MOLDAC REPUBLICA MOLDOVA	**NATIONAL CENTRE FOR ACCREDITATION**

GUIDANCE DOCUMENT FOR ACCREDITATION OF INSPECTION BODIES

according to SM SR EN ISO/IEC 17020:2013

Code DR-OI-07
Edition 4
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Date of approval: 20.07.2020
Date of application: 20.07.2020

CONTENT

1. PURPOSE

The purpose of the present document is to describe the requirements for accreditation of inspection bodies according to SM SR EN ISO/IEC 17020:2013 and to EA/IAF/ILAC documents, AB applicable to this standard in order to ensure unique and consequent application.

2. SCOPE

This document is applied by MOLDAC personnel involved in accreditation process of CAB, also by the inspection bodies who want to manage their operations to meet accreditation requirements.

The term „must" is used to indicate stipulations that are to be mandatory. Individual inspection schemes can specify additional requirements for accreditation.

3. REFERENCE DOCUMENTS

- Law no. 235 from 01.12.2011 on accreditation activities and of conformity assessment with subsequent amendments. .
- SM EN ISO/IEC 17011:2017 – Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies.
- SM SR EN ISO/IEC 17020:2013 – General criteria for the operation of various types of bodies performing inspection.
- SM EN ISO/IEC 17025:2018 – General requirements for the competence of testing and calibration laboratories.
- SM SR EN ISO 15189:2014 – Medical laboratories – Particular requirements for quality and competence.
- SM SR EN ISO 9001:2015 – Quality management systems. Requirements.
- SM EN ISO 19011:2018 – Guidelines for Quality management systems auditing.

IAF/ ILAC applicable documents:

- ILAC P-15:05/2020 – Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies (except p.8.1.3)
- ILAC P-10:01/2013 – ILAC Policy on Traceability of Measurement Results.
- ILAC G 24:2007 – Guidelines for the determination of calibration intervals of measuring instruments.
- ILAC G19:2014 - Modules in a forensic science process
- ILAC G27:07/2019 - Guidance on measurements performed as part of an inspection process

Documents of National Accreditation Centre MOLDAC:

- CA – General criteria for accreditation.
- RA – Accreditation rules.
- PM – MOLDAC Policies.

4. DEFINITIONS AND ABREVIATIONS

4.1. Definitions

For the use of this document, there are terms and relevant definitions from:

- SM SR EN ISO/IEC 17000:2006 – Conformity assessment. Vocabulary and general principles
- SM SR EN ISO/IEC 17011:2017 – Conformity assessment. Conformity assessment. General requirements for accreditation bodies accrediting conformity assessment bodies.
- SM SR EN ISO 9000:2016 – Quality management systems. Fundamentals and vocabulary.
- SM SR EN ISO/ IEC 17020: 2013 - General criteria for the operation of various types of bodies performing inspection.
- SM EN ISO/IEC 17025:2018 – General requirements for the competence of testing and calibration laboratories

4.2. Abbreviations

NAB (ONA) – National Accreditation Body
IB (OI) – Inspection Body
CAB (OEC) – Conformity Assessment Bodies
DR – Reference Documents

5. DESCRIPTION OF ACTIVITIES

5.1 Overview

Accreditation of Inspection Bodies will be performed in accordance with the rules and procedures of National Accreditation Bodies provided for SM SR EN ISO/IEC 17020:2013 and applicable EA, ILAC documents and with the provisions stipulated in the national documents.

5.2 Requirements according to SM SR EN ISO/IEC 17020:2013

Numbers of points in this chapter correspond to numbers of SM SR EN ISO/IEC 17020:2013 elements starting with 4th chapter, and the numbers accompained by letters correspond with numbers from ILAC P15:07/2016.

According to ILAC G27:07/2019 if the inspection activity includes measurements and is performed according to ISO/IEC 17020 accreditation, the following ISO/IEC 17025 requirements apply:

- Selection, verification and validation of methods (point 7.2 of ISO/IEC 17025:2017 and point 5.4 of ISO / IEC 17025: 2005);
- Metrological traceability (point 6.5 of ISO/IEC 17025:2017 and point 5.6 of ISO/IEC 17025: 2005);
- Ensuring the validity of the results (point 7.7 of ISO/IEC 17025:2017 and point 5.9 of ISO/IEC 17025:2005).

4. General requirements

4.1 Impartiality and independence

The requirements from the points 4.1.1 – 4.1.5 are fully apply, taking into account the following:

4.1.3a Risks to the impartiality of the inspection body shall be considered whenever events occur which might have a bearing on the impartiality of the inspection body or its personnel.

4.1.3b The inspection body should describe any relationships that could affect its impartiality to the extern relevant, using organizational diagrams or other means.

Examples of relationships that could influence the impartiality include:

- Relationship with a parent organization
- Relationship with departments within the same organization
- Relationship with related companies or organizations
- Relationship with regulators
- Relationship with clients
- Relationship of personnel
- Relationship with the organizations designing, manufacturing, supplying, installing, purchasing, owning, using or maintaining the items inspected.

4.1.5a The inspection body should have a document statement emphasizing its commitment to impartiality in carrying out its inspection activities, managing conflicts of interest and ensuring the objectivity of its inspection activities. Actions emanating from the top management should not contradict this statement.

4.1.5b One way for the top management to emphasize its commitment to impartiality is to make relevant statements and policies publically available.

4.2 Confidentiality

Standard SM SR EN ISO/IEC 17020:2013 requirements are fully applicable.

5. Structural requirements

5.1 Administrative requirements

Requirements are fully applicable, taking into account following:

5.1.1 The Inspection Body (OI) or the organization from which it belongs must have legal status with headquarters in Republic of Moldova and registered legally.

5.1.3 Description of activities is applied particularly to those that are included in the scope of accreditation.

5.1.4 OI must be able to show what factors were considered in determining the appropriate level of contracted insurance (insurance policy). One of the factors that must be considered is the associate risk with performing inspections. OI shall bear legal responsibility for damage to the costumer as a result of the provision of services under the scope of accreditation and designation. The amount of cover must be proportional to the level and nature of responsibilities that may arise from services provided by OI.

5.1.5 Contractual provisions must be agreed between client and accredited OI for carrying out the inspection.
General terms of providing inspection services must be available. They must identify the type of work, rates and references of the decision of accreditation and designation.

5.2 Organization and management

Standard SM SR EN ISO/IEC 17020:2013 requirements are fully applicable, taking into account following:

5.2.2a The size, structure, composition and management of an inspection body, taken together, shall be suitable for the competent performance of the activities within the scope for which the inspection body is accredited.

5.2.2b “To maintain the capability to perform the inspection activities” implies that the inspection body shall take steps to keep it appropriately informed about applicable technical and/or legislative developments concerning its activities.

5.2.2c Inspection bodies shall maintain their capability and competence to carry out inspection activities performed infrequently (normally with intervals longer than one year). An inspection body may demonstrate its capability and competence for inspection activities performed infrequently through “dummy inspections” and/or trough inspection activities conducted on similar products.

5.2.3a The inspection body shall maintain an up-to-date organizational chart or documents clearly indicating the functions and lines of authority for staff within the inspection body. The position of the technical manager(s) and the member of management referenced in clause 8.2.3 should be clearly shown in the chart or documents.

5.2.4a It may be relevant to provide information concerning personnel which carry out work tasks for both the inspection body and for other units and departments.

5.2.5a In order to be considered as “available”, the person shall be either employed or otherwise contracted.

5.2.5b In order to ensure that the inspection activities are carried out in accordance with ISO/IEC 17020, the technical manager(s) and any deputy(ies), shall have the technical competence necessary to understand all significant issues involved in the performance of inspection activities.

5.2.6a In an organization where the absence of a key person causes the cessation of work, the requirement for having deputies is not applicable.

5.2.7a The position categories involved in inspection activities are inspectors and other positions which could have an effect on the management, performance, recording or reporting of inspections.

5.2.7b The job description or other documentation shall detail the duties, responsibilities and authorities for each position category referred to in 5.2.7a.

6. Resource requirements

6.1 Personnel

Standard SM SR EN ISO/IEC 17020:2013 requirements are fully applicable, taking into account following:
All inspection body's personnel shall know the requirements applicable to products that are inspected by the concerned OI.

6.1.1a Where appropriate, inspection bodies shall define and document competence requirements for each inspection activity, as described in 5.1.3a.

6.1.1b For "personnel involved in inspection activities", see 5.2.7a.

6.1.1c Competence requirements should include knowledge of the inspection body's management system and ability to implement administrative as well as technical procedures applicable to the activities performed.

6.1.1d When professional judgment is needed to determine conformity, this shall be considered when defining competence requirements.

6.1.2a All requirements of SM SR EN ISO/ IEC 17020:2013 apply equally for both employed and contracted persons.

6.1.5a The procedure for formally authorizing inspectors should specify that the relevant details are documented, e.g. the authorized inspection activity, the beginning of the authorization, the identity of the person who performed the authorization and, where appropriate, the termination date of the authorization.

6.1.6a The "mentored working period" mentioned in item b normally includes activities where inspections are performed.

6.1.7a Identification of training needs for each person should take place at regular intervals. The interval should be selected to ensure fulfillment of clause 6.1.6 item c. The results of the review of training, e.g. plans for further training or a statement that no further training is required, should be documented.

6.1.8a A major aim of the monitoring requirement is to provide the inspection body with a tool to ensure the consistency and reliability of inspection outcomes, including any professional judgments against general criteria. Monitoring may result in the identification of needs for individual training or needs for review of the inspection body's management system.

6.1.8b For “other personnel involved in inspection activities”, see 5.2.7a.

6.1.9a To be considered sufficient, the evidence that the inspector is continuing to perform competently should be substantiated by a combination of information such as:

- satisfactory performance of examinations and determinations,
- positive outcome of report reviews, interviews, simulated inspections and other performance assessments (see note to clause 6.1.8),
- positive outcome of separate evaluations to confirm the outcome of the inspections (this may be possible and appropriate in the case of e.g. the inspection of construction documentation),
- positive outcome of mentoring and training,
- absence of legitimate appeals or complaints, and
- satisfactory results of witnessing by a competent body, e.g. a certification body for persons.

6.1.9b An effective program for the on-site observation of inspectors may contribute to fulfill the requirements in clauses 5.2.2 and 6.1.3. The program should be designed considering:

- the risks and complexities of the inspections,
- results of previous monitoring activities, and
- technical, procedural or legislative developments relevant to the inspections.

The frequency of on-site observations depends on the issues listed above, but should be at least once during the accreditation re-assessment cycle, however see application note 6.1.9a. If the levels of risks or complexities, or the results from previous observations, so indicate, or if technical, procedural or legislative changes have occurred, then a higher frequency should be considered.

Depending on the fields, types and ranges of inspection covered by the inspector’s authorizations, there may be more than one observation per inspector necessary to adequately cover the whole range of required competencies. Also, more frequent on-site observations may be necessary if there is lack of evidence of continuing satisfactory performance.

6.1.9c In inspection areas where the inspection body has only one technically competent person the internal observation on-site cannot take place. In such cases the inspection body shall have arrangements in place for external observations on-site, unless other sufficient supporting evidence that the inspector is continuing to perform competently is available (see 6.1.9a).

6.1.10a Records of authorization should specify the basis on which authorization was granted (e.g. the on-site observation of inspections).

6.1.11a Remuneration methods that provide incentives to perform inspections quickly have the potential to negatively affect the quality and outcome of inspection work.

6.1.12a Policies and procedures should assist inspection body personnel in identifying and addressing commercial, financial or other threats or inducements which could affect their impartiality, whether they originate inside or outside the inspection body. Such procedures

should address how any conflicts of interests identified by personnel of the inspection body are reported and recorded. Note, however, that while expectations for inspector integrity can be communicated by policies and procedures, the existence of such documents may not signal the presence of integrity and impartiality required by this clause.

6.2 Facilities and equipment

Standard SM SR EN ISO/IEC 17020:2013 requirements are fully applicable, taking into account following:

6.2.1a Equipment required to carry out inspection in a safe manner may include e.g. personal protective equipment and scaffolding.

6.2.3a If controlled environmental conditions are needed, e.g. for the correct performance of the inspection, the inspection body shall monitor these and record the results. If conditions were outside acceptable limits for the inspection to be performed, the inspection body shall record what action was taken. See also clause 8.7.4.

6.2.3b Continued suitability may be established by visual inspection, functional checks and/or re-calibration. This requirement is particularly relevant for equipment that has left the direct control of the inspection body.

6.2.4a In order to enable tracking when items are replaced, the unique identification of an item of equipment may be appropriate even when there is only one item available.

6.2.4b When controlled environmental conditions are needed, the equipment used to monitor such conditions should be considered as equipment that significantly influences the result of inspections.

6.2.4c When appropriate (normally for the equipment covered by clause 6.2.6) the definition shall include the required accuracy and measurement range.

For the measurement equipments that have a significant influence on the inspection results, should be included the accuracy and the range of measurements.

6.2.6a The justification for not calibrating equipment that has a significant influence on the outcome of inspection (see clause 6.2.4) should be recorded.

6.2.6b Guidelines on how to determine calibration intervals can be found in ILAC G24.

6.2.7a According to ILAC P10 it is possible to perform in-house calibration of equipment used for measurements. It is a requirement for accreditation bodies to have a policy to ensure that such in-house calibration services are performed in accordance with the relevant criteria for metrological traceability in ISO/IEC 17025.

6.2.7b According to ILAC P10 the preferred routes for conformity assessment bodies who seek external services for calibration of their equipment are defined in subsections 1) and 2) of section 2 in ILAC P10. If however, it is not possible to comply with these two routes for any justifiable reason, then it is acceptable to use the routes 3a) or 3b) of section 2 of ILAC

P10. It is a requirement for accreditation bodies to have a policy to ensure that such external calibration services meet the relevant criteria for metrological traceability in SM EN ISO/IEC 17025:2018.

Requirement 6.2.7 about the traceability of the measurements at national or international standards shall meet MOLDAC Policies, code PM, P-03.

6.2.7c Where traceability to national or international standards of measurement is not applicable, the participation in relevant comparison programs or proficiency tests is an example of how to obtain evidence of correlation or accuracy of inspection results.

6.2.8a When inspection bodies use reference standards of measurement to calibrate working instruments, the reference measurement calibrators should have a higher degree of accuracy than that required of the working instruments they are used to calibrate.

6.2.9a Where equipment is subjected to in-service checks between regular recalibrations, the nature of such checks, the frequency and acceptance criteria should be defined.

6.2.10a The information provided in 6.2.7a, 6.2.7b and 6.2.7c for programs of calibration of equipment is valid also for programs of calibration of reference materials.

6.2.11a When the inspection body engages suppliers to perform activities which do not include the performance of part of the inspection, but which are relevant for the outcome of inspection activities, e.g. order registration, archiving, delivery of auxiliary services during an inspection, the editing of inspection reports or calibration services, such activities are covered by the term “services” used in this clause.

6.2.11b The verification procedure should ensure that incoming goods and services are not used until conformance with specification has been verified.

Requirement 6.2.13 is applicable on all soft’s including those with calculation tables whose functions are used.

In all the cases, there should be records of carried tests.

Applicable for all types of soft’s, including text.

It’s necessary to insure that saved data can be consulted and used in an defined period of time, even if occurs a change in the data or in the operating system.

In cases when OI contact providers for performing activities that are relevant for the inspection activities result, as e.g. providing auxiliary services during an inspection, such kind of activities are covered by the term “services” used in this clause.

6.2.13a Factors that should be considered in protecting the integrity and security of data include:

- backup practices and frequencies,
- effectiveness in restoring data from backup,
- virus protection, and

- password protection.

6.2.14 The requirements for equipments described in 6.2.14 are requirements for working standards used by OI.

Measuring equipment must be maintained according to SM EN ISO/IEC 17025:2018. In particular:

- Working standards used in the inspection, if OI hold working standards, must be calibrated with traceability to the international system of units of measurement;
- Measuring equipment must be kept under strict record and be identified;
- Measuring equipment must be controlled (adjusted, regulated) by OI in all cases before being placed or reinstated;
- Frequency of calibration standards and working measuring instruments must conform to the Official List in force.

Responsibility for calibrating standards work needs to be clearly defined and must be met.

When selecting working standards must take into account the expanded uncertainty calculated and prescribed by requirements in applicable normative documents.

6.3 Subcontracting

Standard SM SR EN ISO/IEC 17020:2013 requirements 6.3 are fully applicable, taking into account following:

6.3.1a Inspection activities can overlap with testing and certification activities where these activities have common characteristics (See Introduction of ISO/IEC 17020). For example, examination of a product and testing of the same product can both be the basis for the determination of conformity in an inspection process. It should be noted that SM SR EN ISO/ IEC 17020:2013 specifies requirements for bodies performing inspection, whereas the relevant standard to apply for bodies performing testing is SM EN ISO/IEC 17025:2018 or SM SR EN ISO 15189:2014.

6.3.1b By definition (ISO/IEC 17011, clause 3.1), accreditation is limited to conformity assessment tasks which the inspection body has demonstrated competence to perform itself. Thus, accreditation cannot be granted for activities referred to in the fourth bullet point under note 1, if the inspection body does not have the required competence and/or resources. However, the task of assessing and interpreting the results of such activities for the purpose of determining conformity may be included in the scope of accreditation, provided adequate competence for this has been demonstrated.

6.3.3a In note 2 to the definition of “inspection” in clause 3.1 it is indicated that in some cases inspection may be examination only, without a subsequent determination of conformity. In such cases clause 6.3.3 does not apply since there is no determination of conformity.

6.3.4a If the evaluation of the competence of the subcontractor is based partly or in full on its accreditation, the inspection body shall ensure that the scope of the subcontractor’s accreditation covers the activities to be sub-contracted.

7. Process requirements

7.1 Inspection methods and procedures

Standard SM SR EN ISO/IEC 17020:2013 requirements 7.1 are fully applicable, taking into account following:

7.1.1 The inspection methods are those described in the documents approved by the competent authority, normative documents for the control method and the technical file of the object to be inspected. The OI shall comply with the established requirements and use legalized documents.
The methods shall be fully documented and validated (except for standardized methods). A method is suitable if it achieves the established performance parameters.
Methods published in books, journals, and magazines are not considered standardized because they have been experienced only by the author. Officially acknowledged methods were validated or verified and are equivalent to standardized methods.
7.1.2 - 7.1.4 of the SM SR EN ISO/IEC 17020:2013 standard is fully applied.

7.1.5 Fully applies, including the OI shall perform the applications, orders, contracts analysis. Only after performing the analysis, the contract between the accredited OI and the client will be concluded.

7.1.5a Where appropriate the contract or work order control system should also ensure that:

- contract conditions are agreed
- personnel competence is adequate
- any statutory requirements are identified
- safety requirements are identified
- the extent of any subcontracting arrangements required is identified.

For routine or repeat work requests the review may be limited to considerations of time and human resources. An acceptable record in such cases would be an acceptance of the contract signed by an appropriately authorized person.

7.1.5b In situations where verbal work orders are acceptable, the inspection body shall keep a record of all requests and instructions received verbally. Where appropriate, the relevant dates and the identity of the client's representative should be recorded.

7.1.5c The contract or work order control system should ensure that there is a clear and demonstrable understanding between the inspection body and its client of the scope of the inspection work to be undertaken by the inspection body.

7.1.6a The information referred to in this clause is not information provided by a subcontractor, but information received from other parties, e.g. a regulating authority or the client of the inspection body. The information may include background data for the inspection activity, but not results of the inspection activity.

7.2 Manipulations of inspected elements and standards

Standard SM SR EN ISO/IEC 17020:2013 requirements 7.2 are fully applicable.

7.2.2 Elements that are to be inspected are prepared by the client.

7.2.3 Apparent anomalies notified or observed by the inspector by initiating the process of inspecting the item are recorded and reported to the client.

7.2.4 Specific storage conditions should be defined taking into account the analysis of sensitive points for the final quality of inspected items.

7.3 Inspection records

Standard SM SR EN ISO/IEC 17020:2013 requirements 7.3 are fully applicable, taking into account following:

7.3.1a The records should indicate which particular item of equipment, having a significant influence on the result of the inspection, has been used for each inspection activity.

Records of inspections should be described in management system documents and its archiving must be defined.

This archiving should allow to quickly and securely identifying inspection activities and findings. OI must keep records of the issued inspection report/certificate.

Record keeping period is at least equal to the period between two successive verifications plus one.

7.4 Inspection reports and inspection certificates

Standard SM SR EN ISO/IEC 17020:2013 requirements 7.4 are fully applicable, taking into account MOLDAC Policies, code PM, in special Policy P-08 Policy and rules for use of accreditation symbols and references to accreditation.

In implementing this requirement OI must take into account legal requirements (Article 15 (2), Chapter 5 of the Law 235 of 01.12.2011 on accreditation and conformity assessment).

7.4.4a It may be useful to identify the inspection method in the inspection report/certificate when this information supports an appropriate interpretation of the inspection results.

7.5 Complaints and appeals

Standard SM SR EN ISO/IEC 17020:2013 requirements 7.5 are fully applicable, taking into account following:

The contract referred to 7.1.5 requirement should be stipulated client's right to complain or appeal the IB headquarters.

This procedure must refer also to treat observations, warnings and complaints issued by state bodies.

7.6 Complaints and appeals process

Standard SM SR EN ISO/IEC 17020:2013 requirements 7.6 are fully applicable.

8. Management system requirements

8.1 Options

Options A or B of the standard SM SR EN ISO/IEC 17020:2013 are fully applicable, taking into account following:

8.1.3a Expression of „the present international standard" is a reference to ISO/IEC 17020,

8.1.3b Option B does not impose that the management system of an inspection body should be certified according to ISO 9001. However, when the determining the extent of necessary assessment, the accreditation body should consider if the inspection body has been certified according to ISO 9001 by a certification body accredited by an accreditation body which is a signatory to the IAF MLA, or to a regional MLA for certification of management systems.

8.2 Management system documentation

Standard SM SR EN ISO/IEC 17020:2013 requirements 8.2 are fully applicable, taking into account following:

8.2.4a For easy reference, it is recommended that the inspection body indicates where the requirements of ISO/IEC 17020 are addressed, e.g., by means of a cross reference table.

8.3 Control of documents

Standard SM SR EN ISO/IEC 17020:2013 requirements 8.3 are fully applicable.

8.4 Control of records

Standard SM SR EN ISO/IEC 17020:2013 requirements 8.4 are fully applicable, taking into account following:

8.4.1a This requirement means that all records needed to demonstrate compliance with the requirements of the standard shall be established and retained.

8.4.1b In cases where electronic seals or authorizations are used for approvals, access to the electronic media or seal should be secure and controlled.

8.5 Management review

Standard SM SR EN ISO/IEC 17020:2013 requirements 8.5 are fully applicable, taking into account following:

8.5.1a A review of the impartiality risk identification process and its conclusions (clauses 4.1.3/4.1.4) should be part of the annual management review.

8.5.1b The management review should take into account information on the adequacy of current human and equipment resources, projected workloads and the need for training of both new and existing staff.

8.5.1c The management review should include a review of the effectiveness of systems established to ensure adequate competence of the personnel.

8.6 Internal audits

Standard SM SR EN ISO/IEC 17020:2013 requirements 8.6 are fully applicable, taking into account following:

8.6.4a The inspection body shall ensure that all requirements of SM SR EN ISO/ IEC 17020:2013 are covered by the internal audit program within the accreditation re-assessment cycle.

The requirements to be covered shall be considered for all fields of inspection and for all premises where key activities are performed.

The inspection body shall justify the choice of audit frequency for different types of requirements, fields of inspection and premises where key activities are performed. The justification may be based on considerations such as:

- criticality,
- maturity,
- previous performance,
- organizational changes,
- procedural changes, and
- efficiency of the system for transfer of experience between different operational sites and between different fields of operation.

8.6.5a Competent externally contracted personnel may carry out internal audits.

8.7 Corrective actions

Requirements 8.7 of SM SR EN ISO/IEC 17020:2013 standard are fully applicable.

8.8 Preventive actions

Standard SM SR EN ISO/IEC 17020:2013 requirements 8.8 are fully applicable, taking into account following:

8.8.1a Preventive actions are taken in a pro-active process of identifying potential nonconformities and opportunities for improvement rather than as a reaction to the identification of non-conformities, problems or complaints.

SM SR EN ISO/IEC 17020:2013 include 2 Annexes: Annex A normative and Annex B informative.

According to ILAC-P 15:05/2020, to ensure the independence OI must comply with the provisions of Annex A.

An1 Annex A.1 and A.2 of ISO/IEC 17020 refer to the phrase “items inspected” with respect to Type A and Type B inspection bodies (4.1.6 n1 clarifies the cases when an inspection body may have different types of independence). In Annex A.1 b it is stated that “In particular they shall not be engaged in the design, manufacture, supply, installation, purchase, ownership, use or maintenance of the items inspected”. In Annex A.2 c it is stated that “In particular they shall not be engaged in the design, manufacture, supply, installation, use or maintenance of the items inspected”. The reference to “they” in the above sentences is a reference to the inspection body concerned and its personnel. The items in this case are those items that are specified in the accreditation body’s certificate/annex with respect to the accredited scope of the inspection body (e.g. pressure vessels).

An2 It is considered also as a conflicting activity consultancy provided on the design, manufacture, supply, installation, procurement, use or maintenance of the inspected subjects.

Such linkages include common owners and common owners’ appointees on boards or equivalent. These linkages are acceptable if persons involved do not have the possibility to influence the outcome of an inspection. In particular there exists a possibility to influence the outcome of an inspection if the person has the ability to:

- *influence the selection of inspectors for specific assignments or customers, or*
- *influence decisions on conformity in specific inspection assignments, or*
- *influence remuneration for individual inspectors, or*
- *influence remuneration for specific assignments or customers, or*
- *initiate the use of alternative work practices for specific assignments.*

An3 A “regulatory authority requirement” refers to the fact, that an exception has been written in a relevant law and / or when a Regulatory Authority provides publicly available guidelines on that exception being permitted when it is performed as part of the regulated inspection activity.

5.3 Requirements according to ISO/IEC 17025, to ensure the validity of inspection results

Technical competence shall be demonstrated through participation in inter-laboratory comparisons at national level.
In the absence of PT/ILC at national level, the OI is obliged to ensure the validity of the inspections results through internal activities according to ISO/IEC 17025 or bilateral comparisons.

Ensuring the tests validity shall be performed according to ISO/IEC 17025. OI policy on PT/ILC shall comply with the MOLDAC policy “Policy on the use of proficiency tests and other inter-laboratory comparisons in the accreditation process according to ILAC P9”, code P-02.

Inspection bodies shall ensure that each testing sample used is properly validated and if it is impossible to provide an appropriate range of testing samples, for example due to the nature of the test undertaken, arrangements may be considered. In such cases, the staff subjected to assessment, being monitored, can test the elements available in the normal course of operation of the installation, and then re-tested by a person authorized by the body for this purpose. This is part of the internal validity check route. Each accredited

person or body shall be required to participate in proficiency tests as frequent as possible and available, taking into account the major representation of the important areas of testing and different techniques.

The OI shall immediately inform MOLDAC of the malfunctions of the management system (regarding personnel, equipment) or regarding the correctness of the inspections performed, which may question the conformity of the verified objects with the provisions of the applicable normative documents.

6. SYNTHESIS OF CHANGES

Changes were included on the following pages: 1-5,7,10,13,15,16,17