MOLDAC REPUBLICA MOLDOVA	**NATIONAL CENTRE FOR ACCREDITATION**

GUIDANCE DOCUMENT
FOR ACCREDITATION OF CERTIFICATION BODIES FOR PRODUCTS

according to SM SR EN ISO/IEC 17065:2013

Code DR-OCpr-04
Edition 2
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Date of approval: 17.01.2019
Date of application: 17.01.2019

CONTENT

1. PURPOSE

General requirements to be met by bodies, that certifies products, processes and services for obtaining accreditation are those specified in SM SR EN ISO/IEC 17065:2013 „Conformity Assessment. Requirements for bodies certifying products, processes and services", guides EA, IAF and ISO and in documents mentioned on MOLDAC web site, www.acreditare.md applicable to this standard.

MOLDAC has no responsibility for the documents it issues and the activities that a Certification Body is conducting. Accreditation cannot be used for sharing of responsibilities of a Certification Body.

This document was elaborated to explain certain requirements for accreditation of Certification Bodies for products, processes, services according to SM SR EN ISO/IEC 17065:2013 in order to ensure a unique and consecutive application of all requirements of the standard.

2. SCOPE

The document is applied by MOLDAC personnel involved in accreditation process of CB, as well as all interested parties.

This document applies both in the regulated and in one voluntary area.

The accreditation application review in regulated areas will be covered by MOLDAC together with the designated representative of the regulatory Authority (if it is agreed between Authority and MOLDAC).

MOLDAC will send to the regulatory Authority information about any application for accreditation from the CB side who intend to act as recognized CB, and will require the participation of its designated representative to application review, stating the date and time proposed for this review.

After the document review and the related records to the application, MOLDAC may invite the applicant, if deemed necessary, in order to clarify some aspects of the request being made.

3. REFERENCE DOCUMENTS

- Law no. 235 from 01.12.2011 on accreditation activities and of conformity assessment.
- SM SR EN ISO/IEC 17000:2006 – Conformity assessment. Vocabulary and general principles.
- SM SR EN ISO/IEC 17020:2013 – General criteria for the operation of various types of bodies performing inspection.
- SM SR EN ISO/IEC 17025:2018 – General requirements for the competence of testing and calibration laboratories.
- SM SR EN ISO/IEC 17021:2012 - Conformity assessment. Requirements for bodies providing audit and certification of management systems.

- SM SR Guide ISO/IEC 17067:2011 Conformity assessment. Fundamentals of product certification and guidelines for product certification schemes

- SM SR Guide ISO/IEC 23:2011 Methods for assessing conformity with standards for third-party certification systems

- SM SR EN ISO/IEC 17030:2011 Conformity assessment. General requirements for third-party marks of conformity

- SM SR Guide ISO 27:2011 Guidelines for corrective actions to be undertaken by a certification body in case of misuse of its certification mark

- SM SR Guide ISO/IEC 53: 2011 Conformity assessment. guidelines for the use of a quality management system of an organization in product certification

- SM SR Guide ISO/IEC 28: 2011 Conformity assessment. Guidance on a third-party certification of products

- Other EA documents, IAF applicable

- Rules and procedures of National Accreditation Body.

4. DEFINITIONS AND ABBREVIATIONS

4.1. Definitions

To use this document, the relevant terms and definitions apply 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.
- SR EN ISO/IEC 17065:2013 – Conformity assessment. Requirements for bodies certifying products, processes and services
- SM SR EN ISO 9000:2011 – Quality management systems. Fundamentals and vocabulary.

4.2. Abbreviations

NAB (ONA) – National Accreditation Body

CAB (OEC) –Conformity Assessment Body

OCpr – Certification Body for Products

OCprec – Certification Body for Organic Products

MS (SM) –Management System

CT –Technical Committee

CB (OC) –Certification Body

5. STRUCTURAL REQUIREMENTS

Item numbers in this section correspond to no. of elements of SM SR EN ISO / IEC 17065:2013.

4. General requirements

4.1. Legal and contractual matters

4.1.1 Legal responsibility

CB or organization to which it belongs must make available to MOLDAC a legal document that contains, among the fields of activity declared by the organization, also the scope on which it can perform the activity of products certification. The legal documents that a CB must make available to MOLDAC are:

- Certificate of Registration/Establishment Act/Status and/or other documents to prove their legal status CB;
- Documents concerning the identification of shareholders, the percentage of shares and other relevant information;
- Contract of Association/shareholders and other relevant documents;
- Relevant information on associated bodies (related), including a description of their activities (identification of risk, associate risks, potential conflicts of interests, activities that minimize or remove such conflicts, etc).

4.1.2 Certification agreement

CB must have a legal Agreement (Contract on certification/Contract certification services) that contain at least all the provisions mentioned in clause 4.1.2.2 and the other clauses of the standard SR EN ISO / IEC 17065:2013. This Agreement shall include the rights and obligations of both parties.

4.1.3 Use of license, certificates and of marks of conformity

Additional to standard requirement it is used Law 235/2011.

4.2 Management of impartiality

The management commitment at the top level on the impartiality must be publicly available on the website, as well as the map of the CAB informative documents.

CB shall describe in detail all the activities they carry out and, if relevant, those that the parent organization are carrying and are likely to be incompatible with certification activity. Incompatible activities are those activities considered to affect or create preconditions to affect the independence and/or impartiality of the certification body. It should not be made any statement in marketing materials or presentation, written or oral, to give the impression that the two activities are related.

In order to analyze the structure of CB, MOLDAC will require at least following documents:

- Chart;

- Identifying of the management at the highest level and of head of CB;
- Members of the committees with relevant information about themselves;
- Regulations of Committees;
- Other documents to MOLDAC decision.

CB must analyze and prove to NAB how they manage their work on certification and any other activities that result from its relationship with related bodies to determine the possibilities for conflict of interest. CB must identify those bodies and activities that could, if not controlled properly, to affect confidentiality, objectivity or impartiality, to eliminate conflict of interest, exclude or minimize such risks. The demonstration shall cover all potential sources of conflict of interest, whether they are from the CB or from activities of related bodies. A related body (associated), meaning that which is specified is that one related to CB through common ownership, in whole or in part, common directors, contractual arrangement, a common name, an informal understanding or other means such that the related body have a legitimate interest in any certification decision or potential ability to influence the process.
CB must enable NAB assessment of activities of related bodies to ensure that there is no risk to impartiality. NAB must continually demonstrate how to do (systematic) risk identification of impartiality and to eliminate or minimize risks. If a risk is identified on impartiality, CB should be able to demonstrate how to eliminate or to minimize such a risk. Identification of risks on impartiality should be documented

CB must present to NAB:
- Management commitment at the highest level of impartiality
- Identification, risk analysis and how to remove or minimize/reduce them down to an acceptable level
- The means by which CB get financial support (to demonstrate that it does not affect the impartiality), etc..

CAB, through the records, shows to MOLDAC that both CB (staff / committees / activities they carry), legal entities, separate legal entity, whose part it is, and external resources, do not compromise the impartiality.

4.3 Legal liability and finance

CB shall take appropriate measures to cover liabilities arising from its activities. These are mainly:

- Policy/insurance contract (insured value correlated with the type, size CB (staff / field/certification schemes/volume activities, etc.), based on risk analysis);
- Bank guarantees or provisions (insured value must be related to the type, range and volume of activities based on risk identification);
- State responsibility when required by law.

For CAB to demonstrate that it has the financial resources necessary to operate in a reasonable manner, it shall provide to MOLDAC plans/financial reports, showing that it is able to provide services pursuant to its contractual obligations, it has financial stability and resources required for its activities.

CAB must provide to the MOLDAC evaluation team all documents that have been submitted to the Committee established under item 5.2. of SM SR EN ISO / IEC

17065:2013 by demonstrating that impartiality is not affected by financial pressures and commercial or otherwise.

4.4 Non-discriminatory conditions

A CB could demonstrate that the policies and procedures of the Certification Body (CB) are non discriminatory through:

- unified tariffs;
- access to services for all applicants whose activities are included in the scope of accreditation of CB;
- unconditional access by:
    1. the size of the supplier;
    2. the number of certificate of Conformity (C/C) issued;
    3. its membership of an association, such as builders, or other groups.
- subsequent registration of submitted applications of certification in CB, etc.

4.5 Confidentiality

CAB must provide resources and facilities for the security of confidential information (egg. documents, records).

CB must submit to MOLDAC evidence that CB has ensured that all staff, committees and CAB contracted involved in the assessment meets the requirements of confidentiality.

4.6 Publicly available information

In order to improve the credibility of certification activities, CB shall observe the following principles:

- Impartiality,
- Competence,
- Confidentiality and transparency,
- Access to information,
- Responsibility.

Transparency - access to information via the website, informative folder for applicants containing all certification requirements, schemes, fares, etc.

The information required by clause 4.6 must clearly detail the items included or referenced in the clause 4.1.2.2 and information, or source of information on legal documents in accordance with the product was certificated.

5. Requirements for structure

5.1 Organizational structure and top management

Organizational structure of CB must be determined in the Chart, in CB Regulation or other document to be approved by the top management of the entity in order to prevent its

change in such a manner that could compromise keeping impartiality. CB structure must protect the impartiality of the certification process, identifying leadership, group of people/person who has to hold the responsibility for each of requirements stated in p.5.1.3 of the standard.

CAB will provide to the MOLDAC team at least the following:

- one or more organizational structures/organizational charts showing lines of authority, including cases where CAB is a defined part of a legal entity;
- identification document of top management and of head of CB;
- lists of committee members;
- regulations;
- documents on the identification of critical locations;
- other documents on MOLDAC decision.

CB must have official Rules for the appointment, terms of reference and functioning of each Committee involved in the certification process.
CB should be aware and take action that those Committees involved in the certification process are not a subject to financial, commercial or otherwise pressures.

Authority for the appointment or removal of such committees belongs to CB.

5.2 Mechanism for safeguarding impartiality

CB must have a mechanism, such as Committee for ensuring impartiality or its equivalent, which has:

- to help on development of policies relating to impartiality of its certification activities;
- to counteract any tendency of CB owners to allow commercial or other considerations prevail against objectivity of certification;
- to give their opinion on matters affecting confidence in certification, including openness and public perception;
- to perform an analysis at least ones a year on the impartiality of the certification process within OCpr, etc..

CB shall ensure the participation of all stakeholders in the Committee, representing a balance of interests. Members of this committee must be formally elected. Number of stakeholders, including members will depend on the diversity of CB activity, scope of accreditation (regulated / voluntary), etc. Stakeholders could be:

- OCpr customers;
- beneficiaries of customers;
- producers;
- suppliers of CB customers;
- users;
- consumers;
- regulatory authorities in the field;
- professional associations, education, etc.;
- experts in conformity assessment;
- etc.

This Committee shall have access to all necessary information that does not conflict with operating procedures, to enable it to fulfil all its functions.

6. Resource Requirements

6.1 Certification body personnel

CB must have a sufficient number of competent personnel to cover all activities related to scope of accreditation and certification schemes.

CB personnel involved in the certification process already qualified and approved according to SM SR EN 45011:2003 should be trained and reassessed in accordance with the new criteria of competence approved by him under SM SR EN ISO / IEC 17065: 2013.

CB must have their competence criteria to submit its own records to MOLDAC, verifying on their fulfilment. When CB is employing personnel/experts in certification declared competent by other CB, they must first be trained with their own procedures, evaluated, monitored according to their own criteria of competence.

CB must have a procedure for the management of the competence of personnel involved in the certification process to document the compliance of all requirements of p.6.1.2.1:

Technical competence of personnel must be demonstrated for each of normative documents to which product certification is done.

If CB establishes technical committees or decision-making, then you must define the qualification criteria for members of these committees.

CB should have all the relevant evidence and records (files) to demonstrate the competence of each person (operational or managerial) in relation to certification activity they perform, namely to maintain records on the identity, professionalism, qualifications, performance monitoring authority in the CB, etc up to date.

CB must have a contract with personnel involved in the certification process, providing at least the authority rights and responsibilities, requirements for confidentiality, impartiality and conflict of interest.

6.2 Resources for evaluation

CB must be able to demonstrate to MOLDAC that CB staff involved in certification activities (either internally or under its direct control) knows and meets, depending on the certification scheme, the requirements for testing - SM EN ISO/ IEC 17025:2018; Inspection - SM SR EN ISO/ IEC 17020:2013 for management systems auditing - SM SR EN ISO/ IEC 17021:2012, that the evaluation activities, including outsourced (subcontracted) are performed in a competent, impartial and reliable way, according to requirements from legal documents applicable for such activities.

If this demonstration is based on the accreditation of the subcontractor, then the scope of accreditation shall cover activities performed by it under subcontracting, but scheme requirements must be observed.

In case it subcontracts a CAB (LÎ) not third party, activities will take place in the presence of OCpr expert.
Responsibility for the subcontracted activity is OCpr, which must inform the applicant to certification of its intention to subcontract.

7. Process requirements

7.1 General

Certification schemes operated by CB may be those specified in ISO / IEC 17067 in conjunction with ISO / IEC Guide 28, ISO / IEC Guide 53.
For the certification of (conformity assessment) products covered by technical regulations shall apply CB certification schemes and modules specified in the technical regulations applicable to the product in question.

7.2 Application

The certification body shall require completion of an official form of application/request signed by a representative of the applicant, duly authorized, which must contain the necessary information depending on the certification scheme.

7.3 Application review

CB shall document who is responsible to perform the Application / Request review.
CB must make an application review, identifying opportunities of OCpr (if it is an initial certification, resources, expertise, management), if it has internal resources, or have the need to outsource some activities, etc.

7.4 Evaluation

CB must appoint competent personnel to perform each activity of assessment, to draw up a Plan for assessment activities to ensure that the assessment team is equipped with all necessary for evaluation.

CB must clearly identify for each certification scheme, all applicable regulatory documents.

CB shall assess the conformity of products based on documented procedures for each certification scheme declared.

CB must ensure that the products have been assessed against the requirements of certification field and other requirements specified in the certification scheme.

Whenever applicable, the CB must take into account the measurement uncertainty of the measurement results, especially when the test results are very close to the specified limits.

CB must inform the client on assessment results, including any non-conformities.

7.5 Review

For performing of review, all the information and results of assessment need to be available, prior to it. The file review for the purpose of recommendation of the decision must be performed by a person/group of people who did not participate in the assessment. Recommendations should be documented.

7.6 Certification decision

CB must be responsible and must retain its authority for decisions on certification. The decision must be taken by a person/group of people who did not participate in the evaluation.

7.7 Certification documentation

CB client must provide certification of an official document, containing both the p.7.7.1, 7.7.2 requirements, compliance with requirement 7.7.3 of the standard SM SR EN ISO/IEC 17065:2013 and identify the location/locations where products are manufactured, NM MD product code, other.

CB must have a form of certificate in which to refer to appropriate accreditation and by case, depending on certification scheme, on frequency of surveillance assessments.

7.8 Register of certified products

CB shall maintain records of certified products, identifying at least the date of registration/ number/ description of product/ customer/ DN/ certification scheme/ signature of receipt.

7.9 Surveillance

CB performs assessment for surveillance purposes in cases where is provided by scheme. CB prepares an annual Program of surveillance, for which achieving it is responsible. Surveillance should be established and should include regular surveillance activities to ensure the continuing validity of demonstrating of requirements fulfilment relating to product, process or service, regular supervision labelled products.

7.10 Changes affecting certification

CB must inform the client about changes of certification requirements to verify the implementation of changes, taking into consideration the cases when changes can affect the certification and take action (if there is the case - additional assessments) according to p.7.4 - 7.8.

7.11 Termination, reduction, suspension or withdrawal of certification

If CB:

- withdrawn / restricted / reduced certification field, CB shall take the actions specified by the certification scheme and must make all the necessary changes in official documents for certification, in the public information, in approvals for use of trademarks etc, in order to ensure that it is not provide any indication that the product continues to be certified.
- suspended certification, CB must appoint one or more persons to formulate and communicate to the client the following:
  - necessary actions to lift the suspension and restore product certification (products) in accordance with the certification scheme;
  - any other actions required by certification scheme.

7.12 Records

In the case where the CAB is based on an electronic system for his records, shall have a specific procedure that must be documented. This procedure must define rules for: security, protection, saving and archiving electronic data.

To determine the archival period and the rescue CB must demonstrate that it has taken into account all relevant criteria (regulations, legislation, customer requirements, etc.). Also, the archival/storage period must be established to meet the requirements of the scheme and legal requirements (where applicable) and privacy criteria.

7.13 Complaints and appeals

8 Management system requirements

8.1 Options

8.2 General management system documentation (Option A)

8.3 Document control (Option A)

8.4 Records control (Option A)

8.5 Management review (Option A)

8.6 Internal audits (Option A)

8.7 Corrective action (Option A)

8.8. Preventive action (Option A)

6. SYNTHESIS OF CHANGES

Changes were included on the following pages: 1, 3-6, 9-10.