MOLDAC REPUBLICA MOLDOVA	**NATIONAL ACCREDITATION CENTRE**

REQUIEREMENTS FOR ACCREDITATION TESTING AND CALIBRATION LABORATORIES

Code DR-LÎ/LE-01
Edition 6

Approved by Technical Laboratory Committee
Minutes no. 16 from 05.09.2017

Approval date: 05.09.2017
Application date: 05.09.2017

CONTENT

1. SCOPE

The scope of the present document is to describe the requirements for accreditation of Testing and Calibration Laboratories accordingly to SM SR EN ISO/CEI 17025:2006, EA, ILAC, MOLDAC documents applicable for this standard in order to ensure a uniform and consistent application.

2. FIELD OF APPLICATION

The document is applied to accredited laboratories, those who seek accreditation and MOLDAC personnel involved in the CAB accreditation process.

3. REFERENCE DOCUMENTS

- The Law no. 235 from 01.12.2011 on accreditation and conformity assessment activities with subsequent modifications.

- SM SR EN ISO/IEC 17000:2006 – Conformity assessment. Vocabulary and general principles

- SM SR EN ISO/IEC 17011:2006 – Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies

- SM SR EN ISO/IEC 17025:2006 – General requirements for the competence of testing and calibration laboratories

- SM SR EN ISO/IEC 17043:2011 – Conformity assessment - General requirements for proficiency testing

- EA, ILAC applicable documents:

-	EA – 4/02:2013	mandatory	Expressions of the Uncertainty of Measurements in Calibration (including supplement 1 to EA-4/02)
-	EA – 4/09:2017	guidance	Accreditation for Sensory Testing Laboratories LI which uses sensorial methods to take into account of provisions of this document
-	EA – 4/14:2003	informative	Selection and Use of Reference Materials
-	EA – 4/15:2015	guidance	Accreditation for Bodies Performing non-Destructive Testing OI/NDT which uses methods in nondestructive field to take into account of provisions of this document
-	EA – 4/16:2003	guidance	EA Guidelines on the Expression of Uncertainty in Quantitative testing
-	EA – 4/18:2010	consultative	Guidance on the level and frequency of proficiency testing participation
-	ILAC-P9:06/2014	mandatory	ILAC Policy for Participation in Proficiency Testing Activities

-	ILAC-P10:01/2013	mandatory (from 01.01.2014)	ILAC Policy on Traceability of Measurement Results
-	ILAC-P14:01/2013	mandatory	ILAC Policy for uncertainty in Calibration
-	ILAC G19:08/2014	guidance	Modules in a Forensic Science Process LI/OI which perform accredited activities in forensic filed to take into account of provisions of this document
-	ILAC G24:2007	guidance	Guidelines for the determination of calibration intervals of measuring instruments

EA, ILAC documents can be accessed on following web-pages: www.european-accreditation.org and www.ilac.org

- MOLDAC documents published on the website www.acreditare.md**.**

-	Policy P-02	Policy on use of PTs and ILCs and other inter laboratory comparisons in the accreditation process
-	Policy P-03	Policy on traceability of measurements
-	Policy P-04	Policy on handling the non-conformities
-	Policy P-07	Policy on treating the objections of CAB regarding the names of team members
-	Policy P-08	Policy and rules for using of accreditation symbols and references to accreditation
-	RA	Accreditation Rules
-	CA	General Criteria for Accreditation

4. DEFINITIONS AND ABBREVIATIONS

4.1. Definitions

For using this document, it is applied the relevant terms and definitions from:

SM SR EN ISO/IEC 17000:2006 – Conformity assessment. Vocabulary and general principles.
SM SR EN ISO/IEC 17011:2006 – Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.

SM SR Guide ISO / IEC 99:2012 International vocabulary of metrology (IVM).

SM SR Guide ISO/ IEC 98-3:2011 Guide to the expression of uncertainty in measurement

SM SR EN ISO/ IEC 17025:2006 – General requirements for the competence of testing and calibration laboratories.

SM SR EN ISO/ IEC 17043:2011 – Conformity assessment. General requirements for proficiency testing.

SM SR EN ISO 9000:2016 – Quality management systems. Fundamentals and vocabulary.

SM SR EN ISO 10012:2006 - Measurement management systems. Requirements for measurement processes and measuring equipment.

4.2. Abbreviations

ONA (NAB) – National Accreditation Body

OEC (CAB) – Conformity Assessment Body

SM – Management System

LÎ – Testing Laboratory

LE – Calibration Laboratory

CT – Technical Committee

LAB - Laboratories

5. DESCRIPTION OF ACTIVITIES

Accreditation of testing and calibration laboratories will be performed accordingly to SM SR EN ISO/IEC 17011:2006, applicable EA, ILAC documents, and MOLDAC procedures and rules.

In order that accreditation process to be more clear and unique for all laboratories, MOLDAC approves the present requirements, which are accordingly to SM SR EN ISO/IEC 17025:2006, EA, ILAC documents.

The number of points from this chapter corresponds to the no. of elements from SM SR EN ISO/IEC 17025:2006.

4. Requirements concerning the management

4.1 Structure

The laboratory, which requests accreditation accordingly to SM SR EN ISO/IEC 17025:2006 must provide identification dates which will include the following:

- The complete name, accordingly on statute, the short name or initials, by case;
- Legal status of laboratory and/ or of organization it belongs, Establishment act (by case);
- The copy of Registration certificate;
- Address of head office, telephone/ fax/ e-mail.

If laboratory has more locations, it must be presented all these information for all locations for which are requested accreditation.
Applicable documents in which are presented identification data of laboratory at requesting accreditation:

- Request for accreditation (submitted by a laboratory at requesting accreditation);
- System management manual;
- The legal status of the laboratory or organization it belongs must be clearly identified (private legal entity or belonging to the state) and proved by relevant documents: Copy of organization Statute, Copy of Registration certificate, Copy of incorporation Act;

- The organization Statute, state owned, must emerge from a proper legislative document (Government decision, law) ;
- If the laboratory requests accreditation as a second or third party laboratory, in the statute must be clearly stated the object of activity complying (testing activities and technical analysis);
- Legal responsibility is deemed to Republic of Moldova legislation;
- At the accreditation of laboratories under the jurisdiction of other states, the requirement of legal responsibility must be ensured and evaluated by a competent legal entity in law of respective state, which can adequately support this requirement;
- The laboratory must have a valid civil liability insurance, unless the laboratory is guaranteed by the state by law;
- Insurance must be both contractual and civil liability;
- The insured value must be related to the type, scope and volume of laboratory/ organization work and must be credible being the evidence of its financial strength. This value must result from civil liability insurance;
- If the laboratory does not have its own legal personality compulsory insurance returns to (insurance must cover the entire accredited scope/ requested for laboratory accreditation) organization to which it belongs (the parent organization).

In the Policy of the Quality Field and in the Quality Manual must be documented that laboratory performs its testing and calibration activities so as to meet the requirements of the international standard SM SR EN ISO/IEC 17025:2006.
If the laboratory declares itself competent to perform testing in the regulated area, it must supplementary to the requirements of SM SR EN ISO/IEC 17025:2006, to apply additional the requirements of the legislation from respective field or of the regulatory authorities.

Sufficiently detailed presentation of the locations where testing are performed:

- (LÎ location scheme)
- Property deed for LÎ spaces or
- Lease agreement for them
- In cases in which LI/LE headquarter, in which it develop the testing/calibration activities is placed/ replaced in a location, that previously had another destination (for example: storeroom, production room, living places etc.), laboratory must present in addition a sanitary authorization on operation (by case), or other permissive acts, in accordance with the legislation in force, which will confirm the possibility of use of those locations for carrying out the declared activities.

When are performed activities in temporary locations, on the field or mobile means, there should be stipulations of management, technical competence and procedures for these activities:

- The main scope/ product type of parent organization
- Parent organizational chart indicating the position of laboratory
- All organizational levels between laboratory and top management with the names and positions of managerial staff (matrix of responsibilities)
- Assess of the parent organization influence on the functioning of the laboratory in terms of system management, investments, human resources, supply, etc. (Identification fiche of potential conflicts of interest and preventive actions).

Management staff should be appointed by a decision where is specified the delegation of authority necessary to perform specific tasks and allocation of resources required to laboratory work.

Management and technical personnel must be listed in the job description the authority limits especially in identifying the occurrence of irregularities in the management system and initiation of corrective, preventive actions.

The laboratory must have identified, recorded the necessary resources of tasks (material and huma) and demonstrate in documented way that they exist.

LÎ organizational chart with records:

- Laboratory relations with production departments, human resources, commercial, administrative, etc.
- Organizational levels of the organization (if applicable)
- The limits of authority and responsibility
- The degree of centralization and delegation
- Responsibilities for permanent and/ or contributor personnel

People who provide supervision should be identified; supervisory tasks specified in writing (job description, etc.) and must have adequate competence for a proper supervision.

Supervision hase the scope for:

- monitoring of maintaining technical competence of the laboratory staff;
- monitoring of activities carried out by technical staff on probation period, being under qualification or training, etc.

Functions that have the responsibility of supervision must be identifiable in organizational chart. The way of conducting the supervision must be documented.
Technical management refers to resources staff ensuring, knowledge, skills, methods and procedures to maintain and improve the standard of services provided by the laboratory. Qualifications and experience must be relevant to this responsibility and must be in compliance with the job description.

In large organizations with multiple technical activities may be more people named as technical managers.
In this case entities will operate separately from each other and this will have to come from the organizational chart.
The delimitation lines between entities must be very clear in describing the work of entities.
Each technical manager must meet the job requirements relevant to its entity.

Laboratory management must ensure that every staff member understands the role of each in the system and the extent to which contribute to the achievement of the performance objectives.
.

- LÎ General objectives fiche
- Individual objective fiche

Top management must to ensure an adequate circulation of information and decisions inside the organization and an efficient communication system for all aspects of management system- the description.

Documents

- The organizational chart of parent organization
- LÎ organizational chart
- System management manual
- Declaration on policy concerning the quality
- Job description of SM Responsible
- Order of official appointing of Responsible SM/ labor. contract
- List of Decisions appointing deputies and deputies.
- Job descriptions
- Management commitment
- Security and access procedures
- Labor contract

- Declarations

4.2 Management system

The management system represents the instrument through which the management can apply its policy and can achieve its objectives. The management system should be updated to maintain its adequacy. The review of the system is necessary when there are:

- Modifications of methods, regulations;
- Organization and personnel changes;
- Changes of activities or client requirements;
- Corrective/ preventive actions;

The level of documentation should be appropriate to activity (volume, complexity), to size and organization (independent laboratory, or part of a larger organization with more entities or locations). It is recommended to avoid over documentation, in terms of content and number of copies.

The elements contained in a document, should not be repeated in another document.

Manual of SM may include or make reference to a statement of quality policy, signed by the person with managerial executive function and having the authority to set the policy, organization and allocate resources to the respective laboratory: director of the organization of which the laboratory is part of or director of laboratory if the laboratory is a legal entity. The policy statement should indicate how the stated objectives are achieved.

With the exception of general and permanent objectives listed above will be set Specific, Measurable, Agreed jointly, Achievable, Realistic and Time planned objectives (SMART).

Documents from which results the competency/ achievement of requirements.

LÎ management commitment to comply with the standard SM SR EN ISO/IEC 17025:2006 and to criteria of the accreditation body, to continually improve the SM effectiveness.

Decisions after Management review, analyze their achievement.

Display in public places of the organization of the importance of fulfilling customer requirements as well as those statutory and regulatory.

Except for very large laboratories consisting of several entities or locations, Manual SM may include general procedures by which the requirements of this standard are realized, it ensures a greater unity and coherence.

SM Manual can contain annexes which will make explicit enough: resources (including personnel), organizational structure, system documentation structure (including foreign origin). The presentation:

- Manual of management system
- Lists of internal SM documents (procedures, instructions, etc.)
- Lists of external documents (EA, ILAC, MOLDAC documents, Law of Republic of Moldova, Government Decisions of Republic of Moldova, DN, etc.)

The manual must cover the responsibilities of management positions in the laboratory (head of laboratory, heads of technical units, technical manager and SM manager). The operative technical staff responsibilities are contained in documents (procedures, instructions, programs, etc.).

Manual of management system must present evidence that has been reviewed and approved by top management which recognizes that it represents correctly its intentions, and knowledge and its application is mandatory for personnel.

Documents

- Manual of management system (MSM)
- Lists of procedures on which MSM makes the reference
- Statement/ commitment of top management
- Statement on policy concerning the quality
- SMART objectives of LÎ
- Individual SMART objectives

4.3 Documents control

Submitted documents indicating competence/ achievement of requirements:

- Manual of management system
- Control of documents procedure including filled forms

Procedure for documents control which besides the way of keeping under control the documentation revision and its distribution, presents and analysis rules, approval, modification, and records referring to procedure application. The procedure should define through a complete list or Document lists (internal and external) kept under control, overhaul to date and the situation of its dissemination.
The laboratory must be ensured that:

- All documents, new or reviewed, are verified and approved, by an authorized personnel, before they are issued,
- The editions, reviews of necessary documents in force are placed in all places where activities are performed,
- Modifications are made in a such way to ensure a correct documentation, on time, for each activity and relevant function,
- Documents which are not valid or withdrawn are removed and destroyed, and those stored for different proposes are marked properly,
- It can be identified through records, if personnel knows the edition/ review, in force, for each document,
- The system of the unique identification of documents is documented, known and applied,
- Copies are numbered and the owner is identified,
- When the workplace is changed the assigned documents are withdrawn,
- It is named a person with a responsibility on external documents update,
- If it is the case the interested parties are notified concerning the documents review, the applied system is documented,
- Clear to document how to identify modifications,
- It should be defined the authority limit concerning the content of modifications made by hand,
- It is documented the way of distribution and control of documents disseminated in computerized system, if the laboratory is computer-based and there are intranet,
- It is documented and controlled the access to the respective laboratory of the organization from which the laboratory is part of the intranet network laboratory.

4.4 Requests, tenders and contracts analysis

When this analysis is the responsibility of the Chief of laboratory or another manager, registration concerning analysis may be set up for simple or routine works (currently conducted) in a decision on the forms of carrying out (Yes, Performing, etc.) accompanied by the signature and date. In

general it is necessary to draw up a review of requests, tenders or contracts.
The work performed according to a schedule (daily, regular), written and approved by the management of the laboratory and eventually signed by the client, this program is accepted for executing command staff.

Analysis of new and complex works requiring planning or resource allocation (eventually new) or development/ approval/ validation of test methods, must be registered (the analysis fiche) and stored.

Oral requests for a test (by telephone) are entered in a register or in a form.

The laboratory management must to declare its policy concerning the accepting of new testing activities.

The laboratory must have a documented system for:
- receiving,
- recording,
- identification,
- verification and analysis of orders.

4.5 Subcontracting of testing and calibration

The laboratory should document the respective policy procedure on subcontracting. Subcontracting is permitted only in exceptional cases (e.g.: for a limited period of time, the ability to perform laboratory tests is exceeded) or the client's requirement. The laboratory may declare that it does not subcontract tests.
If the laboratory subcontracts with non-accredited laboratories it must document and implement a procedure for evaluation and selection of subcontractors. Records of such evaluations should be available.

The laboratory should have a list of accepted subcontractors. This will contain:
- Name and address of sun contractor/ Name of contact person
- Type of tests for which was accepted/ period of validity of acceptance
- Type of acceptance based on accreditation or on assessment.

In the case when it is subcontracted testing activities, the laboratory must to obtain the written consent of the client. The laboratory shall assume full responsibility for the work subcontracted.
Individuals who have the authority and responsibility of subcontracting must be identifiable. Privacy issues must be taken into account.
Documents
- Manual of management system
- Evaluation procedure for subcontractors
- Subcontracting procedure.

4.6 Purchasing and supplies services

The laboratory must to:
- declare its supply policy,
- document the procedures, authority, and responsibility of those who elaborate, analyses and approves documents supply
- to document completely and correctly the specific requirements for each category of stocked supplies,
- analyze and approve the supply documents prior to release,

- shall select providers based on assessment of their ability to meet all the specified requirements, including those relating to quality,
- ensure that the goods supplied are not used until they have been inspected or verified and comply with drawn up specifications,

The laboratory will have a list of accepted providers which will include:
- Type of product or service supplied (training, calibration, equipment, software etc.)
- Name and address of the provider
- Name of the contact person
- The date when was assessed and valid period of the assessment

The laboratory must have records of the inspection at reception.
The products which have not been inspected must be separated from those verified and declared compliant. If you make an exception to this rule it should be kept detailed records of the use of the product.

The laboratory must have:
- reception procedures, storing and releasing products in store
  - instructions for checking the products in stock and stock control
  - special instructions for toxic substances, drug precursors
  - spaces and special instructions for storage and handling of supplies, materials, consumables and reagents

Documents
- Manual of management system
- The assessment procedure for suppliers
- Supply procedure
- The procedure for checking goods supplied
- Procedure of storage and stock control.

4.7 Customer service

The laboratory must document its customer service internal or external individuals, businesses or public authorities.
Customer service can be provided:
- before contracting/ performing activities
- during the testing
- in reporting and interpreting the results.

The laboratory cooperation with the client presumes:
- informing its performance method
- participation at testing
- providing clarifications (to the customer) concerning test results

The laboratory must develop one system to obtain feedback from client and to use the gained positive and negative information to update and develop the system management.

Documents
- Manual of management system
- The procedure to obtain feedback
- Questionnaire of clients satisfaction.

4.8 Complaints

Laboratory policy for handling the complaints will cover principles and criteria relating to: consideration of the feedback resource and evaluation of service quality to customers by analyzing

complaints, criteria for the acceptance of complaints (written, verbal, anonymous, etc.), problem-solving and response deadlines, types of actions undertaken at the levels of authority involved.
Laboratory policy must bring out the laboratory's effort to:

- Satisfy as much as possible the requests of the complainant,
- Prevent the image damage of laboratory,
- Use of information from complaints to correct and prevent nonconforming activities.

The procedure will describe the activities performed for the achievement of this policy, inclusive:

- The recording system,
- The forms used for records.

Documents

- Manual of management system,
- Procedure of complaints treatment,
- The register for recording the complaints.

4.9 Activities control of non-conforming testing and/ or calibration

The nonconforming testing activities also include cases in which are made mistakes, losses, accidents, or other deviations from procedures in the testing activity. They can be found in:

- complaints and feedback,
- internal audit,
- quality control of the results.

Control of non-conforming testing works must contain at least:

- Correction of nonconforming work (restoration, completion, etc.) and possibly issued documents (report, etc.),
- Analysis of the causes and taking corrective action if it finds that the nonconforming activity could recur,
- Assessment of previous testing qualities where is possible.

The procedure must specify:

- The way of reporting and recording of nonconforming testing works/ activities,
- Forms used for recording,
- How often are analyzed the records,
- Who participate at analysis,
- Used methods,
- To whom is reported the analysis results concerning the nonconforming testing works, conclusions and corrective actions,
- Who decides above the testing recovering,
- Who communicates to the client about the analysis results concerning the nonconforming testing works.

As a result of nonconformity activities analysis it will be made modifications of management system.

Documents

- Manual of management system
- The procedure of treatment of nonconforming testing activities.

4.10 Improvement

The laboratory must prove a continuously improvement of own management system functioning through:

- application of the policy in quality field,
- non quality cost reduction,
- reducing the frequency and seriousness of nonconforming testing activities,
- reducing the number and seriousness of complaints,
- satisfactory results of the measures of quality control/assurance results,

- the confidence in the system, date and the way of performing internal audits and analysis conducted by management,
- achieving goals established by management system,
- management system objectives linking with economic development of the laboratory,
- increasing trust and customer satisfaction.

4.11 Corrective actions

The laboratory must declare its policy in choosing and implementation of corrective actions such that:

- The client should not be affected,
- The laboratory should be less affected,
- To avoid the reappearance or worsening of non-conformity,
- to prevent future non-conformities.

The laboratory should document the procedure for handling feedback and implementing corrective actions when deviations occur from the policies and procedures documented.

The procedure must specify:

- Responsibilities for cause analysis, the influence of non-conformities and the choosing of corrective actions,
- Responsibilities for conducting/ verification,
- Verification methods of the efficiency of corrective actions,
- Post monitoring implementation of corrective actions.

The way of resolving and effectiveness of corrective actions are verified at internal audits, in areas or activities where corrective actions were taken. Often a non-conformity can be treated in two stages:

- correction of deviation,
- cause analysis and undertaking corrective action to eliminate the causes.

The laboratory must distinguish between correction and corrective action and do not limit itself at corrections.

The management system responsible has a very important role in the implementation of these policies and procedures.

The laboratory must provide for the possibility of initiating corrective actions not only as a result of non-conforming activities, internal or external audits, management analysis, feedback from customers, but also as a result of the comments of the personnel.
Documents

- Manual of management system,
- Procedure of corrective actions.

4.12 Preventive actions

The performant laboratories have as their principal objective the prevention and treatment of non-conformities. On this line the laboratory should regularly analyze the operation of the management system and identify possible sources of non-conformities and possible improvements.

General preventive actions are:

- Infrastructure improvement
- Personnel training in some cases
- Implementing of testing methods using automated equipment
- Procurement of performant equipment, with built-in soft
- Using of methods with increased performance

- Specialized internal audits
- Additional measures of quality assurance results

The laboratory should predict the possibility of initiating preventive actions as a result of the comments of the personnel.

Documents

- Manual of management system
- Procedure of preventive actions

4.13 Records control

The laboratory must implement a documented procedure to control records, including those on computer and submit them to the procedure for classification.

Records kept under control must be clearly identified (name, code, support, data), along with the location, responsible and storage time. The laboratory will have records of management system:

- Organization (organizational chart, description departments, job descriptions)
- Operation (distribution lists/ withdrawal of procedures, instructions, regulations)
- Verification (internal audit reports and minutes of management analysis)
- Carrying out activities and document control
- Personnel (CV, trainings, tests, diplomas, etc.)
- Equipment (equipment fiche, program of maintenance/ verification/ calibration

The records of some activities which are reevaluated periodical (internal audits, analysis, etc.) are kept on a period of minimum one cycle of accreditation.

In the case of records stored electronically it will established clear rules preventing unauthorized access (setting levels of access, passwords, etc.) or amendment of these records.

Records on activities that may affect the parameters or testing results (e.g. maintenance works, metrological verifications, personnel qualification, etc.) are kept on a period of at least one accreditation cycle or during the duration of their use. The recorded information and shelf life must comply with the applicable legislation or customer requirements (if any exists).

When legal or customer requirements exceed these minimum requirements, these are applied. Generally technical and administrative records must allow restoration of the work in question.

Technical records must include:

- The testing program and possible amendments,
- Names of persons who carried out the various parts of the testing,
- Primary data and regardless of form and support
- Special circumstances during the testing performing,
- Enviromental conditions, where is the case,
- Calculations and other processed data
- The final report including amendments and/ or annexes, where is the case (see 5.10),
- Correspondence on testing and report,
- Relevant informations concerning the quality of goods supplied or subcontracted tests.

Documents

- Manual of management system,
- The procedure of records control,
- Instructions of access and classification of information (by case).

4.14 Internal audits

Internal audit is an important means of verifying the adequacy and operation of the management of the laboratory. The internal audits must be conducted by qualified personnel with knowledge in the audited activity, auditing and requirements of the reference standard.
At each audit it will be verified the elements of the management system:

- As degree of suitability for the laboratory activities
- As operating
- As documented
- As possibilities of improvement

Internal audit is performed based on annual program approved by the management of the laboratory. The frequency of internal audits may vary depending on volume, complexity and the level of risk of the activities audited, as well on demonstrated efficasy of the management system and the proven stability. All elements of the management system are audited at least once a year. The internal audit program for the activities of testing and/ or calibration will be developed so that in a cycle of accreditation to report all activities in the field. In developing this program it should take into account the importance of the processes and areas to be audited and the results of previous external/ internal audits.

It is recommended that activities: records and documents control, complaints and activities control of nonconforming testing, to be audited more frequently than once a year.
It is recommended that the audit to be carried out based on detailed questionnaires, approved as documents and known by auditee.

Any technical statistics, used in such cases, are considered useful. The effectiveness of these audits will be verified at the management review.

The documented procedure must specify:

- The manner and criteria for designation of the audit team,
- The manner of performing (instructions/ lists of verification),
- Reporting module,
- The distribution of the report,
- Tracking on solving non-conformities,
- Access to records,
- The period of retention/ archiving.

Documents

- Manual of management system,
- Internal audit procedure,
- The list of auditors,
- Questionnaires (Verification lists),
- Internal audit program,
- Internal audit report.

4.15 Management review

The analysis should be systematic and should consider all components of the management system.

Input data include at least:

- Results of internal/ third party audits
- Laboratory performance (results of PT/ILC)
- Feedback
- Realization level of general and individual objectives

- Adequacy of the management system to the business plan and development prospects
- Assessment of revisions necessary as a result of:
    - Changes of regulations
    - Technical progress
    - Clint's requirements
    - The modification of referential

It is recommended to monitor the processes through specific indicators, where is applicable.

Proposals to improve laboratory management system, can be presented as inputs elements at analysis.

Analysis is conducted as a meeting headed by executive manager who approved quality policy with the participation of all personnel of laboratory having responsibility concerning the quality. As a result of analysis it must be identified:

- Solutions to improve the management system and technical competence to regulatory and clients requirements.
- The necessary material resources, human or training, being able to improve annual planning or establish preventive or corrective actions, if necessary.

The analysis record should be clear and contain explicit output elements and terms of achievement (planning, responsibility, deadlines) and should be sent to persons responsible for carrying out established activities/ measures.
The documented procedure must specify:

- Responsibilities,
- How to conduct, frequency,
- How to report,
- How to distribute the report,
- Access to the records,
- The period of retention / archiving,
- The way of planning and implementation of improvements.

Documents

- Manual of management system,
- The procedure of management review.

5 Technical requirements

5.1 General

The laboratory must to declare its standard of performance in testing and to establish the scope (testing/ products/ methods/ equipment/ personnel) for which requires the accreditation.

The laboratory must specify:

- Regulatory requirements which it is subject to,
- Categories of customers and specific requirements, if any,
- Use of the results, if it is known

Documents

- Manual of management system,
- The accreditation scope with the name of testing, equipment and personnel (approved by accreditation body).

5.2 Personnel

The laboratory personnel should have the studies, trainings, technical knowledge, skills and necessary experience for correctly carrying out the work. These requirements should be assessed in correlation with object and domain of activity of the laboratory.

Laboratory must have enough personnel needed in developing of declared activities (volume, scopes, and shifts) and not less than 2 persons.

If there are requirements of the law, other technical regulations or customer concerning the certification, or other form of attestation of competence, personnel who are executing these testing must have certification or required attestation.

The laboratory must establish a documented training system to ensure that each person is trained in terms of technical and management, and knowledge is maintained and updated in line with its policy.

The training program will be developed into categories according to the degree and type of activity and responsibility/ authority assigned to personnel.
For new employee the training program will have:

- study period and adaptation
- probation activity under supervision
- continuous training.

It is applied also to the transferred staff and to who was assigned a new task (requiring a higher qualification).
Staff competence and training needs will be evaluated permanently.
The staff remuneration should not be a direct correlation between the volume of testing or their results and salary.
The laboratory shall have requirements (job descriptions) and records (personal records) on training, experience and knowledge of the personnel, including one authorized to formulate opinions or recommendations.
Chief of the laboratory, manager of the management system and the responsible on testing must be permanently employed staff.

The personnel based on providing service contract (or whatever you'd call it) must be independent of customers testing and have not participated in the design, manufacture or marketing of tested products.

In particular, duties and responsibilities of temporary staff and/ or intern must be defined in relation to other members of the laboratory. A supervision of such personnel must be ensured on all period to guarantee that temporary staff and/ or intern work accordingly to laboratory procedures. The laboratory must evaluate the competence of temporary staff or intern and keep records.

The same provisions on obtaining skills for particular tasks can be applied. If necessary, staff training can be adapted accordingly to the nature of activities distributed to these personnel.

Personnel management rules should be the subject to some documented provisions.

1.) Use of personnel with a collaboration contract (5.2.3)

ISO/IEC 17025 does not exclude to use external personnel by laboratory with the condition that exist a collaboration contract which will specify the conditions of the staff intervention in the laboratory.

The personnel based on contract which intervenes for not on time missions, which normally are assured by permanent personnel, must meet the same requirements as salaried staff.
In particular, the staff based on contract is identified in the organizational chart of the laboratory, it responds to the same confidentiality requirements, to compliance of procedures and qualification, and upgrading skills as employees of the laboratory.

2.) Use of temporary personnel or an intern (5.2.3)

When a laboratory use a temporary personnel or an intern for realizing the activities from accredited scope it must ensure independently on the duration of the contract that the organizational requirements and skills are satisfied as for other staff. Particularly, the affected tasks and responsibilities must be defined as well the relations between temporary personnel ant interns, and other laboratory members. A supervision of these personnel must be ensured throughout the mission to guarantee that temporary staff and interns are working accordingly to laboratory procedures. The laboratory must evaluate the competence of temporary staff or intern and keep records.

The same provisions on obtaining skills for particular tasks can be applied. If necessary, staff training can be adapted in conformity with nature of distributed activities of these personnel.

3.) Use of personnel which provide activities for several employers

When a laboratory use this kind of personnel, it must identify the employers and potential conflicts of interests and to ensure the confidentiality of information at which personnel has access opposite of his other employers.

4.) Replenishment (replacements), (4.1.5. j)

The eventual absence of replenishment of certain functions must be compatible with the service laboratory displayed. For example, if the laboratory is committed to realize its benefits within the deadline, it must have the resources to meet this commitment and the replenishment for thus persons holding this commitment.

Replacements may be partial, it means to be only on specific tasks related to a function: it is necessary to define precisely which tasks will be replaced.

The replacers must be able to replace the holders at the qualification level expected: it is the laboratory task to ensure surveillance and maintaining of their qualification.

5.) Authorization of the personnel (5.2.5)

Some specific tasks, in particular critical on quality results performing obtain a formal authorization of personnel named empowering-direction. These particular tasks cover the following:

- use of specific equipment (equipment of sampling preparing, use of IT softs for calculation, etc.);
- realization of particular types of sampling, testing or calibration;
- validation of results;
- issuing of opinion and interpretation;
- signing of testing reports.

An authorization can cover more tasks in the same time, for example validation of results and signing of testing reports.

The decision on authorization of one person for a given task is the result of one process. The decision is taken based on his trainings, experience and/ or results of tests (participation at one or more proficiency tests, testing of reference materials, cross testing with a competent technician, task realization with supervision of a competent staff, etc.). The laboratory must have objective

criteria when this is possible. The decision criteria must be documented and the decision made to be justified through records (certificates, planning of internal training, the results of tests…).

Authorizations must be analyzed on a regular basis and the competences to be confirmed. When exists day by day objective proves of tasks learning (for example use of reference material at each number of testing or participation at inter laboratory comparisons), these elements can justify the maintenance of competence and abilities.

The laboratory must foresee the authorization confirmation of one person for a task after certain period without task completion. The need to confirm of technical competence, after a long break in the performance of a certain type of activity and possible changes in the course since the last time the implementation of such activities.

6.) The signatory of testing and calibration reports

The signatory of testing and calibration reports is the person who takes responsibility of the report on the results and certifies that the performing was made in respect of the provisions of SM. It is about main personnel or who received authorization from laboratory department for this activity.

The signatory may have himself the power to validate the results, issuing opinions and interpretations and to rely on the persons entitled to these issues.

In the second case, validating results and if applicable, issuing of opinions and interpretations by authorized persons must be traceable at validation and issuance at laboratory level.

When reports include results validated by different persons it is necessary that signatory of the report to have appropriate knowledge and experience to analyze the correlation of results between them and in relation with the tested product.

7.) Requirements for persons issuing opinions and interpretations

When a laboratory is capable to issue opinions/ interpretations in the report with measurement results, the persons responsible of such comments must be qualified and authorized. The qualification criteria is related to opinions and interpretations that he intends to give. As a authorization of testing and calibration achievement, generally, assigned through testing or calibration method, the authorization of opinions ant interpretations issuing should be associated to one certain field of application (e.g.: conclusions regarding the agronomic quality of soil from physic-chemical data, the types of equipment operation skills for the specific conditions of use, etc…).

The laboratory must take into account the legal requirements for certain categories of employees (e.g. civil servants).
Job description must contain:

- Name and job object (function),
- Job position in organization,
- Content (activities, tasks),
- Minimal conditions of occupation (studies, experience, competence, skills),
- Responsibility and authority,
- Relation of subordination / coordination / collaboration / representation.

One job description can be enough for personnel with the same function, especially in small laboratories.

There must be instructions for maintaining of personnel files. They must document the following:

- Who, where and how are kept the files,

- How and when are updated,
- Access at the personnel files.

In small laboratories or with similar competence of personnel is allowed that all personnel to be authorized, based on job description can be executed all testing.

The laboratories carrying out tests with high degree of specialization or risk must authorize staff which makes sampling, prepares sample, the one who work with different equipment, makes statistical processing, draw the testing report, makes comments or interpretations of results.

There must be records on the satisfying of the competence criteria for this staff.

Documents
- Manual of management system
- Personnel selection, assessment and re-qualification procedure
- Procedure of employment of temporary or permanent personnel
- Description of training system
- Instructions for completing the personnel files
- Model of job descriptions from laboratory
- Rules for authorization, authority list (where applicable).

5.3 Accommodation and environmental conditions

The requirement is applied to the permanent office of the laboratory and especially to equipped mobile laboratories.
The laboratory must declare their own policy on performing testing/ calibration outside the permanent location. Permanent location must have spaces dedicated to:

- Receiving and storage of testing/ calibration objects
- The performance of testing/ calibration
- Data processing and drafting of reports/ certifications
- Storage of records, reports/ certificates
- The reception and storage of reagents and auxiliary materials, supplies, equipment and facilities
- Personnel (dressing room, bathroom, dining room, study, etc.)

Specific procedures for testing/ calibration must state the activities and specific measures that are taken when testing, sampling, calibration is carried out in other locations than the one permanent or it is done on the field (at the customer, etc.).

The laboratory documentation should identify specific environmental conditions required by certain methods and state how to achieve them. In practice should be carried out and monitored environmental conditions affecting the results of testing/ calibrations. The access to the laboratory should be defined so as to not affect the testing/ calibration results (change in environmental conditions or contamination) and to ensure confidentiality of results and respect of ownership of the customer.

Instructions for cleaning, sanitizing and decontamination must be detailed in activities and risks. The program of cleaning and verification of effectiveness must eliminate the risk of cross contamination and satisfy regulatory requirements or their own safety.

The access rules should distinguish between permanent staff access during working hours and based access allowed.

Instructions for cleaning, sanitizing and decontamination must be detailed in activities and risks. The program of cleaning and verification of effectiveness must eliminate the risk of cross contamination and satisfy regulatory requirements or their own safety.

Documents

- Manual of management system
- Annexes location sketch
- Description of specific requirements for each area and the way of monitoring
- The list and description of mobile laboratories or impermanent
- Rules for issuing license/ key
- Access rules staff/ visitors
- Rules for use of protective equipment.

5.4 Testing and calibration methods, and validation of the method.

The laboratory must apply the methods and procedures set in the specifications/ relevant regulations or in criteria against which is evaluated the compliance.

In justified cases can be accepted deviations from the methods and procedures with the condition to demonstrate that the change does not affect the performance of the method and that the staff is able to apply the modified method. For these cases the laboratory shall have a policy, a procedure and consent of the client. All instructions, standards, manuals and reference data relevant to the work of the laboratory must be kept up to date and be easy available to personnel.

Working instructions must cover at least data/ information concerning:

- Type of activity (testing/ calibration)
- Testing/ calibration objects
- Description of the measurand
- Testing and measurement equipment
- Necessary environmental conditions, where applicable
- Testing/ calibration procedure
- Verifications before starting the activity
- Equipment calibration
- Adjustment or internal calibration where applicable
- precautions and safety measures
- Personnel qualification
- Calculation method and data processing
- Criteria of results acceptance

The laboratory must identify the risks associated to the performed activity and to elaborate instructions and safety measures for work.

- Available applicable list of instructions
- Working and protection instructions (evidences, personnel, environment).

The laboratory should declare the policy on choosing the testing/ calibration methods. It must be declared clearly the testing/ calibration activities, in the following way:

- Testing/ calibrations
- Scope
- Performed measurements
- Methods/ Equipment/ Used techniques
- Scope (values) and measurement uncertainty (where applicable)

The methods should be completely documented and validated (exceptions are standardized methods). One method is adequate if it accomplish the established performance parameters.

The methods published in manuals, journals and specialty magazines are not considered standardized because they were tested only in the laboratory of the author.
Approved official methods have been validated or verified in several laboratories and are equivalent to standardized methods.
For standardized methods the laboratory must to confirm that it applies correctly these methods before starting the testing or calibration activity. The laboratory must submit evidence of verification of standardized methods.

In the attempt to change referential of testing (canceled standards, new methods imposed by regulations, or by client, etc.) laboratory must document its policy and procedure for transition to the new testing methods.

The laboratory must to obtain the written consent of the customer before using a non-standard method. The laboratory can be accredited for own methods or which are a non-standard if these are completely documented, validated and adequate, and exist competent personnel for developing and using of them.

Own methods and non-standard methods must:
- be validated before the using of real samples;
- be verified the adequacy against the requirements;
- be revalidated if is changed the analyst/ conditions of testing/ application field;
- be revalidated after a long period of inactivity.

Own methods developed by laboratory must:
- be validated during the development of the method;
- be verified in terms of performance as compared to literature data for similar standard methods;

The standardized methods should be verified under aspect of capability of the laboratory to achieve the requirements of the reference specifications.

The laboratory must have a documented procedure of designing the validation experiments (protocol) and detailed records of experimental obtained results.

The extent of validation and studied performance parameters depends on:
Type of method:
- qualitative/ semi-quantitative/ quantitative
- destructive/ nondestructive
- routine/ reference/ ad hoc/ empirical
- the quantity of sample required for testing and quantity available
- material for testing homogeneity, stability, cost
- field of values (major component or trace)
- intended use of the results
- requirements - regulation or of the client

Declaration of validation is given only based on experimental data if the actual performance of the method fall within predetermined performance.

Documents
- Manual of management system
- The procedure of election and validation of the methods
- The procedure of developing of the method, if appropriate
- Requirements of calcification for personnel involved in developing/ validation of methods
- Validation protocol

For method validation can be used:
- Inter laboratory testing

- Testing between similar laboratories
- Testing in the own laboratory.

5.4.6 Uncertainty estimation of measurement

The policy of laboratory on estimating measurement uncertainties in the laboratory must to comply with the requirements. The laboratory shall document and implement procedure/ procedures for estimation of measurement uncertainty and to identify persons/ functions which apply the procedure/ estimation procedures/ verification/ validation of the results.
The laboratory should estimate the uncertainty of measurement method for each test/ calibration.

The laboratories that make internal calibration must also estimate the measurement uncertainty associated with these calibrations. In these cases the MOLDAC assessment team plan and assesses the work of internal calibrations according to SM SR EN ISO/ IEC 17025: 2006.
The application of relevant requirements in laboratories meets different levels of difficulty depending on the sectors:

For calibration laboratories the assessment and using of uncertainty measurement is well established and is based on the following documents SM SR ISO/CEI 98-3:2011 Guide to the expression of uncertainty in measurement and EA-4/02 Expressions of the Uncertainty of Measurements in Calibration (including supplement 1 to EA-4/02);

For testing laboratories the situation is more contrast.

Actions that must be performed are different for calibration laboratories on the one side and testing laboratories on the other side and are the subject of this document.

This chapter aims to synthesize the information available to MOLDAC and propose actions to help implementing the rules on the mention of uncertainty in the testing reports and use for eventual conformity declarations.

For calibration the laboratory must:

- have documented rules for estimation of uncertainty of measurement;
- estimate this uncertainty of measurement for each calibration performed.

The document EA-4/02 is intended to provide to calibration laboratories a practical method of uncertainty estimation coherent with GUM.

This document provides the foundation for harmonization of estimation methods of uncertainty practiced in different technical areas of calibration.

Based on document EA-4/02 laboratories elaborates documents with specific requirements for uncertainty estimation.

The calibration certificates must to include supplementary to the listed requirements at 5.10.2 if those are necessary for interpretation of calibration results, the uncertainty of measurement and/or conformity declaration with a defined metrological specification or with a chapter referred to this.

The document EA-4/02 states that: in the calibration certificates the complete result of a measurement, which has an estimation of the measurand and the associated expanded uncertainty U, shall be given in the form y ± U".

In calibration certificates, the expanded uncertainty must accompany the estimation of measurand under the form prescribed by EA-4/02. The expanded uncertainty is determined, starting with the uncertainty of composed type made with a coverage factor k = 2 (normal distribution or in such a way that the extended interval to correspond to a probability of coverage of 95%).

For testing

The absence of reference to uncertainty in testing reports or use of these measurement uncertainties to make a declaration of conformity or to interpret the results does not absolve the laboratory on satisfying the previous requirement.

The document EA-4/16 on the estimation of measurement uncertainty for quantitative testing explains various ways to calculate the measurement uncertainty so that the estimation by analyzing uncertainty components, law enforcement composition variations, or use of fidelity and appropriateness of testing methods or analysis, determination of linearity with using reference material or the use of proficiency testing data.

When the standard for testing is not explicit on the estimation of uncertainty, the laboratory must have the following:

- identifying of factors able to influence the result of measurement for all testing, including qualitative testing

- establishing of a list of factors that have a potential impact on the results of the testing (quantitative or non-quantitative testing). In this list certainly is included parameters for which testing method (either standardized or non-standardized) sets a margin of permissible values.

- specifying the elements that allow to bring evidence that can be overlooked the action of taking into consideration the factors that have insignificant influence.

- keeping under control the influential factors (e.g. if the testing method requires subjecting an object at a temperature of 23 ° C ± 1ºC, it should be noted that the affected measured temperature by the uncertainty of measurement are included in this budget).

Quantification (for quantitative testing)

- the availability of data of method fidelity (published value, control maps, inter laboratory testing, etc.), deviation type of loyalty is one of the uncertainty component; deviation type of loyalty can represent a sufficient estimation of uncertainty type of measurement result, if all the factors listed in section 1 were considered in the study fidelity.
- The analyzing and quantifying the influence of each factor identified in paragraph 1.1, influence which is judged significant and which is not considered in the study of loyalty.
- estimation of uncertainty starting from these components.

This is consistent with international guidelines and recommendations GUM.

Including of measurement uncertainty in testing reports.

For uncertainty estimation laboratory must have:

- A logic scheme of testing
- A transparent description of result assessment procedure.

- Whenever possible this description shall be in the form of a mathematical model. The assessment of outcome and model depend on the measurement procedure and the definition of the measurand.
- An identification of the magnitudes that affect the outcome and their interdependencies. It can be used a cause effect diagram or a table of correlations.
- A transparent description of knowledge concerning sizes that occur in the mathematical model (calculation formula). It can de used the distribution of probabilities and statistical evaluations to describe the limitations of knowledge. It must be used all reasonable estimates of all prior knowledge.
- A systematic method of influences composing. It is used the law on error propagation.

In addition to the requirements listed in 5.10.2, testing reports shall also include, where necessary, for the interpretation of testing results, the following:

If applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in testing reports if these are relevant for validation or use of the testing results, when it is a express requirement of the client, or if the uncertainty affects compliance with a limit from specification.

The laboratory shall identify the testing results to confirm the need to include or not the measurement uncertainty in the testing report.

Including of measurement uncertainty in the testing report is a requirement of the client and/ or referential.
Documents

- Manual of management system
- Job descriptions
- Measurement uncertainty estimation procedure.

The laboratory shall have instructions for checking calculations and data transfer. These have to mention:

- Who and when verifies
- How are made verifications (step by step)
- What records are generated

If the laboratory uses statistical techniques for data processing of the testing results, it must be proven the competence in choosing statistical method and its application. It should be identified personnel who have the authority and responsibility for data entry, statistical processing and reporting results. It must have the knowledge and necessary training for job position.

Computer systems must be adequate to the activities and duties to which they are dedicated.
The laboratory must:

- Identify involvement of computers in testing/ measurement/ data processing
- Define the hardware used
- Identify specific systems and sub-systems
- Declare the method of determining the level of adequacy of the software

Using of statistical techniques and data control must be included in the annual internal audit program.

Documents

- Manual of management system
- Job descriptions
- Instructions for data control

- Hard-ware list (manufacturer, configuration)
- Soft-ware list (version)
- Procedures for authorization, control and documentation of programs and modifications to the program
- Procedures for installation and maintain of software
- Procedures for recording and archiving of data computer generated

Identification procedures to ensure continuity of operations including data acquisition, in case of loss of processing capacity of data using computers.

5.5 Equipment

The laboratory must ensure that it has all the equipment necessary to the performance level required by methods in order to generate valid results within the contractual or legal limits. The laboratory shall ensure that it has all the equipment needed to generate valid results, whether such equipment is owned or leased. If there are legal or contractual requirements, the laboratory must demonstrate that the equipment is suitable for applications. The laboratory shall ensure that sampling and testing equipment having a small effect on the outcome (suitable design, inert materials, easy and reproducible operation, and maintenance of the reach of laboratory). For these equipments shall be a program of maintenance, calibration and intermediate checks.

Calibration is not required for devices that are used as transfer means, auxiliary equipment and measuring instruments with large uncertainty limits (e.g. methods semi - quantitative). In this case the Laboratory should have verification procedure and reporting of the results of those checks. The laboratory shall establish the intermediate frequency of testing this equipment.
Example on reporting of the results of checking is shown in Annex 1 of this document, code DR-LÎ/LE-01-A-1.

For measurement equipment and where appropriate for their parts it is advisable to make a validation before use.
For equipment that affects the quality of the measurement results must be accomplished a calibration program. The interval between two successive calibrations depends on the characteristics of the metrological reliability of the means for measuring, the intensity and conditions of use.

The laboratory must keep appropriate documents regarding: commissioning of measuring instruments, repairs of them (annual or more frequent) or calibration before each use.
These activities should be performed by qualified personnel using standards or certified reference materials and records must be kept, especially on the estimated measurement uncertainty.

The laboratory should make verifications (intermediate) at adequate intervals between two successive calibrations to control the maintenance of measurement capacity established at calibration.
These verifications can be made using prepared standards by laboratory and confirmed metrology adequately, other higher class appliances, reference materials or samples, stable in time.

The term "authorized" for personnel of equipment maintenance means "having established this responsibility".

Technical books and manuals of equipment operation, it is advisable, to be translated in full or in extract form comprising instructions for use and maintenance.

Each equipment must be unique identified by serial manufacturing, if this requirement is not accomplished, by a unique identifier (code, number) allocated by laboratory and registered.

It must be kept records of equipment which will meet the requirements of SM SR EN ISO/IEC 17025:2006 standard, point 5.5.5 a-h.

Documents

- Manual on management
- Job descriptions
- Instructions of use and maintenance of equipment
- Procedures of maintenance and intermediary verifications of equipment
- Equipment lease contracts (if applicable)

5.6 Traceability of measurement

Laboratory must to declare its policy concerning the traceability assurance and to document the modality of maintenance and verification of the equipment condition (concerning the calibration). The laboratory policy concerning the traceability must comply with MOLDAC Policies, the Policy on traceability of measurements accordingly to ILAC P10, code P-3. Traceability refers to the requirement making the correlation between the measurement result and national or international reference standards. If this is not possible it must be ensured traceability to certified reference materials. When selecting certified reference materials the laboratory should be guided by EA 4/14 document.

Traceability of common reference standards allows to laboratories to perform testing/ calibrations within the same set of conditions imposed for required measurement. Traceability is established with a stated level of uncertainty, every new link increasing the measurement uncertainty. The traceability makes the link and in the result ensures comparability between measurements made in different laboratories or at different times.

For a measurement to be traceable all measurements associated with values from the equation measurement (calculation formula) must be traceable. Other sizes which are not presented in formula calculation (temperature, pressure, humidity, pH, etc.) can significantly influence the result. Where this happens it should be ensured also the traceability of measurements made for controlling these parameters.

The laboratory must:

- To prove the traceability of measurement results for which request accreditation at national/ international standard.
- To have a calibration program with the following main elements: the calibration period (the time frame between two calibrations is established by the user accordingly to ILAC-G24), the place where are made the calibration and the reference standard which will be used, the uncertainty that should not be exceeded.

We point out that the defining elements of a valid traceability consist of:

i. connection of the instrument (used for getting information from measurement) to a chain traceability, chain at the upper end is consisted by a primary, officially validated standard (usually a national or international standard);

ii. Continuous nature of the chain and transmission operations of measurement units (calibration) made therein; all of these operations must be achieved without exceeding the established uncertainties.

The used standards must be accompanied by a calibration certificate.

If the calibration is performed by an external laboratory and the applicant laboratory does not have its own standard, calibration provider must be able to issue a certificate of calibration where will include the uncertainty value.

In accordance with Policy on traceability of measurements according to ILAC P10, all calibrations performed by laboratories inside the MNI with CMC declared or laboratories accredited by accreditation bodies that are covered by ILAC Arrangements (ILAC MRA), the Regional Arrangements recognized by ILAC or by MOLDAC which is in the process of peer evaluation are considered that they meet the requirements of traceability. Responsibility for compliance with all requirements for calibration activities performed by these establishments may be considered valid in terms of traceability and it is assumed by evaluated laboratory. The minimum content of calibration certificate and criteria for acceptance of certified reference materials are specified in SM SR EN ISO/ IEC 17025: 2006 and EA 4/02.

The MOLDAC assessment team verifies selection criteria and adequate evidence for ensuring traceability and estimation of measurement uncertainty.

Calibrations that cannot be made in SI units have a principle that if a result is calculated to a reference value, this is traceable to that value. Results comparing make sense only if traceability is to common references.

Internal calibration

Accredited testing laboratories/ calibration performing internal calibration of its equipment, but is not accredited as a calibration laboratory must demonstrate that it has the technical competence accordingly to chapter 5 of SM SR EN ISO/ IEC 17025: 2006.
All internal calibrations must be supported by minimal set of elements:

- the laboratory must to maintain documented procedures for internal calibrations;
- internal calibrations should be highlighted in a calibration report which will include at least: unique identification document and the end if it, the description of calibrated object (manufacturer/ type/ serial number) and identification without ambiguousness of it, the number of pages of the document, identification of the main metrological characteristics of the calibrated object, identification of the calibration method, identification of the reference standard and the evidence of metrological traceability of the measurements results, measurement conditions, environmental conditions in which was performed the calibration, the results of calibration and uncertainty of measurement and/ or declaration of conformity, additional information (if appropriate), surname, name and the signature of the person which performed the calibration;
- the recorded calibrations must be kept for a prescribed adequate time;
- personnel records to demonstrate technical competence of the personnel who performs the calibration. The competence evidences include: documented trainings, the results of measurement audits, etc;
- the laboratory must demonstrate the traceability with compliance with MOLDAC Policy P-03;
- the laboratory shall have and shall apply procedures for evaluation of uncertainty of measurement. The uncertainty of measurement will be calculated for each type of calibration and records will be kept for such calculations.
- reference standards must be recalibrated at appropriate intervals to ensure that the reference value is trustful in accordance with ILAC G 24: 2007.

The calibration procedure will include at least:

a) equipment to which is applied the procedure;
b) standards and/ or reference materials used and where possible, associated materials needed;
c) measures to be taken during the use, transportation and storage of standards and reference materials to protect their specifications;
d) requirements for use, transport, storage and preparation of equipment which is needed to be calibrated;
e) environmental conditions which must be kept under control, including applicable limits, any adjustments that depend on environmental conditions and, if required, the minimum period of stabilization prior to calibration;

f) technical instructions for calibration, including the statement of the person or persons responsible for this task, and where possible, any special competence criteria for these people;
g) specification of the measurement results which must be recorded;
h) maximum permissible errors for acceptance of calibration results, where applicable;
i) method of estimation of calibration uncertainty;
j) used criteria for decision of modification of calibration intervals.

Reference standards of measurement held by the laboratory must be used for calibration and only for this purpose. The management of standards will be documented in procedures describing in detail the measures taken to maintain specifications.

Testing laboratories which calibrates their own measuring equipment are not obliged to participate in inter laboratory comparisons for measurements which are calibrated internal, to the extent that they participate in inter laboratory comparison testing in which intervene the considered critical equipment and/ or if it use regularly certified reference materials in testing under discussion.

Documents

- Management manual
- Ensuring traceability procedure
- Criteria for establishment of calibration intervals
- Calibration/ metrological verification program
- Ensuring traceability procedure for different types of measurements
- Verification procedure for the state of calibration equipment
- The procedure for handling own standards (if applicable)
- List of internal standards with estimated uncertainty
- Criteria for calibration/ standard providers
- List of the accepted suppliers (see and 4.6)
- Equipment maintenance fiche
- Job descriptions
- Comparison and reporting procedure
- Internal calibration procedure

5.7 Sampling

The laboratory should define its own policy concerning the sampling. The laboratory policy regarding the sampling must comply with the requirements.
In case when the sampling is under the authority and responsibility of laboratory, it must document the way of how it ensures that:

- Personnel is competent and instructed;
- Exists necessary equipment for performing different type of sampling, accordingly to sampling standards;
- The measuring device incorporated in the sampling equipment is calibrated;
- Sampling procedures are adequate to sample, type of testing and required accuracy;
- Selected sample is representative
- Statistical models used are adequate, known, applied and declared;
- It is established the optimal amount of sample, taking into account the possible need to keep the contra sample;
- There are instructions for checking, registration and operation of sampling equipment or testing results;
- Are defined the conditions of packaging and conditioning;
- seal, if necessary;
- The sample is uniquely identified;

- It was taken safety precautions follow;
- There are defined the transportation conditions;
- Records allow recovery of sampling and interpretation of results;
- The recorded information for each sample are included in the testing report;
- For samplings which are not made at the laboratory, there is attached sampling report.

Documents

- Sampling procedure
- Plan/ sampling map
- Job descriptions
- Training program
- sampling equipment list

5.8 Handling of testing and calibration objects

The laboratory must document the policy and procedure on receiving of samples in work. The laboratory must have:

- a system for identifying samples, code allocation without risk confusion on the all the path in the laboratory
- documented procedures for reception, storage, handling and removal (elimination)
- instructions to avoid deterioration, damage or contamination of the specimen
- instructions for maintaining the environmental conditions
- instructions for safety during transportation
- return service rules to the client, according to the contract
- packing instructions and waste transport
- instructions for neutralization, decontamination and destruction
- safety rules (labor protection)
- rules to ensure confidentiality

Documents

- Management manual
- Procedure of samples processing (with the flowchart) including applicable procedures
- Description of the identification system with specimen
- Verification instructions

5.9 Assurance of quality results of testing

The laboratory shall document its policies and procedures for quality assurance and control of the generated results. Laboratory policy on ILC/ PT must comply with the Policy on the use of proficiency testing and other interlaboratory comparison in the accreditation process according to ILAC P9, EA-2/14 and EA-4/18, P-02 code.

Generally laboratory shall have implemented control measures for quality results.

By participating in the inter comparisons laboratory may:

- assess the quality of generated results
- identification of systematic errors
- assess the own results comparatively to those obtained in other laboratories practicing the same method
- assess comparatively different methods of testing

The obtained results must be reported by the head of laboratory to the management and can generate corrective/ preventive actions. The way is provided the quality of testing and calibration results will be subject to object analysis of the system.

Documents

- Management manual
- Control procedure of quality results
- Criteria for assessment of providers of PT/ ILC
- List of providers of accepted ILC and PT.

5.10 Results report

Activities performed by the laboratory must be covered by a testing report/ bulletin. These documents may only be submitted on paper. **It is not allowed only verbal reporting.**
The laboratory must declare its reporting policy and procedure for preparing and transmitting of reports.
The laboratory must to document:

- The modality of the identification
- Content
- Format
- Signature
- Amendments and Annexes
- Confidentiality ensuring.

The testing report must include:

- All the results of examinations and measurements performed
- Necessary information for understanding and interpretation of the report

All information must be correct, accurate, clear, and objective and presented in a manner that makes them easy to understand and used by reader.
Testing reports must be signed by nominated positions. If the report has multiple pages it must be mentioned on which one will be signed and which are the safety tips to prevent unauthorized reproduction or fraudulent use.

The laboratory must document the way of issuing the supplements to the testing reports.

When in the report are included opinions and interpretations, the laboratory must document the basis upon which they were made. Opinions and interpretations shall be clearly marked also in the testing report. SM SR EN ISO/ IEC 17025: 2006 does not include the definition of opinions and interpretations for the calibration results. Opinions and interpretations refer only to testing results in the strict sense.

A calibration laboratory should not issue opinions and interpretations on calibration certificates.
Presentation of uncertainty of measurement in calibration certificates must comply with ILAC P 14 stipulations.

The declaration of conformity does not replace strictly of the standard paragraphs on the opinions and interpretations. Note 2 of point 5.10.5 (opinions and interpretations) of ISO/ IEC 17025 calls it as a possible element of the "opinions and interpretations included in the testing report" an "opinion on the statement of compliance/ non-compliance of the results with the requirements" it is about one comment on the declaration of conformity, e.g.: on the decision rule used or the possibility to achieve the conformity.

When in the report are included the results of subcontracting, the laboratory must document the manner of identification them.

The laboratory must document electronic way of results transmission.

The laboratory must document the manner of issuance and approval of amendments to the testing reports after they have been issued so as not to result in confusion or misuse.

At the elaboration of Testing Reports/ Calibration Certificates laboratories must comply with MOLDAC Policy on the use of accreditation symbols and references to accreditation, code P-08.

6. ANNEXES

Annex 1 – Minutes of verification

7. SYNTHESIS OF MODIFICATION

Changes has been included on the pages: 1, 6, 32.