MOLDAC REPUBLICA MOLDOVA	**NATIONAL ACCREDITATION CENTRE**

GUIDELINES FOR ACCREDITATION OF TESTING AND CALIBRATION LABORATORIES

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1. SCOPE

This document is a guide that describes the requirements for accreditation of Testing and Calibration Laboratories according to ISO/IEC 17025:2017, applicable EA, ILAC, and MOLDAC documents for this standard in order to ensure a uniform and consistent application.

2. FIELD OF APPLICATION

The document is applied to accredited Testing and Calibration Laboratories, those who seek accreditation, as well as to MOLDAC personnel involved in the accreditation process of CABs.

3. REFERENCE DOCUMENTS

- The Law no. 235 of 01.12.2011 on accreditation and conformity assessment activities with subsequent amendments.
- SM SR EN ISO/IEC 17000:2006 – Conformity assessment. Vocabulary and general principles.
- SM EN ISO/IEC 17011:2017 – Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies.
- SM EN ISO/IEC 17025:2018 – General requirements for the competence of testing and calibration laboratories.
- SM SR EN ISO/CEI 17043:2011 – Conformity assessment - General requirements for proficiency testing.
- SM EN ISO 17034:2016 – General requirements for the competence of reference material producers.
- ISO Guide 31:2015 Reference materials - Contents of certificates, labels and accompanying documentation.
- ISO Guide 33:2015 Reference materials - Good practice in using reference materials.
- ISO Guide 35:2017 Reference materials - Guidance for characterization and assessment of homogeneity and stability.
- SM SR ISO 5725-1:2002 Accuracy (trueness and precision) of measurement methods and results - Part 1: General principles and definitions.
- SM SR ISO 5725-2:2014 Accuracy (trueness and precision) of measurement methods and results - Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method.
- SM SR ISO 5725-3:2014 Accuracy (trueness and precision) of measurement methods and results - Part 3: Intermediate measures of the precision of a standard measurement method.
- SM SR ISO 5725-4:2014 Accuracy (trueness and precision) of measurement methods and results - Part 4: Basic methods for the determination of the trueness of a standard measurement method.
- SM SR ISO 5725-5:2014 Accuracy (trueness and precision) of measurement methods and results - Part 5: Alternative methods for the determination of the precision of a standard measurement method.

- SM SR ISO 5725-6:2014 Accuracy (trueness and precision) of measurement methods and results - Part 6: Use in practice of accuracy values.

- 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 G: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 P 8:12/2012	mandatory	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies
- 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 EN ISO/IEC 17000:2006 – Conformity assessment. Vocabulary and general principles.
SM EN ISO/IEC 17011:2017 – Conformity assessment. 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 EN ISO/IEC 17025:2018 – 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 according to SM EN ISO/IEC 17011:2017, 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 in compliance with SM EN ISO/IEC 17025:2018, EA, ILAC documents.

The number of points from this chapter corresponds to the number of elements from SM EN ISO/IEC 17025:2018.

4. General requirements

4.1 Impartiality

Laboratory activities shall be undertaken impartially, structured and managed so as to safeguard impartiality.

The requirements of paragraphs 4.1.1 - 4.1.5 of ISO/IEC 17025 are fully applicable, taking into account the following:

Through a declaration of impartiality, managing conflicts of interest and the objectivity of its activities, the laboratory management declares its commitment to being impartial. Laboratory management actions should not contradict to this statement.

The commitment to impartiality and objectivity of management shall be publicly available.

The laboratory shall describe any relationships that might affect its impartiality, to a relevant extent, using organizational diagrams or other means.

Contractual arrangements with laboratory personnel should include avoiding commercial, financial or other pressures that could affect laboratory activities.

In organizations where the manager function, which is subordinated to the laboratory head, also cumulated responsibilities for allocating resources for contracting and delivering tested products or testing/calibration services, there shall be commitments, organizational arrangements, procedures, responsibilities and records on the avoidance of conflicts of interest and in particular on the technical decision-making independence of the laboratory regarding the results of the tests / calibrations.

The laboratory shall continually identify the risks of its impartiality. It is advisable to draw up a document in which, depending on the need, the following should be included:

- the analysis of potential risks of impartiality, including the risks arising from its activities or relationships, or from the relationships of its personnel;
- measures to eliminate or minimize impartiality risks;
- action plan: establishing and implementing pertinent actions;
- the laboratory's commitment regarding to its integrity by signing a statement by the top management.

This document should be considered in the management review and, if necessary, reviewed.

Examples of relationships that may affect impartiality are:

- property,
- government,
- management,
- personnel,
- shared resources,
- finances, contracts,
- marketing (including branding) and payment of a sales commission or other incentive to bring new customers, etc.

If a risk of impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes this risk.

4.2 Confidentiality

The requirement is applicable integral.

The laboratory shall declare how ensure the confidentiality of all information obtained or created during the conduct of laboratory activities and of respecting proprietary rights that shall be appropriate to the contractual clauses and arrangements between it and its customers. If the CAB is bound by law or authorized by contractual commitments to issue confidential information, the customer shall be notified, unless prohibited by law, regarding of the information provided.

It is advisable to have a documented classification system of information, each class corresponding to a set of protection measures.

Persons authorized to own or use documents / records shall be declared in writing and the respective documents listed.

Personnel in the course of the activity may be in possession of confidential or secret information (product information, processes, commercial data, personal and health data). In this case, the confidentiality of this information shall be ensured.

The CAB shall require that all personnel, including committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

5. Structural requirements

The requirements of paragraphs 5.1 to 5.7 of ISO/IEC 17025 are fully applicable, taking into account the following:

The laboratory seeking accreditation according to ISO/IEC 17025 shall provide identification data, comprising the following:

- Full name according to status, short names or abbreviations, where applicable;
- Legal status of the laboratory and / or the organization of which it is a part, the Founding Act (if applicable);
- Copy of the Registration Certificate;
- Head office address, telephone / fax / e - mail.

If the laboratory has several premises, this information shall be given for all premises for which accreditation is requested.

The applicable documents presenting the laboratory identification data upon application for accreditation:

- Application for Accreditation (submitted by the laboratory while seeking the accreditation);
- Documented procedures, policies and objectives to meet ISO/IEC 17025 requirements;
- The legal status of the laboratory or organization to which it belongs shall be clearly identified (a private or public law legal person) and demonstrated by relevant documents: copy of the Organization's Statute, copy of the Registration Certificate, copy of the Establishment Act. If the laboratory requires accreditation as a second or third-party laboratory, the status of the

appropriate activity should clearly be mentioned in the organization's status - technical testing and analysis.

- The status of organization, belonging to the state, shall be based on an appropriate legislative document (Government Decision, Law);
- Legal responsibility is considered to be the legislation of the Republic of Moldova;

When accrediting laboratories under the jurisdiction of other states, the requirement of legal responsibility shall be ensured and evaluated by a legal person competent in the law of that State who can adequately support the fulfillment of this requirement;

The laboratory should have a valid civil liability insurance, unless the laboratory is state-insured by law. The insurance shall be both contractual and civil liability.
The insured value shall be correlated with the type, scope and volume of laboratory / organization activity and shall be credible as proof of its financial strength. This value shall be the result of civil liability insurance.
If the laboratory does not have its own legal personality, then the insurance obligation rests (the insurance shall cover the entire accredited / requested area for accreditation of the laboratory) of the organization to which it belongs (the mother organization).

Note: This requirement is applicable to third-party laboratories and second-party laboratories that provide services to external clients.

The laboratory in its papers should define the range of laboratory activities for which it complies with ISO/IEC 17025. The laboratory shall declare compliance with ISO/IEC 17025 only for this range of laboratory activities that excludes laboratory activities provided in a permanently from the outside. If the laboratory declares itself competent to carry out tests in regulated areas, it shall, in addition to the requirements of ISO/IEC 17025, also apply the requirements of relevant legislation or regulatory authorities.

Sufficiently detailed presentation of locations where laboratory activities are carried out:

- The layout of the laboratory
- Property Act for the premises of his laboratory
- Rent contract for these

Where the laboratory's premises in which it carries out its test / calibration activities is located / relocated in a space previously used for other purposes (eg warehouse, production room, living quarters, etc.), the laboratory shall provide additional sanitary authorization (as the case may be) or other permissive documents in accordance with the legislation in force confirming the possibility to use the spaces provided for carrying out the declared activities.

Where the laboratory performs activities in temporary premises, on land or by mobile means, there shall be management arrangements, technical competence and specific procedures for these activities:

- Main areas of activity / product types of the parent organization
- Organizational chart of the mother organization specifying the position of the laboratory
- All organizational levels between the laboratory and top management with the names and functions of the management personnel (Matrix of Responsibilities)
- Assessment of the extent to which the mother organization influences the operation of the laboratory in terms of management, investment, human resources, supply, etc. (Identification of potential conflicts of interest and their minimization).

The laboratory should identify the management that has the overall responsibility for the laboratory.

The management and technical personnel shall specify the authority limits, in particular for:

a) implementing, maintaining and improving the management system;

b) identifying deviations from the management system or procedures for conducting laboratory activities;
c) initiating actions to prevent or minimize such deviations;
d) reporting to the management of the laboratory on the performance of the management system and any improvement needs;
e) ensuring the effectiveness of laboratory activities.

Technical management refers to the provision of personnel resources, knowledge, skills, methods and procedures to maintain and improve the standard of service offered by the laboratory. Qualification and experience shall be relevant to this responsibility.
In large organizations with multiple technical activities, there may be more people appointed as technical managers.
In this case, the entities will work separately from each other and this will have to follow from the organizational chart.
The demarcation lines between entities shall be very clear from the description of the entity's activities. Each technical manager shall meet the requirements of the relevant post for his/her entity.

The laboratory shall have identified, documented, the resources necessary to accomplish the tasks (material and human) and demonstrate documented that they exist.

Laboratory management shall ensure that:
a) communication takes place regarding the effectiveness of the management system and the importance of meeting customer's and other requirements;
b) the integrity of the management system is maintained when changes to the management system are planned and implemented.

The management of the laboratory shall ensure that each staff member understands the role each has in the system and the extent to which it contributes to the achievement of the performance objectives.
- Sheet of general objectives
- Sheet of individual objectives

Top management shall ensure an adequate circulation of information and decision-making in the organization and an effective communication system regarding all aspects of the management system - the description.

6 Resource requirements
6.1 General

The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

The laboratory shall declare its test/calibration performance standard and establish the scope (testing/calibration/products/methods/equipment/personnel) for which accreditation is seeked.

The laboratory shall specify:
- The regulatory requirements to which they are subject,
- Customers categories and specific requirements, if applicable,
- Use of results, if known.

6.2 Personnel

The requirements of paragraphs 6.2.1 to 6.2.6 of ISO/IEC 17025 are fully applicable, taking into account the following:

The laboratory staff shall have the studies, training, technical knowledge, skills and experience necessary to carry out the activities properly and be able to assess the significance of the deviations.

The laboratory shall document the competence requirements for each function that influences the results of the laboratory activities, including requirements related to education, qualification, training, technical knowledge, skills and experience.

The laboratory shall have sufficient personnel to carry out the declared activity (volume, fields, exchanges), but not less than 2 people.

If there are requirements of the legislation, other technical regulations or the client regarding the certification or other form of attestation of competence, the personnel performing the respective tests/calibrations shall have the required certification or attestation.

The laboratory shall establish a training system to ensure that each person is trained in technical and management aspects and knowledge is maintained and updated in accordance with its policy.

The training program will be elaborated according to the categories of study and in accordance with the type of activity and the responsibility/authority assigned to the personnel.
For newly recruited personnel the training program will include:

- the period of study and adaptation,
- the probation period with activity under supervision,
- continuous training.

It also applies to personnel who have been transferred and assigned a new job (requiring a higher qualification).
The competence of the personnel will be evaluated on a permanent basis.
There shall be no direct correlation between the volume of tests or their results and the salary in the remuneration of the staff.

The laboratory shall have procedures and keep records (personal files) regarding the determination of the competence requirements; personnel selection, personnel training; personnel supervision (until authorization); personnel authorization; personnel monitoring (after authorization), including personnel authorized to perform specific activities, including development, modification, verification and validation of methods; analysis of results, including statements of compliance or views and interpretations; reporting, analyzing and authorizing the results.

The most commonly used monitoring / monitoring methods are:
- measurements made on known samples: reference standards, reference materials, incomparable samples, etc;
- blind samples;
- inter/intra laboratory comparisons;
- exams (for assessing intellectual knowledge).

The head of the laboratory, the manager of the management system, shall be permanently employed.

Personnel used on the basis of a service contract (or whatever it might be called) shall be

independent of the test/calibration customers and have not participated in the design, manufacture or marketing of the tested/calibrated products.

In particular, the tasks and responsibilities of temporary and / or trainee personnel shall be defined in relation to other members of the laboratory. Supervision of these personnel shall be ensured for the full duration to ensure that temporary and/or trainee personnel work in accordance with laboratory procedures. The laboratory shall assess the competence of temporary or trainee personnel and keep records.

The same provisions regarding the acquisition of skills for carrying out particular tasks can be applied. If necessary, personnel training may be tailored to the nature of the activities assigned to these personnel.

1.) Use of contract personnel (pct 6.2.1)

ISO/IEC 17025 allows the laboratory to use external personnel provided that there is a collaboration contract specifying the conditions for the intervention of the laboratory personnel. Contract personnel, who work for regular point assignments provided by permanent personnel, shall meet the same requirements as salaried staff. In particular, contract personnel are identified in the organization chart of the laboratory, it meets the same requirements of impartiality and confidentiality, compliance with procedures, qualification and improvement of qualification as the laborer's staff.

2.) Use of temporary or trainee personnel (pct 6.2.1)

When a laboratory uses temporary or trainee personnel to carry out accreditation activities, it shall ensure, independently of the duration of the contract, that organizational and skills requirements are met as for the rest of personnel. In particular, the tasks and responsabilities involved shall also define the relationships between temporary and trainee staff and other members of the laboratory. Supervision of these staff shall be ensured throughout the duration of the mission to ensure that temporary or trainee staff work in accordance with laboratory procedures.

The same provisions regarding the acquisition of skills for carrying out particular tasks can be applied. If necessary, staff training may be tailored to the nature of the activities assigned to these staff.

3.) Employing staff who work for more than one employer

When the laboratory uses such staff, it shall identify employers and potential conflicts of interest and ensure the confidentiality of the information that staff have access to vis-à-vis their other employers.

4.) Supplements (replacements)

The eventual absence of locators for certain functions shall be compatible with the level of service displayed by the laboratory. For example, if the laboratory is committed to achieving its benefits within the specified timeframe, it shall have resources to meet this commitment and therefore have locators in the absence of the holders.

Replacements may be partial, it means only specific tasks related to the function: then it is necessary to define precisely which tasks will be called the locators.

Locators shall be able to replace holders to the expected qualification level: it is the task of the laboratory to ensure the supervision and maintenance of their qualification.

5.) Authorization of personnel (pct 6.2.6)

Certain specific tasks, particularly critical of the quality of performance results, obtain a formal authorization of personnel, called steering powers. These particular tasks relate to:

- use of specific equipment (sample preparation equipment, use of computational software, etc.);
- performing particular types of sampling, testing and calibration;
- development, modification, verification and validation of methods;
- issuing opinions;
- analysis of results, including statement of compliance or views and interpretations signing test reports;
- reporting, analyzing and authorizing the results.

An authorization may cover multiple tasks at the same time, eg validating results and authorizing test reports.

The decision to authorize a person for a given task is the result of a trial. The decision is made on the basis of its training, experience and / or test results (participation in one or more proficiency tests, testing of reference materials, cross-test with a skilled technician, carrying out the task with supervised personnel, etc.). The laboratory shall have objective criteria whenever possible. Criteria for decisions shall be documented and decision taken justified by records (diplomas, internal training plans, test results, etc.).

Authorizations shall be permanently analyzed and the competencies confirmed. When there is daily evidence of objective attribution of tasks (eg use of reference material in each test series or participation in interlaboratory comparisons), these elements may justify maintaining competence and abilities.
The laboratory should provide for confirmation of a person's authorization after an absence period of time, without carrying out the task (e.g. pregnancy period). The need to confirm competence is depend of the duration of the lack of activity of the technical competence required by the task and the possible changes to the manipulation since the last time it was practiced by the interested person.

6.) Authorization of test and calibration reports

The signatory of test and calibration reports is the person who bears the responsibility of the report on the results and implicitly certifies that the performance was performed according to the provisions of the MS. A frame staff is considered or authorized by the laboratory direction for this activity.

The signatory may himself have the skills to validate the results, to give opinions and interpretations, or to rely on empowered persons for these matters.

Validation of results and, where appropriate, the issuing of opinions and interpretations by qualified persons shall be traceable on validation and laboratory-level issue.

When reports include validated results from different people, it is necessary for the signatory of the report to have the right knowledge and experience to analyze the correlation of the results with each other and the tested product.

7.) Requirements for people who give opinions and interpretations (pct. 6.2.6 b)

When the laboratory is able to issue opinions/interpretations in relation to the measurement results, the persons responsable for such comments shall be qualified and authorized. Qualification criteria are closely related to opinions or interpretations that he intends to give. As an authorization to perform tests or calibrations generally attributed by the test or calibration method, authorization to issue opinions and interpretations should be associated with a precise scope (for example: conclusions on agronomic soil quality assessment, starting with physicochemical data, skills for operating types of equipment under specific conditions of use, etc.).

The laboratory shall take account of legal requirements for certain categories of employees (eg civil servants).

8.) personnel competence monitoring (pct 6.2.5 f)

Staff monitoring is a tool for identifying training needs and assessing staff performance.
Monitoring is carried out by:

a) evaluating laboratory records;
b) observation of personnel during tests/calibrations;
c) feedback from the laboratory customer, etc.

The management of the laboratory shall communicate to its staff the tasks, responsibilities and authorities.

The laboratory shall document the competence requirements for each function that influences the results of the laboratory activities, including the requirements related to education, qualification, training, technical knowledge, skills and experience.

6.3 Facilities and environmental conditions

The requirements of paragraphs 6.3.1 to 6.3.5 of ISO/IEC 17025 shall be fully applied taking into account the following:

The requirement applies to the permanent premises of the specially equipped laboratory and laboratories. The laboratory has to declare its policy on testing/calibration outside the permanent establishment. The permanent establishment shall have dedicated spaces for:

- Receiving and storing test/calibrated objects
- Performing the tests/calibrations
- Data processing and drafting of reports/certificates
- Keeping records, reports/certificates
- Reception and storage of reagents, auxiliary materials, consumables, equipment and facilities
- Personnel (dressing room, sanitary group, table space, study, etc.).

Specific test/calibration procedures should specify the particular activities and measures that are taken when tests, sampling, calibrations are performed in non-permanent premises or on site (customer, etc.). The documentation of the laboratory shall identify the special environmental conditions required by certain methods and show how to achieve them. In practice, the environmental conditions affecting the test / calibration results shall be achieved and monitored.

The access in laboratory should be defined in such a way that the results of the tests / calibrations (variation in environmental conditions or contamination) are not affected and the confidentiality of the results and the respect of the customer's property right are ensured. Access rules should distinguish between permanent staff access to program hours and permit-based access.

The cleaning, sanitizing and decontamination instructions shall be detailed on activities and risks. The clean-up and effectiveness check should eliminate the risk of cross-contamination and meet regulatory or safety requirements.

6.4 Equipment

The requirements of paragraphs 6.4.1 to 6.4.13 of ISO / IEC 17025 shall be fully applied taking into account the following:

The laboratory shall ensure that it has all the necessary equipment at the performance level required by the methods, so that it can generate valid results within the contractual or legal limits. The laboratory should ensure that it has all the equipment necessary to produce valid results, whether these are proprietary or leased. If there are legal or contractual requirements, the laboratory shall demonstrate that the equipment is suitable for applications. The laboratory should ensure that the sampling and testing equipment has as little effect as possible on the results (appropriate design, inert materials, easy and reproducible operation, and maintenance at the lab's reach). For this equipment there shall be a maintenance program, intermediate checks and calibration. Calibration is not required for equipment that is used as transfer means, auxiliary equipment and measuring instruments with high uncertainty (eg semi - quantitative methods). In this case, the laboratory shall have verification procedures (internal, external) and report the results of these checks. The laboratory shall establish the frequency of these equipment checks.
The example of reporting the results of the checks is given in Appendix 1 to this document, code DR-LÎ / LE-01-A-1.

For measuring equipment, and where appropriate for their component parts, it is advisable to validate before use. For equipment that influences the quality of measurement results, a calibration program should be developed. The measuring equipment shall be calibrated when:

- measurement accuracy or uncertainty of measurement influences the validity of the reported results and/or
- calibration of the equipment is required to establish the metrological traceability of the reported results.

The time interval between two successive calibrations should be determined by the laboratory taking into account the ILAC G-24 Guideline and the metrological reliability characteristics of the measuring instrument, the intensity and the specific conditions of use.

The laboratory shall keep, as appropriate, documents on: putting into service of measuring instruments, their repairs (annual or more frequent) and calibration before each use. These activities should be carried out by qualified personnel using certified standards or reference materials and records should be kept, in particular on the estimated uncertainty of measurement.

The laboratory shall perform (intermediate) checks at appropriate intervals between two successive calibrations to verify that the calibration capability is maintained at calibration. These checks shall be carried out following a documented procedure and maintained records of the results obtained.
Such verifications may be performed using well-established laboratory standards and metrology-confirmed standards, other larger classroom equipment, reference materials or samples, stable over time.

The term "authorized" for service personnel means "having this responsibility established".

The technical books and the operating manuals of the equipment should be translated in full or in the form of extracts containing instructions for use and maintenance.

Each equipment shall be uniquely identified by the manufacturing order and, if this requirement is not met, by a unique identifier (code, number) assigned by the laboratory and registered.

Equipment records shall be maintained to meet the requirements of ISO / IEC 17025 clause 6.4.13 a-h.

6.5 Metrological traceability

The requirements of paragraphs 6.5.1 to 6.5.3 of ISO / IEC 17025 shall be fully applied taking into account the following:

The laboratory shall declare its traceability policy and document how to maintain and verify the state of the equipment (calibration). The traceability laboratory policy shall comply with the MOLDAC Policy, ILAC P-10 Traceability Policy, P-3 Code. Traceability refers to the requirement to make a correlation between the result of the measurement and the national or international reference standards. If this is not possible, traceability to certified reference materials shall be ensured. Manufacturers of reference materials that meet the requirements of ISO 17034 are considered competent to ensure traceability. When selecting certified reference materials, the laboratory may be guided by ISO Guide 33.

Traceability to common benchmarks allows laboratories to perform tests/calibrations within the same set of required conditions required for measurement. Traceability is established with a declared level of uncertainty, each new link increasing uncertainty of measurement. Traceability connects, or ensures comparability, between measurements made in different laboratories or at different times. For a measurement to be traceable, all measurements associated with the values in the measurement equation (calculation formula) shall be traceable. Other sizes that are not present in the calculation formula (temperature, pressure, humidity, pH, etc.) can significantly influence the result. Where this happens, traceability of the measurements made shall be ensured to control these parameters.
The laboratory shall:

- Demonstrate (ensure) the traceability of measurement results for which it requires accreditation to national / international standards;
- Has a calibration program, the main elements of which are: the calibration period (the time interval between two calibrations is set by the user according to ILAC-G24), the place where the calibration and the reference standard to be used, respectively the uncertainty shall be overcome.

We emphasize that the defining elements of a valid traceability are:

a) the measuring instrument connection (used to obtain measurement information) to a chain of traceability, the upper end of which consists of a validated primary standard (usually a national or international standard);

b) the uninterrupted character of the chain and, implicitly, of the transmission operations of the measuring units (calibration) carried out within it; the fact that all these operations shall be accomplished by fitting with the established uncertainties.

The standards used shall be accompanied by a calibration certificate.

In accordance with the ILAC P10 Measurement Tracking Policy, all calibrations performed by INM laboratories with declared CMC tables or by laboratories accredited by Accreditation Bodies that are covered by ILAC Arrangements (ILAC MRA) or Regional Arrangements recognized by ILAC, are considered to meet traceability requirements. The responsibility for complying with all requirements, so that the calibration activities performed by these units can be considered valid from the point of view of traceability, is assumed by the evaluated laboratory. The minimum content of the calibration certificate as well as the acceptance criteria for certified reference materials are those specified in ISO/IEC 17025, EA 4/02 and ISO 17034.
Calibration that can not be performed in SI units has the principle that if a result is calculated from a reference value, it is traceable to that value. Comparing results makes sense only if traceability is at common references.

Internal calibration

Accredited testing/calibration laboratories that internally calibrate its equipment but are not accredited as a calibration laboratory, shall demonstrate that it has technical competence in accordance with Chapters 6 and 7 of ISO/IEC 17025.

All internal calibrations shall be supported by the following minimum set of elements:

- the laboratory shall maintain documented procedures for internal calibration;
- internal calibrations shall be highlighted in a calibration report which shall include at least: the unique identification of the document and its end, the description of the calibrated object (manufacturer/type/serial number) and the unambiguous identification of the document, the number of pages from which the document is composed, date of calibration, date of issue of the document, identification of the main metrological characteristics of the calibrated object, identification of the calibration method, identification of the reference standard and proof of metrological traceability of the measurement results, measurement conditions, calibration results and measurement uncertainties and/or a statement of compliance, additional information (if applicable), name, surname and signature of the person who carried out the calibration;
- records of internal calibration results shall be kept for an adequate time;
- staff records demonstrating the technical competence of the calibration staff. Evidence of competence includes documented training, measurement audit results, etc.;
- the laboratory shall demonstrate traceability in compliance with MOLDAC P 03 policy;
- the laboratory shall have and apply adequate procedures for the measurement uncertainty measurement. The measurement uncertainty will be calculated for each type of calibration and recordings of these calculations will be maintained;
- Reference standards should be re-calibrated at appropriate intervals to ensure that the reference value is reliable in accordance with ILAC G 24: 2007.

The calibration procedure shall include at least:

- the equipment to which the procedure applies;
- reference standards and/or reference materials used and, where possible, related materials;
- measures to be taken during the use, transport and storage of standards and reference materials in order to protect their specifications;
- the requirements for use, transport, storage and preparation of the equipment to be calibrated;
- the environmental conditions to be controlled, including the applicable limits, any adjustments that depend on environmental conditions and, if necessary, the minimum stabilization period before calibration;
- the technical calibration instructions, including the declaration of the person (s) responsible for that task and, where possible, any specific competence criteria for those persons;
- specify the measurement results to be recorded;
- the maximum tolerated errors for the acceptance of calibration results, where appropriate;
- the way of estimating the uncertainty of calibration;
- the criteria used for the decision to change the calibration intervals.

Laboratory benchmark measurement standards shall be used for calibration and only for that purpose. The management of the standards will be documented in procedures that describe in detail the measures taken to maintain the specifications.

Testing laboratories calibrating their own measuring equipment are not required to participate in interlaboratory comparisons, for internally calibrated sizes, insofar as they participate in interlaboratory comparisons for tests involving critical equipment considered and / or use periodic reference materials certified in the tests in question.

6.6 Externally provided products and services

The requirements of paragraphs 6.6.1 to 6.6.3 of ISO / IEC 17025 shall be fully applied taking into account the following:

The laboratory shall ensure that the products and services that influence laboratory activities, if supplied from outside, are only used if they are appropriate.
The laboratory should have a procedure and keep records for:

- defining, analyzing and approving laboratory requirements for products and services provided from outside;
- defining the criteria for evaluation, selection, performance monitoring and re-evaluation of external suppliers;
- ensuring that products and services provided from outside comply with the requirements established by the laboratory or, where applicable, the relevant requirements of ISO/IEC 17025 before being used or supplied directly to the customer;
- undertaking any actions resulting from evaluations, performance monitoring, and re-evaluations of external suppliers.

The laboratory shall communicate its requirements to external suppliers for:

- products and services to be provided;
- acceptance criteria;
- competence, including any necessary qualification of staff;
- the activities that his laboratory or client intends to carry out at the premises of the external supplier.

The laboratory shall have a list of accepted suppliers, including:

- The type of product or service supplied (training, calibration, equipment, consumables and reference materials, software, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services, etc.);
- Name and address of the supplier;
- Name of the contact person;
- The date on which the evaluation was evaluated and the period of validity of the assessment.

The laboratory shall have records of the inspection at the reception.
Products that have not yet been inspected shall be separated from those verified and qualified as complying. If this rule is waived, detailed records of the use of the product should be retained.

The laboratory shall to document subcontracting cases and a procedure for evaluating and selecting subcontractors. Subcontracting is only allowed in exceptional cases (for example: for a limited time, the ability to perform laboratory tests is exceeded) or to the customer's requirement. The laboratory may declare that it does not subcontract tests.

The laboratory shall have a list of accepted subcontractors. This will include:

- Name and address of subcontractor / Name of contact person;
- Type of tests for which it was accepted / Acceptance validity period;
- Acceptance type based on accreditation or rating.

In the case of subcontracting, the laboratory shall obtain the customer's written consent. The laboratory assumes full responsibility for the subcontracted work.
Persons having the authority and responsibility for subcontracting shall be identifiable. Confidentiality issues need to be considered.

7 Process requirements

7.1 Review of applications, tenders and contracts

The requirements of paragraphs 7.1.1 to 7.1.8 of ISO / IEC 17025 shall be fully applied taking into account the following:

When this analysis is the responsibility of the laboratory chief or other manager, the analysis record may be for simple or routine work (currently performed), in a decision making decision (eg Yes, Making, etc.), with signature and date. In general, it is necessary to draw up an Application, Bid or Contract Analysis Sheet.
In works performed after a program (daily, periodically), written and approved by the laboratory management and eventually signed by the client, this program is considered an accepted order for the executing personnel.
Analysis of new and complex work, requiring planning or allocation of resources (possibly new) or development/approval/validation of test methods, should be recorded (analysis sheet) and kept.
Verbal (telephone) test requests are recorded in a register or a form.
When the customer requests a declaration of compliance with a specification or a test or calibration standard (eg admitted / rejected, falls within tolerance / is out of tolerance), the specification or standard and decision rule shall be clearly defined. Unless it is an integral part of the specification or standard requested, the decision rule selected shall be communicated to the customer and accepted by the client.
When external suppliers are used, the requirements of 6.6 are applied and the laboratory informs the customer of specific laboratory activities to be performed by the external supplier and obtains customer approval.
External laboratory activities may occur when:

- the laboratory has the resources and competence to carry out the activities and, however, for unforeseen reasons, is unable to meet them, in part or in full;
- the laboratory does not have the resources or the competence to perform the activities.

The management of the laboratory shall declare its policy of accepting new test activities.
The laboratory shall have a documented system and records for:

- receipt,
- record,
- identification,
- checking and analyzing orders,
- decision rule.

The laboratory should document the services offered to its internal or external clients: physical, legal or public authorities.

Services offered to customers can be provided:

- before contracting / performing the test activity;
- during the test;
- in the reporting and interpretation of the results.

Laboratory cooperation with the client involves:

- informing him about the performance of the method;
- his participation in tests;
- providing clarifications (customer) about test results.

7.2 Selection, verification and validation of methods

The requirements of paragraphs 7.2.1 to 7.2.2 of ISO / IEC 17025 shall apply in full, taking into account the following:

The laboratory shall apply the methods and procedures mentioned in the relevant specifications / regulations or in the criteria against which conformity is assessed.
In justified cases, deviations from methods and procedures may be accepted provided that the change does not affect the performance of the method and that staff are able to apply the modified method. For these cases, the laboratory shall have a procedure and customer agreement. All

support methods, procedures and documentation, such as instructions, standards, manuals and reference data relevant to laboratory activities, shall be updated and easily accessible to staff.
Work instructions shall include at least data / information on:

- Type of activity (test / calibration)
- Tested / calibrated objects
- Measurement description
- Testing and measuring equipment
- The necessary environmental conditions, where appropriate
- Testing / calibration procedure
- Checks before starting work
- Calibration of equipment
- Internal calibration or calibration as appropriate
- Precautions and safety measures
- Staff qualification
- Method of calculating and processing data
- Acceptance criteria for results

The lab should identify the risks associated with the activities carried out and develop safety instructions and measures.

- List of applicable instructions available
- Work and protection instructions (samples, personnel, environment).

The laboratory shall clearly declare the test / calibration activities as follows:

- Testing / calibration
- Sope
- Measurements performed
- Methods / Equipment / Techniques used
- Scope (values) and uncertainty of measurement (where applicable).

Methods shall be fully documented and validated (except for standardized methods). A method is appropriate if it achieves the set performance parameters. Methods published in textbooks, journals, and specialist journals are not considered standardized because they have only been experimented with in the author's laboratory. Approved official methods have been validated or verified in several laboratories and are equivalent to standardized methods.
For standardized methods, the laboratory should check that they can properly apply the methods before putting them into practice, making sure they can achieve the required performance. Records of verification shall be kept. If the method is revised by the issuing body, verification shall be repeated to the extent necessary. The laboratory shall provide evidence of verification of standardized methods.
In case of changing the test referencing (canceled standards, new rules imposed by the regulations, or customer, etc.), the laboratory shall document the transition procedure to the new testing methods.

The laboratory shall obtain the customer's written consent before using a non-standardized method. The laboratory may be accredited for its own or non-standardized methods if they are fully documented, validated and appropriate and there are competent personnel for their development and use.
Own methods and non-standard methods shall:

- validated prior to use on real samples;
- verifying compliance with requirements;
- revalidated if the analyst / test conditions / scope changes;
- revalidated after a long period of non-use.

The own methods developed by the laboratory shall:

- validated during the development of the method;
- checked for performance compared to literature data for similar standardized methods;

The laboratory shall have a documented procedure for designing validation experiments (protocol) and detailed records of the experimental results obtained.
The extent of validation and the performance parameters studied depend on:
Type of methd:

- qualitative/semi-quantitative/quantitative
- destructive / nondestructive
- routine / reference / ad hoc / empirical
- the amount of sample required for a test and the quantity available
- the material to be tested - homogeneity, stability, cost;
- range value (major component or trace)
- the intended use for the results
- regulatory requirements or customer requirements.

The validation statement is based only on experimental data, if the actual performance of the method is in the default performance.
The laboratory shall have the following validation documents and records:

- Procedure of choice and validation / verification of methods
- Method development procedure, if applicable
- Requirements specification
- Determining the performance characteristics of the method;
- The results obtained;
- Statement of method validation, detailing the degree of matching to intentional use,
- Qualification requirements for personnel involved in developing / validating methods,
- Validation protocol.

When validating methods, the laboratory can also use:

- Interlaboratory tests,
- Tests between similar laboratories
- Testing in your own lab.

7.3 Sampling

The requirements of Sections 7.3.1 to 7.3.3 of ISO / IEC 17025 are fully applicable, taking into account the following:

Where sampling is under its authority and responsibility, the laboratory shall document how it ensures that:

- The staff is competent and trained,
- There are the necessary equipment for performing different types of sampling, according to the sampling standards,
- There are instructions for checking, recording and operating the sampling equipment or test results,
- The measuring device incorporated in the sampling equipment shall be calibrated,
- Sampling procedures shall be appropriate to the sample, type of test and accuracy required,
- Sampling plan and sampling methods are available at the sampling site,
- Sampling plans shall be based, where appropriate, on appropriate statistical methods,
- The sample is representative,
- The statistical models used are appropriate, known, applied and declared,
- The optimal sample quantity is determined, taking into account the possible need to keep ”contraproba”,
- Packaging and conditioning conditions are defined,

- Seal, if applicable,
- The sample is uniquely identified,
- Safety precautions have been taken,
- Transport conditions are defined,
- Records allow you to resume sampling and interpret the results,
- The information recorded for each sample is included in the test report,
- For sampling not carried out by the laboratory, the sampling report shall be attached.

7.4 Handling of testing or calibration items

The requirements of paragraphs 7.4.1 to 7.4.4 of ISO / IEC 17025 shall be fully applied taking into account the following:

The laboratory shall document the procedure for the transportation, receipt, handling, protection, storage, retention and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.
The laboratory shall have:

- a sample identification system, risk-free code allocation throughout the laboratory route,
- documented procedures for reception, storage, handling and removal (disposal),
- instructions to avoid degradation, deterioration or contamination of the samples,
- instructions for ensuring environmental conditions,
- instructions for safety during transport,
- return rules to the customer, according to the contract,
- packing instructions and waste shipment,
- instructions for neutralization, decontamination and destruction,
- safety rules (work safety),
- confidentiality rules.

When the client requests that the object be test or calibrated by recognizing a deviation from the specified conditions, the laboratory shall include a statement of disclaimer in the report, indicating what results may be affected by that deviation.

7.5 Technical records

The requirements of paragraphs 7.5.1 to 7.5.2 apply in full.

7.6 Evaluation of measurement uncertainty

The requirements of Sections 7.6.1 to 7.6.3 of ISO/IEC 17025 are fully applicable, taking into account the following:

The laboratory shall estimate the measurement uncertainty for each test / calibration method.

Internal calibration laboratories shall also estimate the measurement uncertainty associated with these calibrations. In these cases, the MOLDAC assessment team plans and evaluates the internal calibration activity according to ISO / IEC 17025.
Applying the appropriate requirements in laboratories, encounters different levels of difficulty, depending on the sectors.

For calibrations
Accredited calibration laboratories shall evaluate the relevant measurement uncertainty for each measurement and each measurement interval to allow for the interpretation of all the calibration results it delivers.

The uncertainty of the measurement has to be estimated and reported generally in accordance with the method published in the international document entitled "ISO / IEC Guide 98-3 for the expression of uncertainty in measurement (GUM)" or the method described in the mandatory EA documents by referring to that document up.

The laboratory should document and implement the measurement uncertainty estimation procedure / procedures and identify the persons / functions that apply the estimation procedure / procedures / verify / validate the results.

Calibration laboratories requiring accreditation shall indicate "calibration and measurement capability" for the calibration activities included in their accreditation field. This definition is provided in ILAC P14: 01/2013 "ILAC Policy for Uncertainty in Calibration".

For the estimation of measurement uncertainty, the calibration laboratory shall have a mathematical model of measurement that highlights all factors that can affect the measurement result (evaluation of the result and model depends on the calibration procedure and the measurement definition).

In order to determine the level of confidence for the expanded uncertainty and the appropriate coverage factor, different approaches may need to be applied. For such cases, consideration should be given to document EA 4/02 M: 2013 "Evaluation of measurement uncertainty in calibration". This document provides the basis for the harmonization of methods of estimating uncertainty in different calibration technical areas.

The uncertainties estimated by a calibration laboratory shall be correlated with the measurement results obtained during the calibration.

The estimated value of the measurement obtained and reported should be rounded to have a number of digits equal to the estimate of the associated uncertainty. For example, if the measurement value is estimated at 7.08758 as a result of the measurement and the uncertainty is 0.016; the estimated value of the measurement shall be rounded to 7,088. GUM chapter 7, provides guidance on how to round out.

The following information shall be included in the transmission of the measurement results:
a) a clear description of the measure;
b) the value obtained by measurement;
c) expanded uncertainty to a confidence level of 95%;
d) coverage factor (k); and
e) measurement unit of measurement result and expanded uncertainty.

Calibration certificates issued by accredited calibration laboratories shall include measurement uncertainty values and such values shall not be less than "Calibration and measurement capability" as indicated in the Annexes to accreditation certificates.

For testings

The measurement uncertainty policies jointly set by EUROLAB, EURACHEM, CLSI and EA are defined in ILAC-G17:

a) The statement of measurement uncertainty shall contain sufficient information for comparative purposes.
b) GUM, ISO / IEC 17025 are the basic documents. However, sector specific interpretations may be necessary.
c) Only measurement uncertainty in quantitative tests is taken into account.
d) When using a standard test method, there are the following cases:

- when using a standardized test method that contains guidelines for uncertainty assessment, testing laboratories are not expected to do more than follow the uncertainty assessment procedure as set out in the standard;
- if a standard gives a typical measurement uncertainty for test results, labs may quote this figure. In this case, however, the laboratory shall demonstrate full compliance with the test method.

e) The depth of uncertainty assessment may vary in different technical areas.

f) In some cases, it may be sufficient to report standard reproducibility deviations at multiple operating levels as combined uncertainty.

g) In addition, it is appropriate to use specific sources for national / international national / sectoral purposes.

Testing laboratories shall use documents issued by national or international organizations to estimate measurement uncertainty in the test results. References for this purpose are provided in the documents: EA 4/16, ISO 21748, ISO 5725 (1-6), EURACHEM / CITAC guides.

EURACHEM / CITAC and EA 4/16 guide two possible approaches for estimating uncertainty of measurement:

a) formulating a model function with a defined measure, defining each source of individual uncertainty that influences the results, and calculating the contribution of each source to measurement uncertainty: this approach is also known as the "bottom-up" approach.

b) Using the performance data of the method: this is called a "top-down" approach or "empirical approach".

The measurement uncertainty components should be grouped into two types: type A - an evaluation method based on the statistical analysis of a series of repeated and independent observations; type B - method of assessment based on methods other than statistical analysis of observation strings.

The GUM approach can be very useful if each component of uncertainty is individually identified or studied. It has been found, however, that in many test methods, this approach gave figures smaller than the actual measurement uncertainty. It is difficult for the GUM approach to include all the possible components of uncertainty. By using the validation and performance data of the method, it is most likely to include all the components of uncertainty.

Information on the performance of the test method can be obtained from:

- Data accumulated during validation and verification,
- Interlaboratory studies,
- Internal quality control data (quality control maps, etc.),
- External quality assessment data (proficiency tests / interlaboratory studies).

Data so accumulated can be used to evaluate uncertainty about test methods. The following parameters can be considered for quantitative measurements: accuracy, linearity, selectivity.

Not all components of measurement uncertainty contribute equally to uncertainty. In practice, it is estimated that only a few components of uncertainty will significantly contribute to uncertainty. If the components contributing to the measurement uncertainty are less than 1/3 of the largest uncertainty component and the number of these components is low, they should not be included in the estimation of the uncertainty of measurement. However, it should be demonstrated that they are insignificant.

For this purpose, the contribution of each component should be estimated in preliminary studies or the components of uncertainty should be combined. Results that are insignificant should be removed.

After calculating all the standard uncertainties, the combined uncertainty u (y) is estimated as follows:

$$u(y) = \sqrt{u_1^2 + u_2^2 + u_3^2 + ...}$$

As a last step: the expanded uncertainty U (y) is estimated by multiplying the combined uncertainty value with the coverage factor (k) determined on the basis of the confidence interval:

$$U(y)=k.u(y)$$

As a general approach, the preferred confidence level is 95%, for which the coverage factor is 2. For a confidence level of 99%, the coverage factor is 3.
The uncertainty of measurement is reported:

- If the result of a test exceeds a certain tolerance or predetermined limit at the application of the relevant uncertainty (eg legal limit values);
- If the customer requests this.

In the absence of a specific reason, or unless otherwise specified in the test method, the expanded uncertainty value (U) for a measurement result (y) shall be indicated at a confidence level of 95% as follows:
y ± U

- in the measuring unit of measurement.

7.7 Ensuring the validity of results

The requirements of Sections 7.7.1 to 7.7.3 of ISO / IEC 17025 are fully applicable, taking into account the following:

The laboratory shall have a procedure to monitor the validity of its results. Laboratory policy on participation in PT/ILC shall comply with MOLDAC policy on the use of proficiency tests and other interlaboratory comparisons in the ILAC P9 P-02 accreditation process.
In general, the laboratory shall have implemented measures to control the quality of the results.
By participating in intercomparations, the laboratory may:

- evaluate the quality of the generated results,
- identifies systematic errors,
- compares its results with those obtained in other laboratories using the same method,
- evaluate comparatively different test methods.

The results obtained shall be reported by the head of the laboratory to the management and may lead to corrective / preventive actions. The way in which the validity of test and calibration results is ensured will be the subject of system analysis.

7.8 Reporting of results

The requirements of Sections 7.8.1 to 7.8.8 of ISO / IEC 17025 shall be fully applied, taking into account the activities of the laboratory:

The laboratory work shall be covered by a test report / sampling report / expertise / calibration certificate. The reports may be issued in paper or electronic form, provided that the requirements of the standard are met.
The laboratory shall document:

- The way of identification
- Content
- Format
- Signatures

- Amendments and annexes
- Ensuring confidentiality.

The test / sampling / expertise / calibration report shall include:

- all results and test data / sampling / expertise / calibration / results,
- information necessary for the understanding and interpretation of the report / certificate.

The results shall be provided with accuracy, clarity, ambiguity and objectivity and shall include all the information agreed with the client and necessary for the interpretation of the results as well as all the information required by the method used. All reports issued shall be kept as technical records.
The laboratory should be responsible for all the information provided in the report, unless the information is provided by the customer. Data provided by the customer shall be clearly identified. When information is provided by the client and can affect the validity of the results, this should be stated in the report content.
When the laboratory was not responsible for the sampling phase (eg the sample was provided by the customer), it should be stated in the report that the results are applied to the sample received.
Reports shall be signed by authorized persons. If the report has several pages, it is important to mention which signing and what are the security measures to prevent unauthorized reproduction or fraudulent use.
The laboratory should document the way the supplements are issued in the test reports. When providing a declaration of conformity with a specification or a standard, the laboratory shall document the decision rule used, taking into account the level of risk associated with the rule of the decision used, and apply the decision rule. When the decision rule is set by the customer, regulations or other norms, it is not necessary to subsequently consider the level of risk.

Eurolab's ISO / IEC Guides 98-4, Technical Report No.01 / 2017 January 2017 describe possible approaches to the decision-making rule.
When conducting the conformity assessment, there are probabilities related to two types of incorrect decisions, one for the supplier (a) and one for the consumer (b), defined as percentage risk, being the calculation procedure (ISO / IEC Guideline 98-4).

The ISO / IEC Guide 98-4 provides guidance and procedures for assessing the conformity of an element (entity, object or system) with the specified requirements. The element could be, for example, a parallel plan, a food or a blood sample. Procedures can be applied if the following conditions exist: the element is distinguished by a single scalar quantity (measurable property) defined at a level of detail sufficient to be reasonably represented by a true single value; an admissible range of property is specified by one or two tolerance limits; property can be measured and the measurement result expressed in a manner consistent with GUM principles.

The procedures developed in ISO / IEC Guides 98-4 can be used to achieve a range, called acceptance interval, of the admissible measured values of the property of interest. Acceptance limits can be chosen to balance risks associated with acceptance of non-compliant items (consumer risk) or rejection of compliance (manufacturer's risk).

Two types of compliance assessment issues are addressed. The first is to set acceptance limits that will ensure that a desired compliance probability is achieved for a single measured item. The second is to set acceptance limits to ensure an acceptable level of confidence on average as a number of items (identically rated) are measured. Guidance is offered to solve them.

A general approach to the conformity assessment procedure
The decision for the correct definition of a decision rule is the question to be demonstrated by the conformity assessment: compliance or non-compliance with a specification or limit value. Based on the response, either the supplier's risk (α) or the consumer's risk (β) shall be specified.

The definition of a procedure for conformity assessment can be based on the following steps:

a) the specification of a measuring element (Y) and the measuring element to be tested /calibrated;

b) experimental / analytical results (Y estimates of the Y measurement);

c) the standard uncertainty of measurement, u (y), and for a certain level of confidence, the expanded uncertainty (the required confidence level for a factor k considered, eg for a Gaussian sample, is commonly used k = 2 , 00 for a 95% confidence interval);

d) the specification of a single tolerance limit (upper or lower) or the limit tolerance range;

e) definition of acceptance area, rejection area and assumption, base band a type I error probability (supplier risk α) or type II (consumer risk β);

f) a decision rule.

It is important to distinguish between opinions and interpretations and statements of product inspections and certifications as provided for in ISO/IEC 17020 and ISO/IEC 17065 as well as declarations of conformity as referred to in 7.8.6 ISO/IEC 17025 .

When opinions and interpretations are included in the report, the laboratory shall document the basis on which they were made. Opinions and interpretations shall also be clearly marked in the test report.

A calibration laboratory shall not issue opinions and interpretations on calibration certificates. The presentation of the measurement uncertainty in the Calibration Certificates shall comply with ILAC P 14.

When subcontracting results are included in the report, the laboratory should document how they are identified.

The laboratory shall document the electronic mode of transmission of the results.

The laboratory should document how to issue and approve the amendments to the reports issued after they have been issued so as not to generate confusion or misuse.

When preparing test / sampling / expertise / calibration reports, laboratories shall comply with the MOLDAC Policy on the Use of Accreditation Symbols and Accreditation Reference, P-08 Code.

7.9 Complaints

The requirements of ISO/IEC 17025 are fully applicable.

A description of the complaints handling process shall be available upon request to any interested party.

Upon receipt of a complaint, the laboratory shall confirm whether this complaint relates to the laboratory activities for which it is responsible and, if so, then it has to deal with it.

The description of the complaint handling process will include the principles and criteria for: reviewing the feedback resource and assessing customer service quality by analyzing complaints, accepting complaints (written, verbal, anonymous, etc.), terms of dealing and response, types of actions undertaken at the level of the involved authorities.
The results to be communicated to the complainant shall be prepared by, or analyzed and approved by, a non-involved person (s) in the initial laboratory activities under discussion.

The complaint handling process should highlight the laboratory's effort to:

- To satisfy as much as possible the complainant's requests,
- Prevent damage to the laboratory image,
- Use information from complaints to correct and prevent non-conforming activities.

The procedure will describe the activities carried out:

- The recording system,
- Forms used for recordings.

The laboratory is responsible for all decisions taken in the complaint handling process at all levels.

7.10 Nonconforming work

The requirements of ISO / IEC 17025 are fully applicable.

Non-compliant activities also include cases where mistakes, losses, accidents or other deviations from procedures occur in laboratory activity. They can be detected resulting from:

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

Control of non-compliant laboratory activities shall include at least:

- the correction of the non-conforming work (restoration, completion, etc.) and documents eventually issued (report, etc.),
- causes analyzing and undertaking corrective actions, if it is found that non-conforming activity may reappear,
- assess the quality of previous activities wherever possible.

The procedure shall specify:

- how to report and record nonconforming works / activities,
- the forms used for registration,
- how often records are analysed,
- who participates in the analysis,
- methods used,cum se raporteaza
- to whom they report the results of the analysis of non-compliant work, conclusions and corrective actions,
- who decides on the resumption of activities,
- who communicates the results of analyzes of non-compliant activities to the client.

As a result of the analysis of non-compliant activities, records of non-conforming activities and actions will be kept as specified in 7.10.1 (b) to (f) of ISO/IEC 17025 and changes will be made to the management system.

7.11 Control of data and information management

The requirements of ISO/IEC 17025 are fully applicable.

The laboratory shall have access to the data and information necessary to perform the laboratory activities.

The laboratory information management system (s) shall:

a) be protected from unauthorized access;
b) be safeguarded against tampering and loss;
c) to operated in an environment that complies whit provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription.
d) Be maintained in a manner that ensures the integrity of the data and information;
e) Include recording sustem failures and the appropriate immediate and corrective actions.

When a laboratory information management system is managed and maintained off-site or through

an external provider, the laboratory shall ensure that the system provider or operator of the system complies with all the applicable requirements in this document.

The laboratory shall ensure that the instructions, manuals and reference data relevant to the laboratory information management system (s) are readily accessible to the personnel.

Calculations and data transfer shall be checked in an appropriate and systematic manner.

In the case of electronically stored records, clear rules will be established to prevent unauthorized access (setting access levels, passwords, etc.) or changes to these records.

Relevant information regarding the quality of the goods supplied or the subcontracted tests shall apply a documented procedure for the control of records, including those on computer support, and subject them to the classification procedure.

Records kept under control shall be clearly identified (name, code, support, data), together with the place, the responsible and the storage term.

Records of activities that may affect parameters or test results (eg maintenance work, metrological checks, personnel qualification, etc.) shall be kept for at least one accreditation cycle or for the duration of use.
The recorded information and the storage term shall be in accordance with the applicable law, or customer requirements (if any).

When legal or customer requirements exceed these minimum requirements, they apply. In general, technical and administrative records shall enable the work concerned to be restored.

8 Management system requirements

8.1 Options

8.1.1 General

To demonstrate the consistent achievement of ISO / IEC 17025 requirements and to ensure the quality of the results, the laboratory shall:

- establish,
- document,
- implement,
- Maintain a management system.

The management system established by the laboratory may be in line with option A or option B.

8.1.2 Option A

The management system established by the laboratory, under Option A, shall address at least the following:

- management system documentation;
- control of management system documents;
- control of records;
- actions to address risks and opportunities;
- improvement;
- corrective actions;
- internal audit;
- management reviews.

8.1.3 Option B

A laboratory that has established and maintains a management system in accordance with the requirements of ISO 9001 and that is capable of supporting and demonstrating the consistent fulfillment of the requirements of this document also fulfils at least the intent of the management system requirements for option A.

8.2 Management system documentation (option A)

The requirements of ISO / IEC 17025 are fully applicable.

In the management system documentation, policies and objectives shall be established and maintained describing that the laboratory performs its test and calibration activities to meet the requirements of the International Standard ISO/IEC 17025.

Policies and objectives should address the competence, impartiality and consistent operation of the laboratory.

Except for the permanent and general objectives as above, Specific, Measurable, Agreed, Realizable, Realistic, and Scheduled Time (SMART) objectives will be set.

The management of the laboratory shall ensure that these policies and objectives are known and implemented at all levels of the laboratory organization.

If the laboratory declares itself competent to perform tests in regulated areas, it shall, in addition to the requirements of ISO/IEC 17025, also apply the requirements of relevant legislation or regulators.

Laboratory's management commitment is to comply with ISO/IEC 17025 and accreditation body criteria for the development, implementation, and continuous improvement of the management system's effectiveness.

The laboratory shall have identified, documented, the resources necessary to accomplish the tasks (material and human) and demonstrate documented that they exist.

All documentation, processes, systems and records relating to the fulfillment of ISO/IEC 17025 requirements shall be included in the management system (referenced or related to the MS).

Top management shall ensure an adequate circulation of information and decision-making in the organization and an effective communication system for all aspects of the management system.
All personnel involved in laboratory activities shall have access to the parts of management system documentation and related information applicable to their responsibilities.

8.3 Control of management system documents (option A)

The requirements of ISO/IEC 17025 are fully applicable.

The document control procedure describes how to keep documents (internal and external) under control of the requirements under ISO/IEC 17025.

Documents may exist in different forms, such as printed or digital media.

The laboratory shall ensure that:

- documents are approved by authorized personnel as appropriate before they are broadcast;
- documents are periodically reviewed and updated if necessary;
- changes and status of current document revisions are identified;
- the relevant versions of the applicable documents are available at the points of use and, where necessary, their circulation is controlled;
- documents are uniquely identified;
- unintended use of obsolete documents is prevented and an appropriate identification is applied if they are kept for any purpose.

NOTE - In this context, "documents" may be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, books, posters, notifications, memorandum, drawings, plans, etc.

8.4 Control of records (option A)

The requirements of ISO / IEC 17025 are fully applicable.

The laboratory shall apply a documented control procedure for records, including those on computer support.
The procedure shall allow:

- identification,
- storage,
- protection,
- making a backup
- archiving,
- retrieval,
- setting a time for storing and removing its records in accordance with its contractual obligations.

The procedure shall ensure that recordings are kept legible to demonstrate compliance with the requirements of ISO / IEC 17025.

Access to records shall be in accordance with confidentiality commitments and records shall be readily available.

8.5 Actions to address risks and opportunities (option A)

The ISO / IEC 17025 requirements are fully applicable, taking into account the activities of the laboratory.
The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

- give assurance that the management system achieves its intended results;
- enhancing opportunities to achieve the purpose and objectives of the laboratory;
- prevent or reduce undesired impacts and potential failures in the laboratory activities;
- achieve improvements.

The laboratory shall plan:

- actions to address these risks and opportunities;
- how to:
  - integrate and implement these actions into its management system;
  - evaluate the effectiveness of these actions.

To develop a risk management methodology, laboratories may use different guidelines or standards.

Depending on the potential impact on the validity of the laboratory results, action should be taken to address the risks and opportunities.
Risk management may include:

- identifying and avoiding threats,
- taking a risk to materialize an opportunity,
- eliminating the source of risk,
- modifying plausibility or consequences,
- risk sharing or risk retention based on an informed decision.

Risk identification methods vary from common sense and brainstorming, to the use of preset lists for a professional sector, or to the use of standards that set good practice.
For example:
SWOT analysis is a process that identifies the strengths/ weaknesses of an organization.
It can be used for brainstorming.

List of strengths (positive internal factors)	List of weaknesses (internal negative factors)
List of opportunities (external positive factors)	List of threat (external negative factors)

The 4 cells are filled with the relevant information classified according to the diminution of the importance.

For example: Risk Management Guidelines provide different approaches.

The risk assessment can be addressed in the following questions:

- What can happen and why (by identifying risks)?
- What are the consequences?
- What is the likelihood of future risks?
- Are there factors that mitigate the consequences of risk or reduce risk, the probability of risk?

To adequately address the risk in the laboratory, an in-depth analysis of this risk faced by a laboratory should be initiated. The objective should be to indicate certain deficiencies in laboratory activities.

Influences and causes are analyzed based on the risk scenario. Moreover - to classify and assess the risks. This assessment can either trigger measures or accept risk as such. If measures are taken, their effectiveness should also be examined. A risk may be acceptable.

The risk scenario is often easy to define. In this case, similar considerations can be considered as in the case of "preventive measures". Classification and risk assessment is more difficult. In order to be able to make an assessment, the impact, likelihood of occurrence and the likelihood of a risk being quickly discovered should be assessed.

The laboratory decides whether or not to develop a wider risk management methodology than is required in section 8.5 of ISO / IEC 17025, for example by using other guidance or standards.

It is useful to develop a value scale within the organization, regardless of representation: quantitative or qualitative, represented in tables, or graphically presented etc.
A risk assessment can be carried out, for example, through a three-step quote system:

- Impact:
- low (1) - easy to correct - low impact
- Moderate (2) - Errors appearing again but already clear (eg loss of credibility)
- high (3) - serious errors with possible irreducible consequences (up to the danger of life and health).

- Probability of occurrence: very rare (1), rare (2) or frequent (3)

The three-step system results in a 5-step risk assessment.

Impact	3			
	2			
	1			
		1	2	3
Probability				

The lowest risk (1/1 - green) can be classified as acceptable risk, while the highest risk (3/3 - red) usually requires immediate action.

In the case of a small (yellow) risk, it is necessary to decide whether it is still acceptable or whether to take action.

When does the risk assessment take place? Whenever required (eg customer requirements or ISO/IEC 17025) or if it helps to achieve management system goals. This may be common, or occasionally, in case of deviations or changes in laboratory procedures. In fact, the laboratory should face the risks (eg existence, impartiality, validity of its results, etc.) that can lead to failure, loss, damage or other, and can counteract them in an appropriate manner by establishing either MSM, or using other measures.

Clause 4.1.4 of ISO / IEC 17025 requires the identification of risks of impartiality in a continuous manner. For example, for a number of personnel, continued risk management can be ensured by self-declaring the conflict of interest reviewed annually with the obligation to update if there is a new situation that affects impartiality.

The lab is responsible for deciding which risks and opportunities are to be addressed. The Accreditation Body assesses whether the laboratory has established appropriate actions to address risks and opportunities in accredited laboratories.
Opportunities could lead to expanding the scope of laboratory activities, addressing new customers, using new technologies and other possibilities to address customer needs.

8.6 Împrovement (option A)

The ISO / IEC 17025 requirements are fully applicable, taking into account the activities of the laboratory.

The laboratory should identify opportunities to improve its management system and take the necessary action.
Sources of improvement can be identified by:
- analyzing operational procedures,
- use of policies,
- objective analysis,
- analysis of audit results,

- analysis of corrective actions,
- analysis management reviews,
- personnel suggestions,
- risk evaluation,
- analysis of data and results from proficiency tests.

The laboratory should develop a feedback system from its clients, both positive and negative, for:

- improve the management system,

- improve laboratory activities and customer service.

8.7 Corrective actions (option A)

The requirements of ISO/IEC 17025 are fully applicable.

The laboratory shall document the procedure for implementing corrective actions.

1. when a non-compliance occurs, the laboratory shall:

– to act,
– take action to control and correct,
– treat the consequences.

2. to take corrective actions capable of eliminating the cause (s) of non-compliance in order to prevent its recurrence elsewhere by:

– analyzing and eliminating non-compliance,
– determining the causes of nonconformity,
– determining whether there are similar or likely non-conformities.

3. Implement any necessary action.
4. to analyze the effectiveness of any corrective action taken.
5. update, if necessary, the risks and opportunities identified during the planning.
6. to carry out, if necessary, changes to the management system.

Corrective actions shall be appropriate to the effects of non-conformities.

Recordings shall be kept as evidence for:

- the nature of the nonconformities, the cause (s) and any subsequent action taken,
- the results of any corrective actions.

8.8 Internal audits (option A)

The requirements of ISO / IEC 17025 are fully applicable.

Internal audit is one of the important means of verifying the suitability and functioning of the laboratory management system. Internal audits should be conducted by qualified personnel with knowledge of audited activity, auditing, and benchmark requirements.

Internal audits should be performed at planned intervals. At each audit, the elements of the management system will be verified to provide information about:

– the degree of suitability with the laboratory's own requirements for its management system, including laboratory activities;
– the degree of suitability with the requirements of this document;

– the management system on the degree of implementation and whether it is maintained effectively.

The internal audit will be carried out on the basis of an annual program approved by the management of the laboratory. The audit program should include frequency, methods, responsibilities, requirements planning and reporting.

When programming internal audits, the laboratory shall take into account the importance of laboratory activities, changes affecting the laboratory and the results of previous audits.

The laboratory shall:

- to define the audit criteria and the scope of each audit,
- to ensure that the results of the audits are reported to the relevant management,
- to implement appropriate corrections and corrective actions without undue delay,
- to keep records as evidence for the implementation of the audit program and audit results.

The frequency of internal audits may vary depending on the volume, complexity and degree of risk of the audited activities, as well as the proven effectiveness of the management system and the proven stability. All elements of the management system shall be audited at least once a year.
The internal audit program for test and / or calibration activities shall be designed in such a way that all activities in the field are covered in an accreditation cycle.

It is recommended that the audit be conducted on the basis of detailed questionnaires, approved as documents and known to be audited.

Any statistical techniques used in such situations are considered useful. The effectiveness of these audits will be verified on management's analysis.
The documented procedure shall specify:

- the way and criteria for designating the audit team,
- how to proceed (checklists),
- reporting mode,
- how to share the report,
- tracking resolution of nonconformities,
- access to records,
- storage / archiving period.

8.9 Management reviews (option A)

The ISO/IEC 17025 requirements are fully applicable, taking into account the activities of the laboratory.
The laboratory management shall review its management system at planned intervals in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

The inputs to management review shall be recorded and shall include information related to the following:

- changes in internal and external issues that are relevant to the laboratory;
- fulfilment of objectives;
- suitability of policies and procedures;
- status of actions from previous management reviews;
- outcome of recent internal audits,
- corrective actions;

- assesements by external bodies;
- changes in the volume and type of the work or in the range of laboratory activities;
- feedback from customers and personnel;
- complaints;
- effectiveness of any implemented improvements;
- adequacy of resources;
- results of risk identification;
- outcomes of the assurance of the validity of the results; and
- other relevant factors, such as monitoring activities and training.

The analysis takes the form of a meeting led by the executive manager who approved the quality policy, with the participation of all laboratory personnel with quality responsibilities.

The outputs from the management review shall record all decisions and actions related to at least:

- the effectiveness of the management system and its processes;
- improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- provision of required resources;
- any need for change.

The recording of the analysis shall be clear and contain explicit elements of the output and the conditions for realization (planning, responsibility, terms) and shall be transmitted to the persons having responsibilities in the implementation of the established activities/measures.

6. ANNEXES

Annex 1 - Verification Report

7. SYNTHESIS OF MODIFICATIONS

The whole document has been modified to be in line with the new requirements of ISO/IEC 17025:2017.