according to cancelled normative documents. In this case, CAB shall identify cancelled normative documents with mention "ANULAT" (from Romanian - cancelled) in the Requested Accreditation Scope template (code PR-04-F-37-OEC) and submits it to MOLDAC.

7.2 Application for accreditation

MOLDAC explains and makes available folders with documents for each accreditation scheme, on order to facilitate the access of all his clients, on the web-page www.acreditare.md

Each document contained by folders for each accreditation scheme is included in List of Folders and documents for CAB – annex 2 of this document.

MOLDAC informs CAB which seeks accreditation regarding the following:

- MOLDAC policies, General Criteria for Accreditation, Rules for Accreditation, Reference Documents for each accreditation scheme (code DR), the payment scheme for accreditation services, each of accreditation steps as well as related documents,
- Set of documents and related templates, according to the annex to the application for accreditation List of submitted documents by CAB for accreditation according to the annex to the application for accreditation (code PR-04-F-9), and according to the annex for extension of accreditation List of submitted documents by CAB for extension (code PR-04-F-9/e).

In cases in which applicant for accreditation requests a pre-calculation of the costs, MOLDAC offer this pre-calculation, after CAB submits all necessary information for calculation to be made> number of personnel, number of locations and specific scope according to accreditation scheme (for example for certification of products – number of NC codes of four numbers, for ecological products – number if categories, etc.)

CAB submits to MOLDAC Application for Accreditation (code PR-04-F-1), accompanied by the annex to application for initial/re- evaluation (code PR-04-F-9), or for extension (code PR-04-F-9/e), which contains documents/ records which CAB must submit, accordingly to accreditation scheme for which accreditation is seek. In the same time, are submitted other relative documents which are necessary for the accreditation scheme, including Self-

assessment Report (code PR-04-F-30/2-OEC) in which it presents information that accreditation requirements are approached before the beginning of the assessment.

In the case of remote assessments, upon MOLDAC **request**, the CAB shall also submit the necessary information according to the Annex to the Communication Sheet, code PR-04-F-17/1.

The delegate authorized by CAB submits at MOLDACs headquarters the application for accreditation, which has to be signed and stamped by the legal representative from the organization from which CAB is part of.

CAB must inform MOLDAC regarding other accreditations in force, granted by other accreditation bodies for this scheme. This must be indicated in application for accreditation.

MOLDAC analyses information provided by CAB. If folder is not complete, is requested in written for missing information to be submitted within at most 10 working days from the day of notation. Otherwise, request is cancelled and the process can start upon new request.

MOLDAC analyses information provided by CAB, for determination of its compliance with intended purpose of accreditation/ renewal of accreditation and takes decision upon it. At any time in the process of initiating the request, in cases there are evidences of fraudulent behavior, or if CAB gives false information in deliberative way, hides information, MOLDAC can refuse the application and stops the accreditation process.

At the time of submitting the application for initial/ renewal of accreditation or in cases of extension for a new method/ measure or for a new scope, laboratories/ inspection bodies (OI, NDT, LVM) must obey MOLDAC Policy regarding use of Proficiency testing and inter-laboratory comparisons in accreditation process (code P-02).

In cases when an accredited CAB requests for a change of accreditation from one reference standard to another (for example: from ISO/IEC 17025 to ISO/IEC 17020), CAB will submit another application for initial accreditation, accompanied by a set of documents appropriate to new scheme, according to the reference standard. MOLDAC will take in consideration previous experience of the accredited CAB (for example: will exclude preliminary visits, calculating the time spent at the locations and the cost, etc.).

In cases in which, after application for accreditation was submitted, but before the preparation process has started, CAB requests a modification of accreditation scope, it is necessary they request the modification of scope in written, only once, and must submit to MOLDAC the filled in template code PR-04-F-2-OEC, from which will result changes made. In this case, MOLDAC recalculates accreditation costs and informs CAB.

In cases in which CAB requests accreditation for the purpose of recognition, this will be indicated in the accreditation request. In the same time with application for accreditation, CAB will submit the application for recognition.

7.3 Resources review

7.3.1 The proper analysis

MOLDAC Director, along with ŞDA, analyzes the application for accreditation, following aspects being verified:

- MOLDACs capability to perform the CABs assessment according to policies, procedures, its competences defined in MOLDACs Competence Area (code MSM-A-2),
- availability of assessors and experts related to requested area, according to Field of competence Coverage of MOLDAC (code PR-03-F-30-OEC), including the availability of personnel involved in recommendation of decision for specific fields;
- capability of performing the initial assessment in due time (accreditation process takes regularly at most 2 years). Case by case, MOLDAC can extend the period for resources analysis in cases of new accreditation schemes.

Based on resource analysis, MOLDAC decides whether to accept the application or not and informs in writing the CAB.

In cases in which CAB provides conformity assessment activities in other countries, MOLDAC can outsource the assessment, according to its Policy on outsourcing of assessment (code P-06), on which CAB is noted.

In cases in which there is an application from a CAB, with the legal representative registered in other country, MOLDAC accepts this application only according to art.14 from Law no.235/2011 with subsequent amendments.

In cases in which application is from a CAB accredited by other NAB, which is signatory to EA MLA or EA BLA and/or IAF MLA and/or ILAC MRA, from the country in which CAB is legally registered, MOLDAC accepts the application, but during the accreditation process is taken into account previous accreditation of the CAB, according to point 4 of Policy on cross-border accreditation (code P-05).

For accreditation in the regulated field, according to the national technical regulations, MOLDAC informs the regulator regarding the receipt of the application of accreditation from the CAB and may invite its representative to take part at any stage of the accreditation process.

This provision is not applicable if the Technical Regulation does not require the recognition of the CAB.

This stage is finished with one of following decisions:

- a) Acceptance of application – in this case MOLDAC informs CAB regarding the acceptance of the application and the named Lead assessor for this case;
- b) Refusal of application – in this case MOLDAC informs CAB regarding reasons which led to refusal of application.

7.3.2 Accreditation contract

Accreditation contract is concluded after the acceptance of the application for accreditation, the template for the Contract is available on MOLDACs web-page www.acreditare.md

Accreditation contract, edited in 2 copies, signed by legal representative of the organization, is submitted to MOLDAC, in order to be signed by MOLDAC Director. After it was signed, one copy is returned to CAB. Accreditation contract comes into force after it was signed on both sides, beginning with the date of its registration in MOLDAC, and finishes on the expiry date of the accreditation certificate.

After application was analyzed and accepted, based on the information submitted by the applicant, MOLDAC sends to CAB calculation of accreditation cost, which includes the total number of days and the cost calculated in accordance with the scheme for calculating the payment for accreditation services - Annex 1 to Law 235/2011.

The accreditation process continues only after signing of the accreditation contract and payment by CAB of the complete or partial fees calculated by MOLDAC.

According to the contractual provisions (chap. 9 “FORCE MAJEURE”) MOLDAC decides to carry out the remote assessment only if the CAB complies with the conditions above.

Accreditation contract is not negotiable, its provisions are the same for all CABs seeking accreditation or which is accredited and if changes are made; then an addendum covering changes is signed.

In accordance with the document: “Joint ILAC–CIPM Communication regarding the Accreditation of Calibration and Measurement Services of National Metrology Institutes 7 March 2012”, in the case when the calibration laboratories are accredited under INM, these will not use the accreditation granted to support participation at key comparisons and supplementary within CIMP MRA.

7.3.3 Preliminary visit

After contract was signed, for initial accreditation, MOLDAC can start the assessment process with a preliminary visit, if CAB agrees.

The purpose of the preliminary visit is:

- to obtain/ confirm some information regarding to CABs management system (structure, personnel etc.);
- the adequacy on the CABs location;
- to obtain/ confirm some information for the assessment plan elaboration;
- to establish the scope to be subject to accreditation;
- to establish the necessary competence in the assessment team;
- to establish the amplitude and the depth of the evaluation and if the CAB is prepared for accreditation.

Preliminary visit can be conducted only once for one CAB.

The payment for the preliminary visit does not depend on the outcome of the visit. The next stage will start only after the deficiencies identified are solved accordingly to the terms indicated in Annex 1 of this document (code RA-A-1).

CAB shall inform MOLDAC by letter about elimination of deficiencies identified during the preliminary visit.

7.4 Preparation for assessment

7.4.1 Appointment of assessment team

The assessment team consists of a Lead Assessor, and an appropriate number of assessors, technical assessors, if necessary technical experts, so that the entire area of competence proposed for assessment is covered. In cases in which CAB has more than

one location, MOLDAC can name a Team Leader, which has the responsibility for the management of the assessment.

At the appointment of the assessment team members are taken into account the criteria of competence for MOLDAC personnel involved in the accreditation process set out in the Annexes to the procedure Selection, training, authorization and monitoring of the personnel involved in the accreditation process, Code PR-03.

If the laboratory performs internal calibration, these will be assessed at the stage of document review and on-site assessment, and in the assessment team will be included technical assessors and technical experts for the internal calibration indicated in the Application for accreditation.

7.4.2 Communication of the team

Communication of the team is realized with enough time prior the date of assessment, not taking into consideration the assessment's type (on site, witness etc.), acceptance from the CAB being requested.

In some cases, the assessment team may include assessor under training and/or it may be accompanied by monitors, observers, if necessary.

For recognition purpose within regulated area, MOLDAC can invite a representative from regulators to participate as observer in MOLDACs assessment team, at initial assessment or assessment for extension purpose, or for an extraordinary visit. Upon request of regulators, within assessment team can be invited a representative as an observer for reassessments or surveillances.

CAB is informed in advance about the composition of the assessment team, to allow objection to the designation of certain team members or observers.

If the CAB does not agree, it may object with arguments de designation of one or more team members only if:

- there are conflicts of interest that can be proven;
- lack of impartiality can be demonstrated;
- a previous incorrect behavior can be demonstrated.

Refusal can be made only in written, according to art.16 par.(2) point c) of Law no.235/2011 with subsequent amendments; CAB must indicate objective reasons which lead to this. In this case CAB assumes the risk of process delay in accordance with established timetable. MOLDAC reserves the right to use, if necessary, assessors from foreign accreditation bodies, with recalculation of accreditation costs; costs are to be communicated additionally to CAB.

The objections regarding the composition of assessment team is done only in writing and not more than twice.

CAB can refuse the observer, in the same way as for the team member/s.

Final decision regarding assessment team composition belongs to MOLDAC.

MOLDAC analyzes each case of refusal and takes appropriate action in accordance with the Policy on handling CABs objections on assessment team members (code P-07).

In cases in which there are some modifications for the named assessment team, these are communicated to CAB, with an approval being requested.

7.4.3 Tasks of the Assessment team

MOLDAC defines the tasks for each member from the assessment team.

7.4.4 Preparation of CABs competence assessment

MOLDAC evaluates the competence of a CAB, for all activities within its accreditation scope, not taking into consideration the place in which activities are developed. The scope of one applicant is evaluated by use of a combination on-site evaluation and other evaluation techniques, as those mentioned at point 7.6.1. of this document.

In exceptional cases, MODLAC can use remote assessment, which provides evaluation of physical location or of virtual location of a CAB, by use of electronic means.

This method can be used by MOLDAC when all records are available prior and during the assessment, such as access to files and records, possibility to use electronic means, interviewing through electronic means or other methods provided by IAF MD 4:2018 document, in cases in which:

- One or more members of assessment team are out of the country and cannot physically participate in assessment for justified reasons,
- when extreme climatic conditions cannot allow the team to travel and the assessment cannot be postponed for good reason,
- other cases.
- when it is necessary to comply with the provisions of the Commissions for Exceptional Situations of the Republic of Moldova, or of the country where the assessment is expected (for example: war, strike, riots, political instability, geopolitical tension, terrorism, crime, pandemic, floods, earthquakes, hacking-malware, other natural or man-made disasters.).
- the remote assessment may be carried out only on condition that:
 - the assessment was coordinated preventively with the CAB.
 - the CAB has the necessary infrastructure (is endowed with all the electronic means of communication/ facilities necessary to carry out the remote assessment), they are able to ensure an online assessment and have the possibility to use them without interruption.
 - all CAB records are available to MOLDAC, before and/or during the assessment (for example access to records and, where appropriate, to files).
- the assessment should be performed only on those CABs which:
 - during the previous year, including recently there were no complaints or confirmed appeals,
 - have a history of non-conformities at the location to be assessed, namely: previous assessments showed positive results (lack of critical non-conformities and lack of non-conformities which is repeated from year to year),
 - have obtained positive results in the last 2 years for PT/ILC participations, and in the previous cycle they covered the whole field of accreditation through PT/ILC participations, ensuring on ongoing matter the traceability of the measurements, if applicable;
 - ensures compliance with the plan of witnessed assessments, if applicable;
 - comply with its own Surveillance Programs, if applicable,
 - etc.

- The CAB has demonstrated traceability for the compliance of records at the location that is subject to remote assessment.
- The level of risk associated with the assessment is minimal for NAB.
- An activity or activities planned for on-site assessment cannot be fully carried out, and extending on-site assessment is not the best solution.
- The situation requests for the assessment team to return for a follow-up assessment, but another visit is not easy to be organized in a short time.
- CABs that have not submitted relevant changes to MOLDAC, compared to the conditions under which the accreditation was granted/ maintained, such as: legal, commercial, property or organizational status; organization, top management and key staff; main policies; resources and locations; other elements (normative documents), which could affect the CAB's ability to meet the accreditation requirements and whether the CAB informed these changes by a letter sent at most with 2 months in advance.
- For CABs with many locations, MOLDAC may decide not to visit all sites if, during the previous assessment, the CABs have demonstrated positive results (lack of non-conformities) and the activities performed by the CABs are of low risk. In this case, MOLDAC performs the remote assessment for one site, if it is efficient. However, each location included in the scope of accreditation will be assessed at the premises at least once during the accreditation cycle.
- The subsequent assessment at the CAB's headquarters will be broader, planning to cover the accreditation area at least 50% of the conformity assessment activities included in the Annex to the Accreditation Certificate.
- The remote assessment will be performed by at least two assessors from the MOLDAC staff (with different grade Lead Assessor and Assessor/ Technical Assessor).

The remote assessment can be performed for the purpose of:

- surveillance
- follow-up assessment (Closing non-conformities),
- extension with minor impact,
- re-assessment, if the CAB has a small field of activity,
- preliminary visit prior initial accreditation.

7.4.5 How to sample CAB activities

The way of sampling of CAB activities which has to be assessed, as well as determining of assessment type is established according to MOLDAC documents:

- a) Sampling for Laboratories and Inspection bodies, code I-01 (LI, LE, LVM, LM, OI/NDT),
- b) Sampling for Certification and Inspection bodies code I-02 (OCpr, OCprec, OCsmc, OCmsa, OI).

7.4.6 Selection of activities which are to be assessed based on risk

Prior sampling, assessment team takes into consideration the associated risk with activities, locations and personnel covered by accreditation scope, which is described in Instructions for Sampling for each accreditation scheme.

Depending on risk associated to sampling of CAB activities, assessment techniques are established according to Sampling Instructions.

7.4.7 Assessment plan

MOLDAC draws the Assessment plan which include: assessment period, assessment activities, locations in which activities will be assessed, personnel to be assessed, assessment techniques to be used, taking into account Assessment Program, in such way, that during an accreditation cycle, all CAB personnel would be assessed, (so that the entire scope requested for accreditation would be covered), as well as all locations for which accreditation was requested.

For assessment planning are taken into consideration the activity by seasons/ working shifts of CAB.

Assessment plan is drawn based on findings raised after review of documents and records, as well as based on sampling according to applicable MOLDAC documents and taking into consideration the results of previous assessment. The requirements of the accreditation standard, taking into account the risk analysis as described in section 7.9.2 of this document, will also be assessed.

Assessment plan is quite flexible to provide possibility in changing of planned assessment activities.

For Certification Bodies, the CB must inform in writing the Lead Assessor regarding its clients in order to organize the witnessing assessments. MOLDAC also is planning the attendance at the simulated assessments made by CABs staff for the regulated area.

If the testing laboratory performs internal calibration, the calibration procedures will be evaluated.

7.4.8 Communication of plan to CAB

MOLDAC decides with CAB the period for assessment and the assessment plan.

According to the Accreditation Contract, by confirming the plan, CAB is obliged to ensure all conditions for assessment development according to the assessment plan (for example: proper functions of the equipment were appropriate, availability of documents and records, availability of personnel, etc.).

CAB will ensure MOLDACs personnel, where applicable, with trainings regarding safety and provision of appropriate equipment.

7.4.9 Assuring the evaluation team with documents, records

MOLDAC assures the assessment team with suitable documents, upon necessity records from previous assessments as well as appropriate tools for assessment of CAB according to the accreditation scheme [and the used assessment technique \(for example: in case of remote assessment, providing the assessment team with documents/ records electronically\)](#).

7.5 Review of documented information

After CAB pays the fee for the review of documented information, MOLDACs assessment team reviews the CAB documents and records to ascertain compliance with reference standards and accreditation criteria.

If nonconformities were found during documents review, those are sent/ communicated to CAB.

For non-conformities which have a major impact on CABs activity, MOLDAC requests CAB to submit the amended documents as proof of nonconformities closure, in the terms set out in the Stages of accreditation- Appendix 1 to this document.

In cases in which after documents review presented repeatedly by CAB, the raised non-conformities continue to have a major impact on CAV activity, MOLDAC has the right to take the decision of interruption of accreditation process. In this case accreditation process stops, contract is cancelled and CAB is informed.

For resumption, CAB must submit another application for accreditation and to pay another fee for initiation and review of documented information, but not prior 6 months after the date of contract cancellation.

The documents can be presented at the MOLDAC headquarters on hard copy or electronically, or by performing Cloud access to the CAB documents and records.

In cases when review of assessed documents and records reveals conformity with accreditation requirements for requested scope, is passed to the next stage.

7.6 Assessment

7.6.1 Assessment techniques

In order to perform an assessment, MOLDAC uses, but does not limit to, following assessment techniques:

- on-site assessment – assessment which is performed within CAB location/ locations, for determination of its compliance with requirements of reference standard.
- remote assessment – assessment of a CAB by use of electronic means.
- witness assessment – witness by MOLDAC of a CAB which performs conformity assessment activities within its accreditation scope, in order to collect objective evidences on CAB compliance with requirements for requested/ accredited scope.
- document review – conformity assessment of CAB documented information with relevant to accreditation requirements.
- File analysis – assessment of clients' files (vertical assessment/ by records), for determination of its compliance with process requirements.
- measurement audits – measurement activities which are performed as a part of a specific assessment for accreditation, which are not considered integral part of on-site assessment (see MOLDAC Policy code P-02).
- analysis of performance during proficiency testing and other inter-laboratory comparisons.
- unannounced visits – in cases in which CAB manifest a fraudulent behavior, provides false information, when there are established requirements by law, others like: information from mass-media, from the market-place, etc.
- interview – is a way to collect information from interviewed persons.

Findings from assessment are registered by MOLDAC in Management System's templates and are presented to CAB.

Number of assessment days at CAB location/ locations is established by MODLAC based on a risk-based analysis, which takes into account, for example, size of the CAB, the complexity of accreditation scope, type of assessment etc.

7.6.2 Opening meeting

Assessment starts with an opening meeting, during which the Assessment Plan is approved, as well as assessed scope; also being well defined the assessment purpose, accreditation criteria, and [used assessment methods \(for example remote assessment\), etc.](#)

CAB's top management, or a designated person from top management must be mandatory be present at least during opening and closing meetings.

During this meeting, CAB is informed regarding situations in which assessment can be interrupted by lead assessor/ team leader, for example when:

- a) CAB staff/ personnel is exerting pressure/ menace of any kind on assessment team members;
- b) no proper assessment conditions (logistics) are provided;
- c) CAB representatives do not cooperate with the assessment team;
- d) CAB representatives do not provide evaluation team requested records;
- e) CAB does not accept the non-conformities found by the assessment team following the on-site assessment, etc;

or in any other situations which prevents a coherent assessment.

7.6.3 Realization of assessment plan

Lead assessor/ Team leader can modify the tasks of assessment team's members, during the assessment, if it is required, and CAB is informed about it.

In cases in which assessment team decides interruption of the assessment, this is recorded in closing meeting's minutes, which is signed by assessment team and CAB representatives. Mentioned situation is subsequently analyzed within MOLDAC, and CAB is informed in written regarding the follow up or interruption of the process.

7.6.4 Proper assessment

MOLDAC assessment team assesses the CAB competence according to assessment plan.

During the assessment, assessment team members will assess the implementation of the management system and CAB competence through analysis of documented information, which demonstrates its competence for the entire requested scope, including for all locations, for which accreditation is requested.

Assessment team will assess if CAB respects all requirements established in reference standard, CAB MS documents and MOLDAC applicable documents for accreditation scheme.

In cases in which it is demonstrated that CAB did not provide proper conditions for assessment team to conduct the assessment (for example: delay in providing of requested records by assessment team, personnel requested by assessment plan does not attend

the assessment, etc.), CAB will support the consequences regarding the delay of accreditation process.

7.6.4.1 Witness assessment

MOLDAC performs the CAB witness assessment as follows:

- a) During CAB's initial accreditation/ extension: MOLDAC establishes based on risk analysis, scopes which will be witnessed;
- b) Accredited CABs: MOLDAC performs witness assessments for the entire accredited scope, during one accreditation cycle.

Witness assessments are planned by team leader/ lead assessor and are realized, according to CAB Assessment plan for one accreditation cycle, which is sent to CAB.

For laboratories which provide services in permanent locations, witness assessments are carried out, usually, during on-site assessments. For LI/ LE/ LVM/ OI-NDT/ OI which provide services at clients, CAB shall organize within 2 months (exception activities by seasons) prior and after on-site assessment witness of activities for MOLDAC assessment team members at client.

In case of certification bodies witness are carried out, usually, before, during and after the on-site assessment, only at clients which have the planned producing processes active. When planned witness assessment is impossible to be carried out at OC client because of lack of requests, these can be transferred for next assessment, but no more than once.

In the case of food safety management system certification bodies, MOLDAC will observe at least one assisted assessment each year for Group 2 "Food and Fodder Industries", Category C "Food Manufacturing" and D "Production of Feeding stuffs" (Indicated in Table A.1 of ISO / TS 22003: 2013) where this group falls within the scope of the accredited scope of the certification body and at least one assisted assessment in each of the other groups during a accreditation cycle (provision of IAF MD 16 document).

In cases in which CAB provides conformity assessment services to client with legal location in other country CAB must include them in the Report on provided services (code PR-04-F-6-CAB).

CAB has the obligation to ensure witness of its activities to MOLDAC.

Scopes sampled to be witnessed, as well as their number, is established by team leader/ lead assessor together with assessment team, according to MOLDAC documents.

During one accreditation cycle, MOLDAC shall witness, depending on accreditation scheme, taking into consideration at least risk associated with CAB activities, the period of CAB activity, number of locations, number of personnel, number of activities indicated in accreditation scope and the average of risk of those (the product is highly dangerous or not, the testing/ calibration/ inspection/ verification/ analysis method is complex or not):

- for OCpr – all groups of products (NC chapters of 2 numbers), for which accreditation was granted;
- for OCprec/ OCpr DOP/IGP – each category of products,
- for OCsmc – each IAAF technical group
- for OCmsa – each sub-category
- for OI (LVM, OI, OI/NDT) – inspection scope/ sub-scope, type and object subjected to inspection, non-destructive testing methods

- for LI – each sub-discipline
- for LE – each metrological sub-scope
- for LM – each discipline.

Assessment team prepares the assessment plan for each CAB, for each type of assessment.

To perform witness assessments, CAB must inform MOLDAC team regarding the planned date for assessment at client, in written, which can be submitted by e-mail, fax, etc.

In this case, CAB provides to MOLDAC evaluation/ audit/ inspection plan with at least 10 days prior the visit to the client. CAB shall inform MOLDAC, in written, on following:

- Relevant data on client,
- Relevant data on product/ process/ economic activity and product category,
- Scheme/ module/ evaluation system used by CAB,
- Relevant normative documents, technical regulations etc.
- Planned date to perform activities at CABs client,
- The CB additionally will send to MOLDAC the Audit Plan, the justification for calculation of the audit time, the report of the previous audit (where applicable), information on the auditor's competence.

The date of the witness assessment will be agreed with MOLDAC after obtaining the client's agreement.

The number of witnessed assessments may be increased or decreased depending on the results of the previous assessments, the risk associated to CAB activities, described above.

For regulated area, in cases in which witness assessment cannot be performed, MOLDAC can assess CAB competence at least within one simulated assessment performed by CAB, as well as through following assessment techniques:

- Interview of CAB personnel, involved in analysis of request, in performing tasks of conformity assessment, document review, reporting, decision making, etc.,
- Assessment by records/ indirect (for example by personnel files), and in case on surveillance is assessment maintenance and updates of personnel competence,
- Verification of some study cases performed by CAB,
- Assessment of verification for some calculations, projects etc.
- Etc.

In areas regulated by national regulations, if during two-years-in-a-row witness assessments cannot take place, because of lack of clients or other ascribable reasons, MOLDAC will propose withdrawal of accreditation or restriction of a part of the scope.

In cases in which during witness assessment non-conformities are raised, those are treated accordingly to PR-04.

7.6.4.2 Internal meeting of assessment team

Prior closing meeting, an internal meeting of assessment team takes place, for analyzing of findings. To carry it out, CAB must ensure MOLDAC assessment team with proper working place.

During this meeting, raised findings are analyzed and classified by lead assessor, based on their impact on management system and accreditation scheme credibility, according to Policy on treatment of non-conformities (code P-04).

After this meeting, assessment team performs closing meeting during which all raised findings during assessment are presented.

7.6.5 Disagreements within assessment team

In cases in which assessment team cannot agree regarding raised findings, they can address for clarifications to the MOLDAC top management, so that during closing meeting final findings could be presented to CAB.

7.6.6 Reporting of assessment

7.6.6.1 Closing meeting

Assessment ends with a closing meeting during which all conclusions of the assessment team are exposed by team leader/ lead assessor, who presents comments regarding competence, conformity of the assessed scope as well as found non-conformities, observations on areas for which improvements are possible.

Non-conformities, findings during assessment, are presented in an official way to the legal representative of CAB, which signs of awareness. One copy of Repots of non-conformities remains at CAB.

CAB can require from assessment team clarifications regarding findings, including identified non-conformities, if there are some, as well as their substantiation. Any divergences regarding the raised findings and/or conclusions of assessment, between assessment team and assessed staff, those must be discussed and, if appropriate, solved during closing meeting.

If CAB does not agree with some non-conformity recorded by assessment team, it has the possibility to address to Professional College of MOLDAC, for clarifications.

7.6.6.2 Assessment report

MOLDAC sends to CAB the assessment report regarding the results of assessment within terms defined in RA Annex 1.

MOLDAC elaborates the Assessment report, which contains comments on competence of management system of CAB as well as on assessed scopes, based on all information and evidences collected during:

- a) Document and records review,
- b) On-site assessment,
- c) Witness assessments,
- d) Files review etc.

and sends it to CAB within at most two weeks from the end of the assessment at the CAB location.

Assessment report can be filled in with results from witness assessments which took place after report was sent to CAB, records being made in the Annex to Assessment report.

For accreditation in regulated area by national regulations, lead assessor/ team leader prepares Assessment report for recognition.

If the report regarding assessment results differs from the result which was given by the end of the assessment, MOLDAC will provide an explanation to the CAB, in written form.

7.6.7 Responsibility for assessment report

MOLDAC is responsible for the content of all assessment reports.

7.6.8 Treatment of non-conformities

For treatment of the non-conformities, MOLDAC established the Policy P-04.

According to P-04, CAB must establish and send to MOLDAC the following:

- i. Root cause of non-conformities,
- ii. The average of non-conformities,
- iii. Specific actions to be taken for their elimination:
 - Corrections,
 - Corrective actions,

and finally, to analyze the efficiency of taken corrective actions.

CAB must take appropriate corrections/ corrective actions according to P-04, due terms established in RA Annex 1.

In cases in which lead assessor/ team lead consider that cause analysis, corrections and corrective actions are not enough, CAB must modify analysis of non-conformities, but at most once, according to P-04.

For observations stated in areas in which improvements are possible, CAB must gather documentary evidence of improvement, if those are accepted, and to present them to MOLDAC.

7.6.9 Analysis of evidences for removal of non-conformities

After the established by BAC corrective actions were accepted by EvŞ/ ŞE, the completed non-conformity Reports and the evidences of closing the non-conformities raised during the assessment are to be presented by CAB to MOLDAC Secretariat, within terms established in RA Annex 1.

MOLDAC may decide:

- a) To analyse evidences of effective implementation of actions taken by CAB, or
- b) To carry out a follow-up assessment in order to verify the effectiveness of implementation of corrective actions and decide where it will take place (at CAB location or at CAB's client). MOLDAC agrees with CAB the period for that follow-up assessment, respecting terms established in Annex 1 of this document.

The results of analysis for removal of non-conformities are recorded by MOLDAC and CAB is informed regarding this analysis.

In cases when lead assessor consider that evidences on closing of non-conformities are not enough, it has to require additional information from CAB, but not more than once.

During initial accreditation, in cases in which CAB does not present evidences for removal of non-conformities, due terms established in RA Annex 1, accreditation process is stoped, and the contract is terminated.

Accreditation process can be resumed only after a new accreditation request is submitted, after at least 6 months after termination of process.

7.7 Accreditation decision-making

7.7.1Types of decisions

The responsibility for decision making belongs to MOLDAC and this step cannot be outsourced.

MOLDAC can take one of following types of decisions:

- a) Granting/ non-granting the accreditation (integral, partial, conditioned) for:
 - i. initial accreditation
 - ii. extension

Decision is taken based on recommendations from Accreditation Recommendation Commission.

- b) Maintenance of accreditation for renewal of accreditation

Decision is taken based on recommendations from Accreditation Recommendation Commission.

- c) Restriction of accreditation:

- i. upon CAB request – without recommendations from Accreditation Recommendation Commission;
- ii. as a result of assessment – based on recommendations from Accreditation Recommendation Commission.

- d) Suspension of accreditation (integral, partial)

- i. upon CAB request – without recommendations from Accreditation Recommendation Commission;
- ii. as a result of assessment – based on recommendations from Accreditation Recommendation Commission
- iii. in case of critical non-conformity - based on the non-conformity report presented by the evaluation team

- e) Lifting of suspension of accreditation

- i. without assessment – based on recommendations from Accreditation Recommendation Commission
- ii. during the planned/ extraordinary assessment – based on recommendations from Accreditation Recommendation Commission

- f) Withdrawn of accreditation:

- i. upon CAB request – without recommendations from Accreditation Recommendation Commission;
- ii. as a result of assessment – based on recommendations from Accreditation Recommendation Commission
- iii. expiration of accreditation

- g) Confirmation of ongoing fulfilment of reference standard requirements and of accreditation criteria applicable to accreditation scheme:
 - i. after surveillance – based on proposal of assessment team, without recommendations from Accreditation Recommendation Commission,
 - ii. after lifting of suspension – based on proposal of assessment team and on recommendations from Accreditation Recommendation Commission.
- h) Confirmation of ongoing fulfilment of reference standard requirements and of accreditation criteria after an update of modifications:
 - Analysis of documented information without assessment – based on proposals from assessment team, without recommendations from Accreditation Recommendation Commission,
 - During the planned/ extraordinary surveillance – based on proposals from assessment team and, if necessary, can be involved the Accreditation Recommendation Commission.

If decision is unfavourable, MOLDAC informs CAB in written, by motivating causes which led to this decision.

In cases in which, during initial accreditation process, decision of non-granting the accreditation is taken, the accreditation contract is terminated, and accreditation process can be resumed only after CAB submits a new accreditation request, but not earlier than after 6 months.

In force-major cases (for example death, natural calamities, etc.), the decision of extension of accreditation can be granted, with indicated reasons. The period of accreditation extension cannot be longer than 6 months.

If the accreditation of the CAB is required before obtaining the recognition, MOLDAC grants conditional accreditation after obtaining positive results in the witnessed assessments, subsequent to the granting of the conditional accreditation.

An assessment for the purpose of conditional accreditation consists of a pre-assessment (as described in point 7.3.3) and an assessment (as described in Chapter 7.6.4), in order to assess the competence of the CAB based on the interview and verification of files and records at the CAB's premises. This assessment is concluded in a report and, after closing any non-conformities, ends with the assessment team's recommendation.

In this case, MOLDAC may take the decision to grant conditional accreditation for a period of 1 year. In the scope of accreditation, explicit references will be made to the status of temporary/ conditional accreditation and restrictions.

Conditional accreditation stipulates that the CAB must:

- invite MOLDAC to the first certification in order to carry out the witnessed assessment;
- demonstrate that the whole certification process complies with the requirements of the reference standard.

After conditional accreditation has been granted, MOLDAC will carry out an witnessed assessment during the first activity of the CAB followed by an assessment at the CAB headquarters. The additional assessment must be completed within one year of accreditation. The decision to change the conditional accreditation to a regular (ordinary) one will be taken again.

Conditional accreditation will expire (so it will not be withdrawn) if MOLDAC was not able to complete/ perform the additional assessment before the expiry date of the accreditation, because:

- MOLDAC could not carry out the on-site assessment;
- The CAB could not close the non-conformities found during the additional assessment with a positive result.

If the CAB has not informed MOLDAC within six months from receiving conditional accreditation regarding the witnessed assessment referred to above and/or the additional assessment, there is a risk that the accreditation will not be changed to a regular (ordinary) one before it expires. This risk must be borne by the applicant.

The recognition authority will be informed by MOLDAC in case of expiration of the conditional accreditation.

Conditional accreditation does not apply to CABs that have been previously recognized, without being accredited, that have had the opportunity to provide conformity assessment services in those regulated areas and, as a result, can provide the conditions for conducting the witnessed assessment.

In regulated area, after a positive decision was taken on granting/ extension of accreditation, MOLDAC submits CABs file, together with a recognition request, to the respective authority for recognition due terms established in Annex 3 of this document. In cases of restriction of accreditation scope, suspension of accreditation (integral, partial), withdrawn of accreditation, MOLDAC informs respective authority regarding taken decision.

The process of recognition of CAB is described in Annex 3 of this document.

7.7.2 Person who takes the decision

Decision is taken by MOLDAC Director; in case of its missing, or in cases s/he was involved in accreditation process of CAB, decision is taken by MOLDAC Deputy Director. In cases when MOLDAC director is absent, and the Deputy Director is involved in assessment process, accreditation decision is taken by a person appointed by Order.

Decision is taken according to RA p.7.7.1. MOLDAC sends signed decision to CAB.

MOLDAC established that decision is taken within terms established in Annex 1 to this document.

In case when terms cannot be respected, MOLDAC will inform CAB with no delay, in writing, regarding the decision taken including the justification, if appropriate.

7.8 Accreditation information

7.8.1 MOLDAC submits to CAB:

- a) Decision on accreditation,
- b) Accreditation Certificate and afferent annex/ annexes – in cases of initial accreditation/ extension/ modification/ renewal of accreditation;
- c) CAB assessment program for one accreditation cycle - in cases of initial accreditation/ extension/ modification/ renewal of accreditation;

- d) Agreement on use of accreditation symbol - in cases of initial / renewal of accreditation;
- e) Accreditation symbol on electronic device – in case of initial accreditation/ modification of accreditation symbol.

Accredited CAB can use MOLDAC accreditation symbol, accordingly to provision of Policy and rules on use of accreditation symbol and reference to accreditation (code P-08) as well as to legislation in force.

Accredited CAB has to make reference on their web page to MOLDAC's web page, to inform its clients and its applicants regarding accreditation benefits, and must make available all conformity assessment activities covered by accreditation.

7.8.2 MOLDAC provides to the accredited CAB through an accreditation certificate, afferent annexes and by web page www.acreditare.md information regarding accreditation, which involve:

- a) Identity and national accreditation mark of MOLDAC;
- b) Name of accredited CAB;
- c) The unique identification of accreditation;
- d) Name of legal entity, if it differs from CAB name;
- e) Name of sites and activities performed at each location;
- f) Accreditation scope;
- g) Date of initial accreditation, expiration, last modification or renewal,
- h) A conformity declaration and a reference to international standard/s and/or other normative documents, including edition or revision used for assessment of conformity assessment body.

Accreditation certificate is valid for 4 years if all accreditation requirements are ongoing fulfilled.

The effective date of accreditation granting is the same date or a date after the decision regarding accreditation was taken.

7.8.3 Accredited scope is detailed by MOLDAC in annex/ annexes to Accreditation certificate, published on MOLDAC web-site.

7.8.4 MOLAC does not use at this moment the flexible scope of accreditation.

7.9 Accreditation cycle

7.9.1 Duration of one accreditation cycle

Accreditation cycle is of 4 years, starting with the date of issuing of Accreditation Certificate, and ends with date of its termination. One accreditation cycle involves 3 surveillances, but the last one can be transformed in re-assessment.

After initial accreditation, surveillances will be performed as follows:

- a) first surveillance (S1) will be performed not later than after 15 months from the last assessment performed at CAB location;
- b) second surveillance (S2) will be performed not later than 15 months after S1 from the last assessment performed at CAB location;
- c) third surveillance (S3)/ re-assessment (R) will be performed not later than 16 months after S2, from the last assessment performed at CAB location.

For re-assessment, CAB must submit to MOLDAC with at most 6 months before expiration of validity of the accreditation certificate, the request of accreditation renewal, together with documents requested in List of documents submitted by CAB (code PR-04-F-9).

In cases in which CAB does not submit the request for accreditation renewal with 6 months' prior expiration of accreditation certificate, exceeded period will be taken from CAB, last risking not to get renewal of accreditation in time, and the process of renewal of accreditation will change into initial accreditation; CAB's number will be kept, without its accreditation history being indicated.

In cases when CAB does not submit request for renewal of accreditation in terms indicated above, MOLDAC performs S3 surveillance.

In cases in which CAB does not accept surveillance S3 to be performed, MOLDAC initiates the process of suspension, followed by withdrawal of accreditation.

Note: The requirements described in paragraphs 7.9.1, 7.9.2 and 7.9.4 of this document will be applied by MOLDAC, from the moment of modification of the scheme for calculating payments for accreditation services.

Until the Modification of the Calculation Scheme, the frequency of the surveys will be performed in accordance with the previous rules as follows:

"...Accreditation cycle is 4 years, starts with the date when Accreditation Certificate is issued and ends with the date of its expiry. One accreditation cycle is composed of four time frames between on-site assessments:

- A - S1
- S1 - S2
- S2 - S3
- S3 - S4/R

At the assessment with accreditation purpose will be assessed 100% of conformity assessment activities included by the CAB in the requested scope.

At each surveillance at least 25% will be assessed, while at the reassessment at least 50% of conformity assessment activities included in Annex to Accreditation Certificate.

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec
2017				A						S1		
2018										S2		
2019										S3		
2020										S4/R	R	R
2021	R	R	R	R								
2022				S1								
2023				S2								
2024				S3						S4/R	R	R
2025	R	R	R	R								

During the S3 at the closing meeting EvŞ informs CAB with MOLDAC rules, and namely, if CAB does not submit an application for reassessment 6 months before Accreditation Certification expires, it should present to MOLDAC Information presented by CAB regarding the performance of the fourth surveillance, for the assessment of those minimum 25% planned. Otherwise, MOLDAC will take decision on suspension till the expiry date of Accreditation Certificate..."

7.9.2 CAB assessment program for one accreditation cycle

Once accreditation certificate was issued, MOLDAC submits to CAB the assessment program for one accreditation cycle, taking into consideration all gathered information of the management system and CAB activities, as well as its performance. This program includes location and CABs activities which are to be performed.

Assessment program can be changed during one accreditation cycle, and CAB is informed regarding these changes.

During assessment for initial accreditation is assessed, through different types of assessment techniques, 100% of conformity assessment activities, which were included by CAB in the requested accreditation scope. During each surveillance will be assessed at least 30% of activities, and during re-assessment – at least 40% from activities included in Annex to Accreditation certificate/ requested accreditation scope. At the same time, the requirements of the standard will be sampled, depending on the risk assessment, the results of previous evaluations, information on changes occurring within the CAB, etc. Obligatory will be the requirements of the standard that have a major impact on the management system, namely:

- The process (through direct evaluations, through records, etc.)
- Management analysis,
- Internal audit,
- Complaints and calls,
- Document control,
- Checking records.

During re-assessment are assessed all requirements of the reference standard, according to which accreditation was granted.

7.9.3 Confirmation of accreditation requirements fulfilment (surveillance)

Surveillance is performed according to provisions 7.6.4-7.6.9 and represents the way by which MOLDAC verifies continuous compliance of accreditation criteria by CAB. During planning of surveillances are taken into account CABs activities by seasons/ working shifts.

With at least 1-month prior surveillance, CAB fills in the template “Information provided by CAB for surveillance” (code PR-04-F-41), forms and afferent documents, and submits them to MOLDAC.

Additionally, OCsm fills in the template “Survey for data collection regarding OCsm activity” (code PR-04-F-58).

In cases in which CAB modified Management System documents, it will submit list of CAB MS documents in which will be indicated current edition and/or revision, date of approval, and will attach to this list modified pages/ documents.

MOLDAC calculate the surveillance costs, and CAB pays is based on invoice issued by MOLDAC.

Usually, surveillance process includes the following:

- ✓ documents assessment, which involves analysis of modifications made between two consecutive assessments,
- ✓ records assessment regarding maintenance of CAB MS,

- ✓ on-site assessment (at CAB location), including assessment of locations in which key-activities* are performed,
- ✓ witness assessments,
- ✓ follow-up assessments, if applicable,
- ✓ other evaluation techniques, if appropriate, described at point 7.6.1. of this document,
- ✓ proposals of assessment team regarding compliance with accreditation criteria, for defined accreditation scope (decision).

Note*: key-activity – technical activity which may have a major influence on the results of testing/ analysis/ calibration/ metrological verification/ inspection/ certification and activities of CAB management system:

- Formulation and approval of policies,
- Development and approval of process and procedures,
- Selection, training, approval and monitoring of personnel,
- Control and monitoring of subcontractors,
- Analysis of contracts,
- Planning of activities (testing/ calibration/ verification/ inspection/ certification etc.),
- Reporting and issuing of relevant documents (testing/ analysis/ inspection reports, calibration/conformity certificate, metrological verification bulletin, etc.).

Surveillances take place according to assessment program, which is available to CAB from the moment accreditation was granted.

When planning surveillance assessments in terms of frequency and scale, is taken into consideration the performance of the CAB Management System, as:

- missing complaints and confirmed calls;
- a high level of customer satisfaction for CABs;
- no non-conformities for certain activities over a determined period;
- the effectiveness of internal audits;
- an excellent system for determining and implementing corrective actions;
- frequency of participation and positive results in PT/ILC (for laboratories).

On-site surveillances, along with extensions, can be done by assessors and technical assessors with the involvement of technical experts in case of need.

MOLDAC can accept the CAB surveillance review 1 month before or after the period indicated in the surveillance program. If the deviation from the surveillance program requested in writing by the CAB with the reasoned reasons is greater than 1 month, it is analysed by EvS together with SDA.

Deviation can be maximum with 3 months after the date of the evaluation program, without affecting the deadline for the next assessment.

If non-conformities are identified during the surveillance, they are treated in accordance with the provisions of the Policy on Handling the Non-conformities (code P-04).

CAB is informed by the lead assessor during the last surveillance that the term of validity of the accreditation is to expire, as well as the consequences of the non-timely re-assessment.

Following the surveillance, MOLDAC Director takes the decision to confirm the fulfilment of the accreditation requirements for the defined accreditation scope, according to point 7.7 of this document.

7.9.4 Reassessment

The duration of an accreditation cycle is 4 years and the CAB must request reassessment 6 months before its expiration by submitting to MOLDAC the set of documents modified from the original accreditation or the last reassessment including records on the implementation of management system, according to the List of Documents submitted by CAB (code PR-04-F-9).

If the reassessment is to commence at the latest 13 months after S2 surveillance but no longer than 15 months, the overdue term will be from the CAB account, the one provided for the removal of the nonconformities, as set out in Annex 1 to this document.

If CAB does not fall within the terms set out in RA Annex 1, the reassessment process will be transferred to the initial accreditation process, and the accreditation certificate will be retained and the accreditation history will not be indicated.

The reassessment should confirm the competence of the CAB and cover all the requirements of the standard for which the CAB is accredited and cover at least 40% of the technical activities/ accreditation scope.

MOLDAC assessment team takes into account all the information and experience gained during the previous assessments carried out in the previous accreditation cycle.

The team leader/ lead assessor proposes the immediate suspension of the CAB if finds a critical non-conformity, according to the provisions of the Accreditation Contract, clause 6.2.10.

MOLDAC may change the assessment teams for reassessment and, if needed, for surveillance, in order to avoid the evaluators being familiarized with the assessed CABs and thus diminishing the objectivity of the assessors.

MOLDAC Director takes the decision regarding accreditation according to p.7.7.

If the laboratory performs internal calibrations, those will be assessed during document review and on-site assessment.

7.9.5 Extraordinary assessment

Extraordinary assessments may be carried out in one of following cases:

- a) Complaints to the CAB if, following the analysis of the complaint, it is decided by the regulatory authorities or other courts,
- b) MOLDAC findings on violation of accreditation requirements by CAB (from mass media, other CABs, market, appeals, etc.),
- c) Significant relevant changes reported by CAB arising from the conditions under which accreditation was granted/ confirmed, as follows:
 - legal, commercial, of property or organizational status,
 - organization, top management and key-personnel,
 - main policies,
 - resources and locations,

- scope of accreditation
- modification of accreditation conditions,
- other elements which can affect the capacity of CAB to perform accreditation requirements.

Case a) is treated according to PR-05 procedure regarding claims.

In case b), MOLDAC records the finding and asks for additional information from the CAB. MOLDAC Director may decide to make an extraordinary assessment. In this case an assessment team is appointed, which draws up the assessment plan focused on the issue. The team performs the extraordinary assessment no later than 5 working days after the assessment plan has been communicated. Based on the results of the assessment, the accreditation decision is taken, based on the proposal of the assessment team and the CRA counsel, by case.

In case c), when CAB communicates changes to MOLDAC, according to p.7.9.3 above regarding the conditions under which accreditation was granted/ confirmed, MOLDAC analyses the effect of these changes on compliance with the accreditation requirements and may propose:

- 1) to assess the appeared changes during the next assessment, or
- 2) to perform an extraordinary assessment, or
- 3) to start the process of scope extension.

In case 1), MOLDAC decides to update the necessary documents (for example the Accreditation Certificate, the Annex to the accreditation certificate, CAB Register, etc.)

In cases 2) and 3) the assessment will be performed according to points 7.6.4-7.6.9 described above, and the decision which is to be taken by MOLDAC Director will be according to point 7.7 of this document, based on proposals from assessment team.

The activities of reducing the scope of accreditation and/ or activities of modification of Accreditation Certificate and/ or of Accreditation scope, including the assessment activities of internal calibrations performed by laboratory/ inspection body, are to be paid by CAB. The calculation of the works will be carried out according to the cost of the actual time used to perform the given activity in accordance with the calculation formula in the Scheme for payments calculation for accreditation services - Annex 1 to Law 235/2011, with subsequent amendments.

In cases when there are modifications of the normative documents from the annex to the Accreditation Certificate, CAB is obliged to analyse the modifications from the new documents:

- a) if modifications have a minor impact on conformity assessment activities (testing, calibrations, medical examinations, verifications, inspections, certifications) CAB fill in the template on Information regarding the changes from the conditions under which accreditation of CAB was granted/ confirmed (code PR-04-F-53) available on MOLDAC website www.acreditare.md and send it to MOLDAC together with the results of comparative analysis of provisions from new and cancelled normative documents.
- b) if modifications have a major impact on conformity assessment activities (testing, calibrations, medical examinations, verifications, inspections, certifications), CAB has to fill in an Implementation Plan of modifications, by indicating the terms of realization. After realization of Plan, CAB fill in the template on Information regarding the changes from the conditions under which accreditation of CAB was granted/ confirmed (code PR-04-F-53) available on MOLDAC website

www.acreditare.md and send it to MOLDAC together with the results of comparative analysis of provisions from new and cancelled normative documents, together with the Implementation Plan and with the evidences of its realization (trainings, internships, etc.).

MOLDAC assesses the modifications presented by CAB and decides if the assessment will take place:

- at MOLDAC premises, or
- during the next assessment, or
- within an extraordinary visit.

If the CAB requires maintaining the accreditation for conformity assessment activities upon client's necessity according to the cancelled normative documents, it should identify the cancelled normative documents in the Requested Accreditation Scope by mentioning "CANCELLED" and send it to MOLDAC. In this case, MOLDAC will modify the annex to the Accreditation Certificate, will send to CAB the modified Annex/ Annexes and will respect the procedures into force for performing the planned surveillances.

As a result of an extraordinary visit, the decision taken by MOLDAC Director will be according to point 7.7 of this document, based on proposals from assessment team.

For accredited and recognized CABs, MOLDAC informs the competent authority of decisions taken following extraordinary assessments.

7.10 Extending accreditation

Assessment for extending accreditation is carried out according to p.7.2.-7.8. of this document.

Extending accreditation can be required for both scope and locations.

The extension of the scope of accreditation may be carried out during the surveillance visits, in which case the assessment team shall verify, as a matter of priority, the technical competence for the field for which the extension was requested.

CAB submits the application and the documents for extension according to the List of Documents submitted by the OEC (Annex on Request).

The extension of the scope should be subject to the same accreditation standard against which the CAB has been accredited.

MOLDAC treats an extension request, for another accreditation standard, as a new accreditation application.

Extending accreditation can be done:

- in the same time with surveillance/ renewal of accreditation;
- between two assessments, upon CAB's request.

The impact of extending can be classified, for example, in:

1. **major** - when requesting extension for a new product, method, location, category, activity, object inspected, etc.

2. **minor** - when requesting an extension for a product falling within NC heading (Combined Nomenclature of Goods) for which OCpr has been accredited or for an activity in a subcategory for which OCsm has been accredited, or for a test method for which the LÎ has accreditation, but the product matrix is new, etc.

In the result of the analysis of the documented information presented on the extension request, depending on the impact of the extension on the accredited domain, MOLDAC decides to carry out the evaluation:

- a. at the headquarters of the CAB,
- b) and / or to the CAB customer,
- c) or at the headquarters of the ONA (amendment of the Accreditation Certificate / Appendices to the Accreditation Certificate) according to point 7.9.5 of this document.

In the case of a) and b) MOLDAC draws up the Plan for Extension Assessment, taking into account the risk of the requested scope, the experience gained regarding CAB's management system and other factors and shall include the assessment techniques to be applied by the assessment team according to p.7.6.1 of this document.

In cases in which during the assessment non-conformities are raised, provisions of P-04 Policy are applied.

The decision on accreditation is taken by the MOLDAC Director, in accordance with p.7.7 of this document.

After each extension, MOLDAC reviews and re-sends the CAB Assessment Program for the accreditation cycle (code PR-04-F-38).

Extension of accreditation is granted within the same period of validity of current accreditation.

Note: CAB may request the extension of the Accreditation scope not more than once in six months.

MOLDAC revises the Accreditation Certificate and its annex only after the CAB returns the previous Certificate of Accreditation with its annex/ annexes in original to the MOLDAC Secretariat.

7.11 Suspending, withdrawing or reducing accreditation

7.11.1 Suspending accreditation/ lifting suspension of accreditation

MOLDAC has the right to suspend the accreditation in the following situations, provided also at p.6.2.10 of the accreditation contract:

- a) Upon CAB's request,
- b) As a result of assessment:
 - i. the CAB does not inform within 2 months of the occurrence of changes in status, organization, top management and key personnel, major policies, resources and locations, accreditation, and other such elements that may affect the ability of the CAB to meet the accreditation requirements.
 - ii. If the corrective actions performed by the CAB as a result of unsatisfactory results in PT/ILC were not effective.

- iii. CAB does not eliminate the nonconformities found by the assessment team under the conditions and deadlines established by MOLDAC.
- iv. If critical non-conformities are identified during the assessment of CAB, which, through the effects it generates, significantly affects the credibility of CAB.
- v. CAB involves personnel whose competence cannot be demonstrated in activities covered by accreditation,
- vi. CAB disagrees with carrying out the surveillance/ extraordinary assessment in accordance with rules established by MOLDAC.
- vii. The accredited CAB does not comply with the rules for the use of MOLDAC accreditation symbols or accredited status.
- viii. During surveillance is established that CAB cannot demonstrate competence for accredited scope.
- ix. CAB does not comply with the provisions of the accreditation agreement regarding payment.
- x. If CAB provides certification against any standard used as a reference for accreditation (for example: ISO/IEC 17025, ISO/IEC 17021-1, etc.).

The MOLDAC Director takes the decision according to p.7.7 of this document and CAB is informed of the decision.

In case of suspension, MOLDAC indicates this in the Accredited CABs Register, published on the website, specifying whether the suspension was decided following the CAB request or was decided by MOLDAC.

In the Annex to Accreditation Certificate placed on website, the partially or integrally suspended Scope is identified by cutting text by using Font option "cut text with one line", as for example:

No.	Type/ Testing name	Materials / product	Reference document
MICROBIOLOGICAL METHODS			
1	Determination of Staphylococcus aureus (detection)	Food	SM SR EN ISO 6888-1:2011 SM SR EN ISO 6888-3:2013 item 9.1
2	Determination of Bacterioides coliforme (detection)	Food	SM ISO 4831:2010 item 9.1

At the same time, the suspended scope is identified "by screen" with the date of scope suspension.

When CAB is accredited and recognized, MOLDAC informs the competent authority about suspension.

Lead assessor/ team leader propose immediate suspension of the CAB in case if a critical non-conformity was raised, according to P-04 provisions.

Decision on suspension is taken by MOLDAC Director and cannot exceed 12 months.

Decision on lifting of suspension of accreditation can be taken in any moment, when causes of suspension were removed.

The CAB must request in writing the lift of the suspension with at least 60 working days before the expiry of the suspension period, specifying the ways of solving the issues that led to the suspension. MOLDAC may carry out an extraordinary assessment to verify the situation referred to by the CAB, and it shall provide the conditions for carrying out this assessment within 30 working days from the date of submission of the request for lifting the suspension.

If CAB does not undertake necessary measures for lifting suspension prior 6 months till expiration date of accreditation certificate, then re-assessment process will be transferred to the initial accreditation process, and on the issued accreditation certificate, the OEC number will be kept and the accreditation history will not be indicated.

If the suspension refers only to a part of the scope, then the CAB may submit the application for re-assessment for the scope for which it maintains its accreditation, without including the suspended activities in the requested scope.

In case of suspension the CAB shall:

- not issue any document under MOLDAC accreditation for suspended area;
- not use the accreditation symbol or reference to the accredited statute due the suspension period;
- analyze the impact of nonconformity of the documents issued under accreditation and to undertake corrective actions / corrections needed to eliminate nonconformities;

The suspension may be lifted before the end of this period, if it is found, through documented evidences provided by CAB, or by follow-up assessment, by assessment team, that the implementation of corrective actions is appropriate.

If suspension is lifted, MOLDAC modifies information of suspension from Accredited CAB Register, as well as the Annex to CAB Accreditation Certificate (disables the Font option "cut text with one line" of suspended scope), published on the website.

The period of validity of the Accreditation Certificate remains the same after the suspension is lifted.

7.11.2 Accreditation restriction

Accreditation restriction may take place:

- following the CAB request;
- if after the expiry of the suspension period, the CAB did not demonstrate the effectiveness of the taken corrective actions for the suspended scope.

If the accreditation scope is restricted following the CAB request, this must explicitly request this in writing to MOLDAC, mentioning the scope for which the restriction is applied.

Accreditation restriction may relate to the restriction of the competence area of the CABs or one or more of its sites, based on objective proofs, provided by the assessment team.

MOLDAC has the right to restrict the accreditation in situations pointed in 6.2.11 from Accreditation contract.

MOLDAC Director takes the decision in accordance with p.7.7. of this document and the CAB is informed in writing about the decision.

MOLDAC issues a new certificate for the CAB, modified according to the restriction decision, only after the CAB returns the previous Certificate and Annex/es in original.

MOLDAC updates the CABs Register, by publishing the new Annex with the restricted scope on the website www.acreditare.md

If the CAB is accredited and recognized, MOLDAC informs the competent authority on the restriction.

The restriction does not affect the validity period of the accreditation certificate.

7.11.3 Accreditation withdrawal

MOLDAC has the right to withdraw accreditation in situations mentioned at p.6.2.12 of Accreditation contract.

MOLDAC Director makes the decision of accreditation withdrawal according to p.7.7. of the present document, and the CAB is informed of the decision.

In the accreditation withdrawal decision is mentioned the cause of withdrawal, by indicating if withdrawal was made upon CAB request or decided by MOLDAC.

In case of withdrawal of accreditation, MOLDAC excludes the CAB from the Register of accredited CABs published on the website www.acreditare.md, while the accreditation contract is legally terminated.

If the CAB is accredited and recognized, MOLDAC informs the competent authority about the withdrawal.

The CAB may submit a new application for initial accreditation only after 6 months from the withdrawal of accreditation.

7.11.4 Termination of accreditation process

Termination of the accreditation process takes place in the situations described in clause 6.2.9 of the Accreditation Agreement as well as in the cases described below:

- a) at the request of the CAB,
- b) if the CAB did not request reassessment,
- c) if the initial accreditation process fails.

In the case of a) and b) the OEC and the accredited CAB Register, PR-04-R-8-OEC code are excluded, the updated register is placed on the MOLDAC website.

In the case of c) MOLDAC invites the respective OEC to return the set of documents / part of the submitted documents, under signature.

7.12 Complaints

Complaints are treated according to Procedure on treatment of complaints and appeals (code PR-05).

7.13 Appeals

CAB may appeal to any unfavorable decision regarding accreditation issued by MOLDAC in accordance with the Procedure on treatment of complaints and appeals (code PR-05) available on the MOLDAC website - www.acreditare.md

7.14 Records on conformity assessment bodies

MOLDAC maintains records on CABs to demonstrate that accreditation requirements have been effectively met.

The records submitted by the CAB, both on hard copy and electronically/ on Cloud are kept under control by MOLDAC, in accordance with the procedure Control of documents and records, code PR-01.

Access to the electronic records has only the assessment team and the SDA. With the permission of the MOLDAC Director, other MOLDAC representatives (for example internal auditors) may also have access.

Records regarding CAB are kept at least during current accreditation cycle, plus the entire previous accreditation cycle (4+4).

7.15 Accreditation transfer

7.15.1 If the accredited conformity assessment activities undertaken by a CAB, are transferred to another legal entity (a new CAB), the application and documents concerning the transfer of accreditation must be submitted by the legal representative of the legal entity seeking to benefit from the transfer of accreditation or by the authorized representative of accredited entity, who give its accredited activities to a new entity in the process of creation.

The accreditation can be transferred under the following conditions:

- the new CAB meets MOLDAC accreditation requirements
- the policy and the management system remain unchanged
- the management and key personnel remain unchanged;
- the staff remains unchanged;
- the specific procedures remain unchanged;
- the Infrastructure (site, equipment, facilities, etc.) remain unchanged.

The legal entity to which accreditation is transferred provides MOLDAC with the necessary documents demonstrating that the above conditions are fulfilled.

MOLDAC is assessing the applicant documents and if one of the above conditions is not satisfied, decide to conduct an extraordinary on-site assessment in accordance with point 7.9.5. of this document.

The assessment cost is covered by the new body/ new legal entity.

The accreditation contract is terminated and a new contract is signed with the new legal entity. The new Accreditation Contract has the same validity with the Certificate of Accreditation.

The decision of accreditation granting, in case of transfer, is taken by MOLDAC Director.

If the transfer beneficiary is already accredited and the accreditation of the entity gives its accredited activities may be attached to the scope of a transfer recipient (adsorption), in this case, a new Annex to the Accreditation Certificate is issued which includes both scopes; the certificate number of beneficiary and validity period is kept. The date of the Accreditation Certificate and Annex of the beneficiary of transfer remains the same.

Where two legal entities are joined:

- a) one non-accredited and one accredited - an initial accreditation process;
- b) both accredited - document analysis, extraordinary assessment, if applicable, decision with or without CRA, accreditation certificate with a new number and validity period identical to that of the certificate with the lowest term.

The evaluation program correlates with the accreditation scope of the new accrediting beneficiary.

7.15.2 The transfer of accredited certifications of Management Systems.

In cases in which MOLDAC has the argued information regarding the transfer of certifications, in cases when issuing Certification Body of Management Systems does not cooperate with the accepting Certification Body, and suspends or withdraws the transferring client's certification without cause, NAB undertakes actions on MS CB as follows:

- invites both parties to clarify the situation during a discussion session,
- in case when issuing MS CB does not respect the requirements of IAF MD 2 document, MOLDAC suspends the accreditation, or withdraws it in cases when the CB does not undertake measures for lifting the suspension.

8 INFORMATION REQUIREMENTS

8.1 Confidential information

MOLDAC ensures through the accreditation contract the confidentiality of the information obtained and created during the accreditation process of the CAB.

The use of information technology applicable to assessments shall be mutually agreed by MOLDAC and the CAB, in accordance with information security and data protection measures and regulations, before their use for assessment purposes. If the parties do not reach a consensus on the confidentiality of the remote assessment, MOLDAC will use other methods and terms for conducting the assessment.

MOLDAC considers confidential all information such as: information related to the structure and operation of the CAB, its managerial, contractual and statutory relationships, staff, resources and internal documentation, as well as any other information declared by the applicant for accreditation, except information which CAB makes available to the public, or where agreed between MOLDAC and CAB (for example: for the purpose of claiming complaints).

If MOLDAC is required by law or authorized by contractual arrangements to provide confidential information, unless prohibited by law, the CAB shall be notified of the information provided.

Confidential information is passed on to third parties only with the written consent of the CAB that holds that information, unless the law requires such information to be disclosed without such consent.

Statements of state security, consumer and environmental security, and any other information that by its nature indicates a violation of applicable law, are not considered confidential information.

In the regulated area, upon request of the regulatory authority, MOLDAC provides the assessment results.

MOLDAC treats confidentially the information obtained from sources other than the CAB (as an example of complaints, information received from regulators, etc.) and in this case does not disclose the source of the information, unless agreed with the source.

MOLDAC requires all personnel, including members of the committees, contractors, staff of external bodies or persons acting on behalf of the accreditation body, to keep confidential all information obtained or created during the performance of the activities of the accreditation body, except in the cases provided for by law.

Persons who have not concluded MOLDAC employment contracts but participate in CABs assessments as interpreters, translators, observers, sign confidentiality statements.

If MOLDAC intends to disclose information other than that mentioned in section 8.2, it shall inform the CAB in advance.

8.2 Publicly available information

8.2.1 MOLDAC makes available to the public electronic media (website MOLDAC, Facebook, Twitter, etc.) or other means without request and updates at the appropriate intervals at least the following information:

a) Information regarding accreditation body:

1. information on the authority under which the accreditation body operates - through Law 235/2011 and GD 77/2013 published on the MOLDAC website;
2. a description of the rights and obligations of the accreditation body - through the public accreditation contract on the MOLDAC website;
3. general information on the means by which the accreditation body obtains financial support - through Law 235/2011 and GD 77/2013 published on the MOLDAC website;
4. information on the activities of the accreditation body other than accreditation - through Law 235/2011 and GD 77/2013 published on the MOLDAC website;
5. information on the international recognition agreements in which he is involved - through the MOLDAC website, Twitter, Facebook, reports, brochures and accreditation certificate.

b) information on the accreditation process:

1. detailed information on its accreditation schemes, including its assessments and accreditation processes - through the MOLDAC website and the *Monitorul Oficial*, in which the reference standards for accreditation are published,
2. reference to documents containing accreditation requirements - through General Accreditation Criteria (code CA), public on the MOLDAC website,
3. general information on the scheme for calculating payments for accreditation services - in Annex 1 to Law no.235/2011, published on the MOLDAC website,
4. a description of the rights and obligations of the conformity assessment bodies - through the public accreditation contract on the MOLDAC website,
5. information on procedures for submission and handling of complaints and appeals - through PR-05, published on the MOLDAC website,
6. information on the use of the accreditation symbol and other references to accreditation - through P-08 and the Agreement on use of the national accreditation symbol, public on the MOLDAC website.

8.2.2 MOLDAC publishes and updates on its website the Register on accredited CABs on each accreditation scheme. These registers contain the following information:

- name, address, contact data of CAB,
- the number and validity of the accreditation certificate,
- data related to the extension/ restriction/ modification of the accreditation scope,
- accredited locations and scopes.

In exceptional cases, access restriction to some information, is done upon CAB request.

8.2.3 MOLDAC notifies the CAB through its website about any changes to its accreditation requirements. Due this, MOLDAC develops and publishes Transitional Information Documents (code DI) and revises and publishes on the website reference documents (code DR and CS) and, where applicable, general accreditation criteria (code CA), accreditation rules (code RA) and/ or policies (code PM).

If the Information Document refers to the transition to a conformity assessment scheme (e.g: DI - Transition to ISO 22000: 2018 for OCsmsa), chapter 2 of the MOLDAC Responsibilities "MOLDAC Responsibility", will indicate MOLDAC responsibility to the application of both versions of the Standards on the Accreditation Certificate until the end of the transition period.

In the case of modifications, MOLDAC takes into account the stakeholders' positions before deciding on the exact form and effective date of the changes as follows:

- in consultation with the Accreditation Council - the documents of Reg, CA, RA, PM are amended,
- with consultation of the Technical Committees - the documents DI, DR, CS, I are amended

8.2.4 MOLDAC verifies how each accredited body complies with the modified accreditation requirements in the course of surveillance, re-assessment or extraordinary assessments. Due this, MOLDAC documented in the RA and PR-04 how CABs are assessed to comply with the changes. Assessment of the changes is recorded by the assessment team in the evaluation report (code PR-04-F-30-OEC).

Throughout the validity period of accreditation, the CAB has the obligation to pursue the MOLDAC website in order to keep up to date with all applicable documents (policies, criteria, regulations, rules, etc.).

MOLDAC provides through the www.acreditare.md site information of OEC accredited as follows:

- a) MOLDAC signatory status,
- b) Organizational chart,
- c) Financial report, activity report,
- d) List of assessors,
- e) The Register on accredited CABs with an indication of the name of accredited CAB; unique identification of accreditation; the name of the legal entity and, if different, the locations and activities performed at each location; accreditation field; the date of initial accreditation; expiration date; date of the last change; a declaration of conformity and a reference to the international standard(s) and/or other normative documents, including the edition or revision used for the assessment of the conformity assessment body,
- f) Information required for CABs, such as RA, CA, PM, Reg, depending on the accreditation scheme such as field of competence, DR, DI, CS, etc.,
- g) Procedure on treatment of complaints and appeals,
- h) Calculation scheme for payments of accreditation services,
- i) The accreditation contract and the additional agreement to the contract in case of necessity, the agreement on the use of the accreditation symbol,
- j) Other information related to MOLDAC activities, such as: EA resolutions; reports on participation in EA Technical Committees, IAF/ILAC General Assembly, MAC meetings, horizontal committees, etc.

9 FINANCIAL OBLIGATIONS

The accreditation fees are approved by Law no. 235 of 01.12.2011 with subsequent amendments, Annex No. 1 Calculation scheme of payments for accreditation services, which is published on MOLDAC website: www.acreditare.md.

The payment of accreditation services is mandatory according to the Accreditation Contract; payment is made by CAB entirely or 50% of it prior to the start of the accreditation process and 50% prior to the on-site assessment, based on the invoice issued by MOLDAC.

10 RIGHTS AND OBLIGATIONS

10.1 CABs rights and obligations

The rights and obligations of accredited CABs are stipulated in art.16 of Law no. 235 of 01.12.2011 regarding the accreditation and conformity assessment activities with subsequent amendments, as well as in the Accreditation Contract.

10.2 MOLDAC rights and obligations

MOLDAC rights and obligations are stipulated in art.8 of the Law no. 235 of 01.12.2011 on accreditation and conformity assessment activities with subsequent amendments, as well as in the Accreditation Contract.

MOLDAC makes publicly available on the website, and keeps up-to-date information on accredited CABs.

MOLDAC has established the Policy on Measurement of Traceability (code P-03), through which provides the information on the appropriate ways to obtain the traceability of measurement results in the field for which CAB accreditation is granted.

MOLDAC provides information regarding the European and international agreements in which it is involved on its website.

MOLDAC reports to the EA Secretariat of any significant change in its status and/or its operating practices regarding:

- a) Competence,
- b) Impartiality,
- c) operational capacity, such as legal status, relationship with government, management staff, contact persons, accreditation criteria and procedures, address addresses,

within a period of up to one month depending on the outcome of the impact analysis on apparent changes.

The NAB provides an impact analysis on the reported changes without delay.

MOLDAC notifies in writing, within a maximum of three months, the other EA MLA signatories of any withdrawal or reduction of the scope covered by the EA BLA Agreement.

MOLDAC notifies the CAB of any changes to its accreditation requirements, takes into account the positions of stakeholders before deciding on the correct form and effective date of change, and performs the CAB assessment on the new changes.

MOLDAC develops Informative Documents (code DI-CAB-01) regarding the period of transition to the new versions of the accreditation standards according to the provisions of IAF, ILAC, EA documents, present them at the meetings of the Technical Committees depending on the specifics of the information document, in order to consider the positions of stakeholders, decide the correct form and the effective date of change. After making the decision and informing/ publishing the modified requirements, MOLDAC checks that each CAB fulfills the modified requirements.

10.3 Reference to accreditation and use of accreditation symbols

The National Accreditation Mark MOLDAC is described and approved by Law no. 235 from 01.12.2011 regarding accreditation and conformity assessment activities, with subsequent amendments, art.13 and Annex 2.

The use of the National Accreditation Mark, accreditation symbols and references to accreditation is established by MOLDAC in ["Policy and rules on the use of accreditation symbols, the ILAC MRA combined mark, the IAF MLA combined mark, and references to accredited status under EA-1/19, EA-3/01, ILAC P8 and IAF ML2, IAF PL8 \(code P-08\)](#)

11 ANNEXES

ANNEX 1 – Accreditation Process Phases
ANNEX 2 – List of the Folders of document
ANNEX 3 – The recognition process

12 SYNTHESIS OF MODIFICATIONS

There were included modification on the following pages [1](#), [9](#), [11](#), [13](#), [14](#), [15](#), [16](#), [17](#), [23](#), [24](#), [34](#), [36](#), [37](#), [41](#), [42](#).