

#### THE GOVERNMENT

**DECISION** No. 77 of 25.01.2013

### on the reorganization of State Enterprise "Accreditation Centre on Product Conformity Assessment"

Published: 01.02.2013 in the Official Gazette No. 22-25 Art No: 117

**AMENDED** 

GD 411 of 08.05.18, MO 150-155/11.05.18 Art.460

GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044

throughout the decision and the Regulation, to the appropriate grammatical form, the words "Ministry of Economy", in any grammatical form, shall be substituted by the words "Ministry of Economy and Infrastructure" by *GD 411 of 08.05.18*, *MO 150-155 / 11.05.18 Art.460* 

Under par. (4) Art. 7 and letter a) par. (2) Art. 33 of Law 235 of 1 December 2011 on accreditation and conformity assessment activities (the Official Gazette of the Republic of Moldova, 2012 No. 46-47, Article 136), with subsequent amendments, and Art. 14 of Law 146-XIII of 16 June 1994 on State Enterprise (The Official Gazette of the Republic of Moldova, 1994, No. 2, Art. 9), with subsequent amendments and supplements, the Government DECIDES:

#### [Issuing clause as amended by GD961 of 08.08.16, MO256-264/12.08.16 Art.1044]

- 1. The State Enterprise "Accreditation Centre on Product Conformity Assessment" shall be reorganized by transformation into the Public Institution "National Accreditation Centre in Moldova" (MOLDAC).
- 2. The Ministry of Economy and Infrastructure is assigned as Founder of the Public Institution "National Accreditation Centre in Moldova" (MOLDAC).
- 3. The Ministry of Economy and Infrastructure shall ensure reorganization of the company in accordance with the legislation in force.
- 4. Regulation on the organization and functioning of the Public Institution "National Accreditation Centre in Moldova" (MOLDAC) is approved (attached).

- 5. The Public Institution "National Accreditation Centre in Moldova" (MOLDAC) is the successor of rights and obligations of the State Enterprise "Accreditation Centre on Product Conformity Assessment"
- 6. Patrimony led by the State Enterprise "Accreditation Centre on Product Conformity Assessment" shall be transmitted under Public Institution "National Accreditation Centre in Moldova" (MOLDAC) management.
- 7. The Ministry of Economy and Infrastructure, jointly with the State Chancellery, shall provide, free of charge, premises for the Public Institution "National Accreditation Centre in Moldova" (MOLDAC).
- 8. Government Decision No. 690 of 13 November 2009 "on the approval of the Regulation on the organization and functioning of the Ministry of Economy and Infrastructure, structure and staff limit of its central office" (The Official Gazette of the Republic of Moldova, 2009, No. 166-168, Art.768), with subsequent amendments and supplements, shall be amended as follows:

Paragraph 1 of decision, paragraph four shall read as follows:

" List of institutions subordinated and monitored by the Ministry of Economy and Infrastructure, according to Annex No. 3;"

Annex No. 3 shall read as follows:

"Annex No. 3 to Government Decision No. 690 of 13 November 2009

# LIST of institutions subordinated and monitored by the Ministry of Economy and Infrastructure

#### 1) Subordinated:

Public Property Agency
Licensing Chamber
Consumer Protection Agency
State Inspectorate for Technical Supervision of Hazardous Industrial Products
Energy Efficiency Agency
State Energy Inspectorate, mun. Chisinau
National Institute of Standardization
National Institute of Metrology

#### 2) Monitored:

National Accreditation Centre in Moldova (MOLDAC)";

in Annex No. 5, position "State Enterprise "Accreditation Centre on Product Conformity Assessment"" shall be excluded.

9. Government Decision No. 1646 of 31 December 2003, On the creation of Accreditation System of products conformity assessment" is repealed (The Official Gazette of the Republic of Moldova, 2004, No. 19-21, Art. 153).

**DEPUTY-MINISTER** 

**Vladimir FILAT** 

Countersigns:

Deputy Prime Minister, Minister of Economy Minister of Finance

Valeriu Lazar Veaceslav Negruta

Approved by Government Decision No. 77 of 25 January 2013

#### REGULATION

### on the organization and functioning of Public Institution "Accreditation Centre on Product Conformity Assessment" (MOLDAC) Chapter I GENERAL PROVISIONS

- 1. Regulation on the organization and functioning of Public Institution "National Accreditation Centre in Moldova" (MOLDAC) regulates the mission, core functions, tasks and rights of MOLDAC, as well as its activity organisation.
- 2. MOLDAC is designated under the law to act as single national accreditation body and has the aim of implementing the state policy in the field of accreditation and conformity assessment.
- 3. MOLDAC is a legal entity, has a stamp with the State Emblem of the Republic of Moldova and its name, bank accounts, including currency accounts.
- 4. MOLDAC shall be monitored by the central body of public administration responsible for quality infrastructure and shall not be subordinated to any public or private authorities, except as provided in par. (4) and (5) Art. 7 of Law No. 235 of 1 December 2011 on accreditation and conformity assessment.
- 5. MOLDAC shall operate in accordance with the Constitution of the Republic of Moldova, legislative acts, Presidential decrees, ordinances, normative acts and Government provisions, international treaties to which Moldova is party, and the provisions of this Regulation.
- 6. MOLDAC is organized and operates so as to comply with Law No. 235 of 1 December 2011 on accreditation and conformity assessment, Reference Standard SM SR EN ISO/CEI 17011 "Conformity assessment. General Requirements for Accreditation Bodies accrediting conformity assessment bodies", documents of European and international accreditation organizations (EA, ILAC, IAF), that underlie Mutual Recognition Arrangements and conformity assessment results at EU and international level.
- 7. MOLDAC revenue and expenditure budget is formed and approved under Law No. 235 of 1 December 2011 on accreditation and conformity assessment.
- 8. The cost of accreditation is calculated in accordance with Annex No. 1 to Law No. 235 of 1 December 2011 on accreditation and conformity assessment.

### Chapter II MOLDAC MISSION, CORE FUNCTIONS, POWERS AND RIGHTS

- 9. MOLDAC has the mission to develop accreditation and conformity assessment and to establish confidence in the impartiality, independence and technical competence of accredited conformity assessment bodies (CABs), aiming primarily to:
- 1) contribute to increasing the competitiveness of products and services in globalized markets, by providing accreditation services to conformity assessment bodies in all areas where accreditation is required both compulsorily and voluntarily;
- 2) contribute to the promotion of free movement of goods and services, ensuring European and international recognition of accreditation and conformity assessment results of products and services, conducted at national level;
- 3) promote the protection of the health and safety of persons and environmental protection by ensuring representation of national interests in international and European accreditation bodies

and other relevant organizations;

4) be organized so as to be independent from the conformity assessment bodies which it assesses and commercial pressures, and to ensure that no conflicts of interest occur with conformity assessment bodies.

#### 10. MOLDAC core functions are:

- 1) creating conditions for the recognition of conformity assessment activities by signing the multilateral recognition agreements with the European Cooperation for Accreditation and regional and international organizations for accreditation and to ensure that membership;
- 2) awarding authorities and consumers' confidence in the competence, impartiality and integrity of accredited conformity assessment bodies;
- 3) identification of the conformity assessment activities for which the CAB is competent to perform accreditation of testing and certification to national requirements;
- 4) providing training and knowledge transfer in the field of accreditation and testing, without being in consulting services for obtaining / maintaining accreditation or certification of technical competence;
- 5) CAB evaluation requesting the right to operate in the fields covered, for the purpose of their subsequent recognition by the regulatory authorities. Ways of cooperation and obligations of the parties are stipulated in the convention which is presented as Annex hereto and is integral part thereof;
- 6) make decision on the CAB accreditation, applying for recognition in the field covered, where the applicant CAB meets the accreditation criteria of reference standards, documents of European and international accreditation organizations adopted at national level, of the relevant technical regulations, and complies with the requirements of regulatory authorities applicable to CAB recognized for their area of competence.
- 11. For carrying out its core functions, MOLDAC shall exercise the powers set out in Art. 8, Art.14<sup>1</sup> paragraph (10) and (11) of Law No. 235 of 1 December 2011 on accreditation and conformity assessment.

#### [Point 11 amended by GD961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

#### 12. MOLDAC shall have the following rights:

- 1) to request and receive, under the law, information from central bodies of public administration, local government authorities, businesses and other organizations and institutions working in areas related to its competence, irrespective of their type of property;
  - 2) to apply, as established by legislation, measures to implement the MOLDAC activities plan;
- 3) to convene meetings with decision-makers from ministries, other central administrative authorities, scientific institutions and other bodies on matters within its competence;
- 4) to own, use and manage its property, budgetary means and special means available under the law in force;
- 5) to carry out activities that support, develop, improve the accreditation and conformity assessment in accordance with the practices in the field, without contradicting the basic activities

#### of MOLDAC:

- 6) to make use, under the law, of the financial resources necessary for carrying out its activities at national and international levels:
  - 7) to become a member of international, European and regional accreditation organizations;
- 8) to develop and submit the Ministry of Economy and Infrastructure proposals for promotion on improving the legislation in its field;
- 9) to involve, if necessary, experts from various fields of the national economy complying with the special requirements set for carrying out the accreditation activity;
  - 10) to organize conferences, roundtables, workshops with stakeholders;
  - 11) to participate in national and international projects and programs in the field.
- 13. MOLDAC shall be headed by a director appointed on a competitive basis, by order of the head of the central body of public administration responsible for quality infrastructure. The Director of the Centre shall have Moldovan citizenship, higher education degrees in technical or economic areas and experience in the field of accreditation and / or conformity assessment of at least 5 years, including at least 3 years in administrative position.
- 14. The Director of MOLDAC shall be dismissed, by order of the head of the central body of public administration responsible for quality infrastructure, in the following cases:
  - 1) loss of citizenship;
  - 2) incapacity to exercise the function of health reasons;
  - 3) choice in another position;
- 4) conviction for committing crimes of intent or conviction to imprisonment by a final court decision.

[Point14 amended by GD961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

- 15. The Director of MOLDAC shall:
- 1) bear the overall responsibility for carrying out properly the functions and duties accruing to MOLDAC and to its work;
  - 2) bear personal responsibility for the efficient use of funds, according to purpose;
- 3) approve, within the budget limits, the staff list and its structure, forms and manner of MOLDAC employees' remuneration;
- 4) appoint, modify, suspend and terminate under the law, relations with MOLDAC employees, employ and dismiss the contractual staff of MOLDAC;
- 5) ensure rational use of budgetary resources according to their destination, in accordance with Moldovan law, as well as the integrity of the material goods of MOLDAC;
- 6) issue, under the law, orders, approve documents (regulations, procedures, instructions, etc.) and other documents related to the MOLDAC activity and control their execution;
  - 7) take decisions on granting / not granting, maintaining, extending, suspending and

withdrawing accreditation;

[Point 15 sub point 7] amended by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

- 8) ensure the relevant staff training and development, provide technical and material endowment thereof:
  - 9) represent MOLDAC in relations with legal persons from Moldova and abroad;
- 10) represent the interests of Moldova in international and European accreditation bodies and other organizations relevant to this activity, sign agreements for cooperation and mutual recognition with accreditation bodies from other countries;
  - 11) motivate employees and apply disciplinary sanctions under the MOLDAC law.

[Point 16 repealed by GB 411 of 08.05.18 MO 150-155/11.05.18 Art.460]

[Point16 amended byGD961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

[Point 17 repealed by GB 411 of 08.05.18 MO 150-155/11.05.18 Art.460]

[Point 17 in the wording of GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

18. Structure and staff shall be approved by order of the Director of MOLDAC.

MOLDAC shall consist of divisions and sections, under their own regulations, approved by the Director of MOLDAC.

- 19. Correspondence of MOLDAC shall be signed by the Director and the relevant positions' stuff within MOLDAC, vested with this right by order of the Director.
- 20. The Director of MOLDAC shall have the right to first signature on all documents. In the absence of the Director, the right to first signature shall lie with the person holding responsible positions within MOLDAC under the Director's order.
- 21. The signature on the MOLDAC documents and correspondence shall be in written form or, under the law, may have other forms as well.
- 22. MOLDAC shall collaborate with ministries, other central administrative authorities, local government authorities, other organizations and public institutions.

Commissions, committees and working groups that are convened to address and solve specific issues may be created within MOLDAC. Specialists from various fields can be involved in the work of the commissions, committees and working groups.

Annex to Regulation on the organization and functioning of the Public Enterprise "National Accreditation Centre of Moldova" (MOLDAC)

## **CONVENTION \* The Parties:**

II	ie re	eguiatory at	umorny:_							
as	the	competent	authority	responsible	for	recognition	of	conformity	assessment	bodies

(CABs) that performs specific tasks in relation to a conformity assessment procedure and proves independence, impartiality and integrity, in accordance with a technical regulation's provisions for recognition

**MOLDAC** as the national accreditation body, to ensure procedural and organizational framework for implementing the provisions on the recognition of accredited CABs seeking the right to operate in areas covered by Annex No. 3 to Law No. 235 of 1 December 2011 on accreditation and conformity assessment for which there are essential requirements provided in the technical regulations, in accordance with Art. 4 paragraph 6 of Law No. 420-XVI of 22 December 2006 on technical regulation activity, agree as follows:

### Chapter I GENERAL PROVISIONS

1. This Convention sets:

and

- 1) requirements applicable to CABS requesting accreditation for recognition;
- 2) obligations of the parties;
- 3) way in which parties will be involved and will work for:
- a) assessment of CABs requesting accreditation for recognition;
- b) surveillance of recognized CABs,

so as to ensure a high level of confidence in relation to proving and maintaining the ability and competence of recognized CABs to perform specific tasks in the application of the following technical regulations:

Technical regulation:
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- 2. References to technical regulations referred to Point 1 of this Convention can be modified by the regulatory authority, correlated to developments in the regulatory framework, by amending the Convention signed between the parties.
- 3. Organization and functioning of CABS requesting accreditation for recognition must correspond to the appropriate reference standards, taking into account the specific requirements applicable to recognized CABs and, where appropriate, the additional requirements set by the regulatory authority.

#### **Chapter II**

#### PARTIES' FORM OF COOPERATION

- 4. The request for accreditation and recognition, file of documents requested from CABs in relation to the application for accreditation and recognition, shall be submitted by CABs at the MOLDAC premises, that shall record it in the Register of requests for accreditation for recognition. The application form for accreditation and recognition, as well as content of the documents file shall be determined by MOLDAC with the consent by the regulatory authority.
- 5. MOLDAC shall inform the regulatory authority when CABs apply for accreditation for recognition. Information shall be forwarded by the MOLDAC secretariat in written (email, fax), within 5 working days from the registration of the application.
- 6. The regulatory authority, through its representative, may participate as an observer in the MOLDAC assessment team both for initial and subsequent assessments of CABs, on supervision, extending accreditation, reaccreditation, and unplanned assessments required by the regulatory authority.
- 7. The regulatory authority, when deemed necessary, shall delegate its specialist designated for the area requested in the accreditation by the CABs and shall submit to MOLDAC in writing, within 5 working days, the name and contact details of the person designated. The designated representative shall liaise with MOLDAC.
- 8. MOLDAC shall publish information about accreditation granted on its website, at the Section: "Accredited conformity assessment bodies in the area covered".
- 9. After granting the accreditation, MOLDAC shall draw up an assessment report for recognition, including the name of accredited CABs, assessed area, assessment results. The template of the evaluation report for recognition shall be drafted by MOLDAC, with the consent

by the regulatory authority and form part of the MOLDAC management system.

10. After granting the accreditation, MOLDAC shall submit the regulatory authority, within 5 working days, CABs' request for recognition, assessment report for CABs recognition, the decision taken, copy of the certificate of accreditation, documents file on the request for recognition, requested from CABs.

#### [Point 10 amended by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

- 11. The regulatory authority shall analyse the MOLDAC assessment report for recognition and the attached documents.
- 12. The regulatory authority, by its order, shall recognise the applicant CABs, where compliance with the applicable requirements set out in the relevant legislation is proven by it, and shall inform MOLDAC about the decision taken within 5 working days.
  - 13. Recognition is given to the period of validity of the accreditation certificate.
- 14. MOLDAC shall inform CABs on the granting of recognition by the regulatory authority and shall include them in the Single Register of recognized CABs. Information on recognition shall be published on the MOLDAC web page.
  - 15. MOLDAC may conduct an extraordinary assessment of CABs in the following cases:
- a) When there are complaints and appeals by third parties on the CABs' or their clients' activity;
- b) Where MOLDAC/the regulatory authority finds or is notified on infringement by recognised CABs of the conditions under which the accreditation / recognition was granted (relevant information in the media, information from government control agencies and other information sources etc.);
- c) Where the recognised CABs modify certain conditions according to which the accreditation / recognition was granted.
- 16. MOLDAC shall inform the regulatory authority on the extraordinary evaluation results, as well as the decision taken.
- 17. Following the examination of the results of extraordinary assessment carried out by MOLDAC, the regulatory authority, by its Order, shall suspend / restrict the field for which recognition was granted or withdraw recognition of certain CABs in the case of non-compliance with requirements according to which recognition was granted or where CABs request so. The regulatory authority shall submit to MOLDAC a copy of the order issued.
- 18. Conditions of suspension, restriction or withdrawing recognition of Conformity Assessment Bodies shall be determined by the regulatory authority.
  - 1) The Regulatory Authority shall suspend recognition in the following cases:
  - a) upon request by the recognized conformity assessment body;
- b) where the recognized conformity assessment body was suspended accreditation according to the decision of accreditation suspension, adopted and submitted by the National Accreditation Centre;
- c) where, by Decision of the regulatory authority, there was found misuse of the status of recognized conformity assessment body (including in relation to incorrect references to the certification system, certificates or marks, as well as advertising, catalogues etc.);
- d) in case of an issued court decision on the insolvency of the CAB, under the Insolvency Law No. 149 of June 29, 2012 or open liquidation proceedings under the Civil Code, in both cases pursuant to the extract from the State Register of Legal Entities.
  - 2) The Regulatory Authority shall restrict recognition in the following cases:
  - a) upon request by the recognized conformity assessment body;
- b) where the recognized conformity assessment body has not proven proficiency for part of the accredited field, according to the decision of accreditation restriction, adopted and submitted by the National Accreditation Centre.
  - 3) The Regulatory Authority shall withdraw recognition in the following cases:
  - a) upon request by the recognized conformity assessment body;
- b) where the recognized conformity assessment body was withdrawn accreditation according to the decision to withdraw accreditation, adopted and submitted by the National Accreditation

#### Centre:

c) where the performance of the recognized conformity assessment body ceased due to its deletion from the State Register of Legal Entities.

[Point 18 in the wording of GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

19. Any changes in the status of the recognised CABs, following the suspension / restriction / withdrawal of the field for which recognition was granted shall be published by MOLDAC on its web page.

# Chapter III PARTIES' OBLIGATIONS

- 20. The obligations of the regulatory authority:
- 1) cooperation with MOLDAC under the terms set in this Convention;
- 2) appointment of a representative and substitute thereof, for each technical regulation in its field of competence and inform MOLDAC, in written, of the name and contact details of the designated persons;
- 3) insurance by designated representatives of liaison with MOLDAC in the specific area subject to their designation;
- 4) submission for approval of draft amendments to the technical regulations mentioned at Point 1 of the Convention, signed by MOLDAC and the competent authority, as well as informing MOLDAC on the amendments to the respective technical regulations, approved and published;
- 5) recognition of the accredited CABs by MOLDAC that comply with the requirements / criteria applicable to recognized CABs; [Point 20 sub point 5] amended by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]
- 5<sup>1</sup>) recognition of accreditation certificates issued by the national accreditation bodies signatory to the Multilateral Recognition Agreement with European Cooperation for Accreditation, that have passed peer evaluations;

[Point 20 sub point 5] introduced by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

6) informing the National Accreditation Centre within 5 working days from the decision to grant, extend, suspend, withdraw suspension, restrict or withdraw recognition of the CAB or non-granting recognition, stating the grounds for non-granting;

[Point 20 sub point 6] in the wording of GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

7) informing the National Accreditation Centre, within 5 working days following the adoption of the Decision, on the recognition of conformity assessment bodies, accredited by national accreditation bodies, signatories to the Multilateral Recognition Agreement with European Cooperation for Accreditation.

[Point 20 sub point 7] introduced by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

- 21. MOLDAC shall have the following obligations:
- 1) performing accreditation by using the appropriate reference standards, taking into account the specific requirements applicable to recognized CABs and, where appropriate, the additional requirements set by the regulatory authority;
- 2) informing the regulatory authority about any application for accreditation of recognition received from a CAB, within 5 working days following the receipt thereof;
- 3) accepting participation of the designated representative of the regulatory authority as an observer in the assessment team;
- 4) accepting participation of the designated to the assessments related to the initial accreditation and subsequent assessments for accreditation surveillance, extension, reaccreditation or unplanned assessments of recognized CABs, specifying the period when the assessment will be performed;
- 5) making available to the regulatory authority of documents necessary to the analysis of recognition, in accordance with Point 10 of this Convention;
- 6) publishing and maintenance of the Single Register of Recognized Conformity Assessment Bodies on the MOLDAC web page;

[Point 21 sub point 6] in the wording of GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

#### [Point 21 sub point 7] excluded by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

8) informing the CAB that applied for recognition on granting, refusal, suspension, withdrawal of the suspension, restriction, withdrawal of granting / refusal to grant recognition by the regulatory authority;

[Point 21 sub point 8] amended by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

9) informing the regulatory authority urgently on any matters or special situations related to the activity of recognized CABs, which they have been made aware of;

[Point 21 sub point 9) amended by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044] [Point 21 sub point 10) excluded by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

11) informing the regulatory authority on the surveillances program agreed with the recognised CABs;

[Point21 sub point 11] amended by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

- 12) designation of a contact person in relation to the regulatory authority and informing, in writing, the regulatory authority about his name and contact details;
- 13) informing the regulatory authority, within 5 working days following receipt of any decision on accreditation for recognition, received from a CAB on the granting, maintaining, extending, suspending, withdrawing suspension, restriction or withdrawal of accreditation.

[Point 21 sub point 13] introduced by GD 961 of 08.08.16, MO 256-264/12.08.16 Art.1044]

# Chapter IV AMENDMENTS

22. This Convention may be revised and amended by written agreement of the Parties.

# Chapter V ENTRY INTO FORCE AND DURATION OF THE CONVENTION

The Convention shall enter into force on the date of signature by both Parties and valid until the moment when one of the Parties communicates in writing the intention of termination thereof.

For THE REGULATORY AUTHORITY	Director of MOLDAC			
Signed at on the date of	month year, in two original			

\*) Provisions of the Convention template can be supplemented or amended within negotiations between the Parties on its signing, in compliance with the legal provisions.