



NATIONAL ACCREDITATION CENTRE

CRITERIA FOR EVALUATION OF CONFORMITY ASSESSMENT SCHEMES

Code: I-03

Edition [2](#)

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Approved by Accreditation Council
Minutes [no.12 of 23.05.2018](#)

Date of approval: [23.05.2018](#)

Date of application: [23.05.2018](#)

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1. PURPOSE

This document contains the procedure and criteria, which should be used by MOLDAC while evaluating a conformity assessment scheme at the request of a scheme owner and general requirements for scheme evaluation and acceptance of it, being adequate for level 4 of EA MLA and harmonized with standards at level 3 of EA MLA (see EA-1/06).

The process is established in order to provide a common approach for the operated Conformity Assessment Schemes.

2. SCOPE

This instruction is applied by MOLDAC personnel (technical assessors, assessors and technical experts) involved in accreditation process of conformity assessment bodies, by the owners of conformity assessment schemes, by conformity assessment bodies as well as other interested parties. This instruction is applied, if necessary, along with Accreditation Rules, code: RA and/ or Accreditation process procedure, code: PR-04.

This document is mandatory for conformity assessment schemes for voluntary domain and for assessment of national regulated schemes.

3. REFERENCE DOCUMENTS

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

SM SR EN ISO/CEI 17011:2017 „General requirements for Accreditation Bodies accrediting Conformity Assessment Bodies”.

Regulation (EC) 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and on abolishment of Regulation (EEC) no. 339/93.

RM Law no. 235 of 01.12.2011 on accreditation and conformity assessment activities, with subsequent modifications.

EA-1/22 A:2016 EA Procedure and Criteria For the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members

EA-1/06 A-AB:2017 EA Multilateral Agreement Criteria for signing Policy and procedure for development

EA-2/17 M:2016 EA Document on Accreditation for Notification Purposes

Including other EA, IAF, ILAC documents that can be found on the website <http://acreditare.md/> in document "General criteria for accreditation".

4. DEFINITIONS AND ABBREVIATIONS

4.1. Definitions

In this document are used definition from SM SR EN ISO/CEI 17000:2006 and [EA-1/22 A :2016](#).

4.2. Abbreviations

ONA – National Accreditation Body
OEC – Conformity Assessment Body
ŞDA – Head of Accreditation Department
EvŞ – Lead Assessor
EvT – Technical Assessor
ExT – Technical Expert
SEC – Conformity Assessment Scheme
PS – Scheme Owner
[CC – Conformity Certificate](#)
[CI – Inspection Certificate](#)
[OI – Inspection Body](#)

See Abbreviation list, code PR-01-A-1, attached to the procedure of Document and Records Control code PR-01.

5. RESPONSIBILITY AND AUTHORITY

Responsibilities and authorities of involved functions are described in the chapter 6 of this instruction.

6. DESCRIPTION OF ACTIVITIES

CRITERIA FOR EVALUATION OF CONFORMITY ASSESSMENT SCHEMES

instruction describes the requirements for the content of conformity assessment schemes and general information on the structure of the request for recognition of a new Conformity Assessment Scheme.

6.1 Requirements for the content of the conformity assessment schemes

While designing a Conformity Assessment Scheme to be recognized by MOLDAC, Scheme Owner should take into account the provisions of this document.

Criteria indicated in this document emerge from requirements of relevant ISO/CASCO standards and guides. A complete list of these standards and guides is available in CASCO Toolbox, which can be accessed on ISO website (www.iso.org).

Scheme Owner (PS) should comply with ISO/IEC 17011 standard as a general guide, while elaborating normative documents for conformity assessment, paying a special attention to principles from clause 4 and to guidelines from clauses 5 and 6.

ISO/IEC 17067 provides principles and guidance for understanding, development, operation or maintenance of product, processes and services certification schemes.

Instructions are related to:

- ✓ Scheme owner (§6.3)
- ✓ Development of product certification schemes (§ 6.4)
- ✓ Scheme content (§ 6.5)
- ✓ Maintenance and improvement of a scheme (§ 6.6)
- ✓ Scheme documentation (§ 6.7)

These principles and guidelines should be applied by PS in defining products, processes and services certification schemes. They can also be used as applicable to the establishment of inspection schemes and management systems certification schemes or schemes that include testing and calibration activities.

Requirements to establish persons certification schemes are included in the clause 8 of the ISO/IEC 17024 standard.

The following table provides an overview of the elements, which Conformity Assessment Scheme (SEC) should include, at least, for different types of conformity assessment activities.

Table
General presentation of elements for different types of assessment activities

Conformity assessment activity	Description (at least) of elements
Calibration and testing (including medical analyses)	<ul style="list-style-type: none"> - Scope (object, matrix, domain etc.); - Calibration and testing methods; - Performance features of methods; - Applicable requirements for laboratories, additional to the international standards for laboratories, e.g. ISO/IEC 17025 or ISO 15189; - Requirements against which the object will be tested or calibrated. This requirements can be international standards, or legal requirements, or standards provided within sector, or specifications of a group of manufacturers; - Specific requirements on for example internal and/or external procedure of quality control and/or performance features, if any.
Inspection	<ul style="list-style-type: none"> - Scope (object, matrix, domain etc.); - Requirements against which an object should be judged (assessed); These requirements can be international standards, or legal requirements, or standards provided within sector, or specifications of a group of manufacturers; - Inspection methods, if relevant, including any examinations which should be performed as a part of conformity assessment activity;

	<ul style="list-style-type: none"> - Requirements applicable to inspection bodies, additional to ISO/IEC 17020.
Certification	<ul style="list-style-type: none"> - Certification object: <ul style="list-style-type: none"> ✓ Management systems; or ✓ Products, services and processes; or ✓ Persons (expertise, competence). - Requirements against which certification object should be assessed and certified. These requirements can be international standards, or legal requirements, or standards provided within sector, or specifications of a group of manufacturers; - Description of certification system; - Requirements applicable to certification bodies, additional to international standards for certification bodies.

6.2 General information on structure of application for scheme evaluation

Addressing of scheme owner for recognition of a new Conformity Assessment Scheme, submitted to MOLDAC for accreditation consists in filling the application, which contains 3 specific annexes.

Organization that defined the scheme should complete:

- Annex 1 Information provided by conformity assessment scheme owner,
- Annex 2 Guide for validation of certification schemes, applicable only to new certification schemes,
- Annex 3 Evaluation questionnaire of conformity assessment scheme.

Above listed annexes are filled and sent to MOLDAC secretariat only in cases when Scheme Owner has elaborated a new scheme and requests its recognition.

In cases when a part of scheme is covered by:

1. a national or international standard issued by a standardization body – INS, ISO, CEN, ASRO, UNI, BSI, etc.,
2. other normative documents issued by standardization body – ISO/PAS, ISO/TS, CWA, etc.,
3. normative **acts** issued by regulators (Law, GD, order, etc.),
4. normative **acts** issued by regulators (Law, GD, order, etc.), additionally filled in by CAB (CAB is owner),
5. a scheme recognised on international and European level (GLOBAL GAP, BRC, IFS, etc.).

CAB fills in only Annex 3 Evaluation Questionnaire of conformity assessment scheme and submits it to MOLDAC secretariat, along with set of documents, attached to Application for accreditation.

Evaluation of conformity assessment schemes is carried out by assessment team approved by MOLDAC Director at the stage of review of documents submitted by CAB, according to MOLDAC procedures in force.

7. RECORDS

Completed Annexes:

Annex 1, code I-03-A-1
Annex2, code I-03-A-2
Annex3, code I-03-A-3

8. ANNEXES

Annexes to application for recognition of a conformity assessment scheme:

Annex 1 – Information provided by conformity assessment scheme owner
Annex 2 – Guide for validation of certification schemes
Annex3 – Evaluation questionnaire of conformity assessment scheme

9. SYNTHESIS OF MODIFICATIONS

There have been introduced modifications on the following pages: [1](#), [3](#), [4](#), [6](#), [7](#).