

LAW No. 05/L – 117

ON ACCREDITATION

Assembly of Republic of Kosovo,

Based on Article 65 (1) of the Constitution of the Republic of Kosovo,

Approves

LAW ON ACCREDITATION

**CHAPTER I
GENERAL PROVISIONS**

**Article 1
Purpose**

1. This Law defines the principles of accreditation and rules of the accreditation of conformity assessment bodies performing conformity assessment activities in Kosovo.
2. This Law is fully in compliance with the Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 on setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93 insofar as it relates to accreditation.

**Article 2
Scope**

This Law is applicable for accreditation of conformity assessment bodies performing conformity assessment activities in Kosovo.

**Article 3
Definitions**

1. Terms used in this Law have the following meaning:

- 1.1. **Accreditation** – an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, additional requirements including those set out in relevant sectorial schemes, to carry out a specific conformity assessment activity;
- 1.2. **National accreditation body** – the sole body in a state that performs accreditation with authority derived from that state;
- 1.3. **Kosovo General Accreditation Directorate (hereinafter DAK)** - the only national accreditation body in Kosovo;

1.4. **Logo of the Kosovo General Accreditation Directorate** – logo used by the Kosovo General Accreditation Directorate to identify itself as defined by applicable Law on state symbols;

1.5. **Conformity assessment** – the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

1.6. **Conformity assessment body** – the body that performs conformity assessment activities including calibration, testing, certification and inspection;

1.7. **Technical Specification** – the document that prescribes technical requirements to be fulfilled by a product, process or service;

1.8. **Harmonised standard** – a European standard adopted on the basis of the request made by the EU Commission for the application of European Union harmonised legislation;

1.9. **Peer evaluation** – a process for the assessment of a national accreditation body by other national accreditation bodies, carried out in accordance with the requirements determined by the European and international organizations for accreditation, and where applicable, additional sectorial technical specifications;

1.10. **Rules of accreditation** – rules of the national accreditation body defining the accreditation process, rights and obligations of those involved in the accreditation process, and criteria/conditions to be met by the conformity assessment body in order to gain the accreditation;

1.11. **Accreditation certificate** – a document stating that a conformity assessment body fulfils all the requirements stated in the rules of accreditation, and is competent to perform conformity assessment activities for a specific scope;

1.12. **Accreditation symbol** – a symbol issued by the accreditation body to be used by the accredited conformity assessment body to indicate its accredited status;

1.13. **Appeal** – a request by a conformity assessment body for reconsideration of any unfavourable decision made by **Kosovo General Accreditation Directorate**;

1.14. **Complaint** - an expression of dissatisfaction by any person or organization to Kosovo General Accreditation Directorate, regarding to its activities or the activities of an accredited conformity assessment body;

1.15. **Surveillance** – a set of activities, except reassessment, performed by Kosovo General Accreditation Directorate to monitor the continued fulfilment of requirements for accreditation by accredited conformity assessment bodies;

1.16. **Reducing accreditation** – a process of cancelling accreditation for part of the scope of accreditation;

1.17. **Extending accreditation** – a process of enlarging the scope of accreditation;

1.18. **Suspending accreditation** – a process of temporarily making accreditation invalid, in full or for part of the scope of accreditation;

1.19. **Withdrawing accreditation** – a process of cancelling accreditation in full;

1.20. **Consultancy** – a participation in any of the activities of a conformity assessment body that is subject to accreditation;

1.21. **Ministry** – respective Ministry for trade and industry.

Article 4 **Accreditation application**

1. Accreditation of conformity assessment bodies is voluntary.
2. Accreditation may be rendered mandatory for performing specific conformity assessment activities if laid down so in a specific law or regulation.
3. Kosovo General Accreditation Directorate shall perform its activities on a not-for-profit basis.
4. Provisions of this Law shall apply to the accreditation of bodies that perform conformity assessment activities both in the areas that are regulated with legal acts of Kosovo and to the accreditation of bodies that perform conformity assessment activities in the areas that are not regulated with legal acts of Kosovo.

CHAPTER II **ORGANIZATION OF ACCREDITATION IN KOSOVO**

Article 5 **Kosovo General Accreditation Directorate**

1. Accreditation activities are performed by the Kosovo General Accreditation Directorate established as an independent state administration body, which is under the Ministry.
2. The structure and organization of DAK ensure impartiality and objectivity in the decision for accreditation.
3. Law on the State Administration of the Republic of Kosovo shall be applied for establishing, organization and functioning of DAK, unless otherwise stipulated by this Law.
4. Organisation and functioning of DAK is regulated through a sub-legal act approved by the Government of Kosovo.

Article 6 **Obligations of DAK**

According to the provisions of this Law, DAK should apply even the Kosovo national standard

that adopts the relevant European harmonised standard and international standard, as well as documents issued by European and international organizations for accreditation, defining general requirements for the accreditation bodies accrediting conformity assessment bodies.

Article 7
Activity areas of accreditation by DAK

1. The activity areas of accreditation are as follows:

- 1.1. accreditation of testing and calibration laboratories;
- 1.2. accreditation of medical laboratories;
- 1.3. accreditation of inspection bodies;
- 1.4. accreditation of product certification bodies;
- 1.5. accreditation of management systems (quality, environment etc.) certification bodies;
- 1.6. accreditation of personnel certification bodies; and
- 1.7. accreditation of other conformity assessment bodies.

Article 8
Competencies of DAK

1. DAK performs the following tasks:

- 1.1. evaluates through accreditation the competence of conformity assessment bodies;
- 1.2. supervises the continuous fulfilment of the requirements for carrying out specific conformity assessment activities;
- 1.3. provides the expertise and trainings to the state administration bodies for issues that are related to the accreditation of conformity assessment bodies;
- 1.4. establishes and makes publicly available the Rules of Accreditation based on the relevant Kosovo national standards adopted from the European and international standards, as well as documents issued by the European and international organizations for accreditation;
- 1.5. keeps and makes publicly available a Register of the Accredited Conformity Assessment Bodies;
- 1.6. makes publicly available information on its activities and about the results of the peer evaluation

1.7. represents and participates in the activities of the European and international accreditation organizations.

Article 9

Principle of non-competition

1. DAK shall not provide or carry out services provided by conformity assessment bodies.
2. DAK shall not provide consultancy services and shall not have a financial or managerial interest in a conformity assessment body.
3. DAK shall not compete with other national accreditation bodies. It shall not provide services outside the borders of Kosovo, except in cases and under conditions defined in paragraph 3 of Article 24 of this Law.

Article 10

Financial resources of DAK

1. The financial resources for the activities of DAK shall be provided from the State Budget.
2. Donations by conformity assessment bodies are not allowed.
3. The amount of financial resources necessary for the operation of DAK shall be determined on the basis of the activities defined in the Annual Work Plan.
4. The Ministry and respective ministry for finance shall ensure appropriate financial resources to DAK for:
 - 4.1. proper performance of its tasks;
 - 4.2. payment of the membership fees in the European and international accreditation organizations;
 - 4.3. participation in the activities of the European and international accreditation organizations;
 - 4.4 payment of external accreditation personnel.

Article 11

Accreditation fees

1. DAK accreditation services shall be charged based on expenditures for the performed work.
2. Accreditation fees shall be established by sub-legal acts issued by the Ministry.

Article 12
Bodies of DAK

1. The DAK bodies are:
 - 1.1. General Director;
 - 1.2. Professional Council.
 - 1.3. Accreditation Council.

Article 13
General Director

1. DAK shall be managed by the General Director.
2. General Director of DAK shall take the decision on Accreditation.
3. Appointment, discharge, functions and responsibilities of the General Director are implemented in accordance with the provisions of the respective Law on Civil Service of the Republic of Kosovo and the Regulation on appointment procedures for senior managerial positions.
4. Recruitment of officials of DAK shall be made in accordance with the conditions and criteria specified in the applicable provisions of the Law on Civil Servants of the Republic of Kosovo.

Article 14
Professional Council

1. DAK shall establish the Professional Council in order to ensure the effective and balanced involvement of all interested parties, and safeguard the impartiality, transparency and fairness between stakeholders in the accreditation process.
2. The Professional Council shall provide professional opinions and recommendations to the General Director of DAK in terms of development of the accreditation system in Kosovo that includes policies, procedures, annual and long term plans, extension of accreditation activities and necessary human and financial resources.
3. The General Director of DAK shall not take decisions on issues referred to in paragraph 2 of this Article without previous recommendations of the Professional Council.
4. General Director of DAK shall appoint the members of the Appeals Commission, from the recommended list of the Professional Council.
5. The mode of establishing the Professional Council, scope, as well as selection and appointment of its members shall be regulated with a sub-legal act issued by the Ministry.

Article 15

Accreditation Council

1. General Director of DAK shall establish the Accreditation Council, the members of which shall be different from those who carried out the assessment of the conformity assessment body.
2. The Accreditation Council provides recommendation to the General Director for taking the decision on accreditation for each particular case of assessment.
3. The mode of establishing the Accreditation Council, scope as well as selection and appointment of its members shall be regulated with a sub-legal act issued by the Ministry.

Article 16

Supervisory body of DAK

1. The Ministry is a supervisory body that performs supervision of the legality of the DAK, includes monitoring of fulfilling the requirements laid down in the Article 6 of this Law, taking into account confidentiality of data about the conformity assessment bodies that are DAK customers.
2. The Ministry shall take into consideration the result of the Peer Evaluation during the surveillance of DAK referred to in paragraph 1 of this Article.

CHAPTER III

ACCREDITATION PROCESS

Article 17

Accreditation procedure

1. DAK shall, whenever requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity.
2. Accreditation is performed based on the application submitted by the conformity assessment body.
3. DAK and a conformity assessment body regulate by contract the mutual rights and obligations concerning the obtaining of the accreditation certificate and maintaining the accreditation.
4. DAK shall keep the confidentiality of the information obtained in all accreditation cases.
5. DAK shall issue an accreditation certificate to the conformity assessment body where it is found to be competent.
6. If it is found that, during the finalization of accreditation process, the conformity assessment body has failed to meet some of the requirements for accreditation, DAK shall issue a decision on rejection of the accreditation or to grant accreditation with a reduced scope of accreditation.
7. The validity of the conformity certificate shall be issued with the time-limit not longer than

four (4) years. The accredited conformity assessment body shall continuously comply with the accreditation requirements over the period in which the accreditation certificate is valid.

8. DAK shall draft and make publicly available the Rules of Accreditation to the conformity assessment bodies where there is specified in details the process of accreditation.

9. DAK shall set up necessary procedures, by internal acts, to ensure efficient and appropriate management of internal controls of the entire accreditation process.

Article 18

Accreditation symbol

DAK shall allow an accredited conformity assessment body to use the accreditation symbol in order to show its status of accredited conformity assessment body.

Article 19

Surveillance of an accredited conformity assessment body

1. DAK shall monitor the conformity assessment body to which it has issued an accreditation certificate by performing regular surveillance. During the surveillance, DAK shall decide on the continuation of the accreditation or any changes in the accreditation scope.

2. If an accredited conformity assessment body requests an extension of the accreditation scope, the assessment of competence in the extended scope can be done during the surveillance.

3. Where DAK ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or has committed a serious breach of its obligations, DAK shall take all appropriate measures within a reasonable timeframe to reduce, suspend or withdraw its accreditation.

4. The conformity assessment body can lodge an appeal against the decision of DAK by which the accreditation is reduced, suspended or withdrawn.

5. During an assessment, DAK shall verify whether the conformity assessment body has performed a conformity assessment in an appropriate manner, taking into account the size of a company, the sector in which the company operates, its structure, complexity of the product technology and the mass or serial nature of the production process.

Article 20

Working groups

1. DAK may establish professional working groups on standing or temporary basis for the purpose of providing expertise on specific issues in the accreditation procedure as follows: technical committees, persons' evaluation committee and other fields.

2. Technical committee is a technical body that provides technical expertise in certain fields of accreditation.

3. Persons' evaluation committee is a body that evaluates and monitors persons involved in the

process of accreditation regarding their qualification, competence and experience as well as their performance in certain fields and scopes.

Article 21
Appeal procedure

1. DAK shall establish a procedure for the resolution of appeals.
2. Appeals shall be reviewed by the Appeal Commission referred to in the paragraph 4 of Article 14 of this Law, which makes recommendations to the General Director.
3. The decision of the General Director is a final decision, whereas against it an administrative dispute can be initiated in the competent court.

Article 22
Complaint procedure

1. DAK shall establish a procedure for resolving complaints related to its activities or activities of a conformity assessment body accredited by DAK.
2. A complaint shall be resolved by the General Director of DAK.

CHAPTER IV
INTERNATIONAL COOPERATION

Article 23
International activities of DAK

1. DAK shall fulfil the standards to be a member of the European and international organizations of accreditation and shall take part in their activities.
2. DAK shall be subject to peer evaluation organised by the European organization for accreditation, and shall sign agreements on mutual recognition of accreditation.
3. In Kosovo, the equivalence of the services delivered by those accreditation bodies which have successfully undergone peer evaluation referred to in the paragraph 2 of this Article, are recognized.
4. Consequently to the paragraph 3 of this Article, the accreditation certificates of those accreditation bodies and the attestations issued by the conformity assessment bodies accredited by them, are accepted.

Article 24
Cross-frontier accreditation

1. Conformity assessment body may request accreditation from a national accreditation body outside Kosovo only in one of the following cases:

1.1. when DAK does not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;

1.2. when DAK has not successfully undergone peer evaluation referred to Article 23 paragraph 2, in respect of the conformity assessment activities for which the accreditation is sought.

2. DAK may accept applications for accreditation from a conformity assessment body outside Kosovo under the conditions defined in paragraph 1 of this Article.

3. When DAK accepts a request for accreditation from a conformity assessment body established in another country, DAK shall inform the national accreditation body of the country in which the conformity assessment body is established. In such cases, the national accreditation body of the country in which conformity assessment body is established may participate as an observer.

4. DAK may request another national accreditation body to carry out the assessment activity. In such case, the decision on accreditation shall be made by DAK which also issues the accreditation certificate.

CHAPTER V TRANSITIONAL AND FINAL PROVISIONS

Article 25 Transitional provisions

The Government of Kosovo shall provide DAK with the necessary work spaces and facilities, and DAK shall take over from Kosovo Accreditation Directorate the tangible assets and equipment intended for carrying out the tasks relating to accreditation as well as the employees who perform these tasks.

Article 26 Validity of accreditation certificates

1. By entry into force of this Law, the accreditation certificates issued by the Kosovo Accreditation Directorate (DAK) remain valid throughout their validity period, except if acted contrary to Article 19 paragraph 3 of this Law.

2. Accreditation activities that commenced prior to the entry into force of this Law shall be finalised in accordance with this Law and regulations referred to in the Article 28 of this Law.

Article 27 Issuance of sub-legal acts

Government and Ministry shall issue sub-legal acts determined by this Law within one (1) year from the day of entry into force of this Law.

Article 28

Sub-legal acts applicable until the issuance of new sub-legal acts

1. Provided that they are not in contradiction with this Law and until the issuance of new sub-legal acts for the proper implementation of this Law, applicable sub-legal acts will continue to remain in force as follows:

1.1. Regulation (MTI) No. 02/2016 on Accreditation Council;

1.2. Regulation (MTI) No. 04/2016 on Professional Accreditation Council;

1.3. Regulation No. 29/2012 on internal organization and systematization of jobs of the Ministry of Trade and Industry, in parts which regulates the organisation of “Kosovo Accreditation General Directorate” (Articles 45 to 50);

1.4. Administrative Instruction No. 19/ 2012 on designing the form, content and usage of the accreditation logo;

1.5. Administrative Instruction No. 4/2013 on setting up accreditation tariffs.

Article 29

Repealing provisions

With the entry into force of this Law there shall be repealed: The Law No. 03/L-069 on Accreditation and the Law No.04/L –007 on amending and supplementing of the Law No. 03/L-069 on Accreditation.

Article 30

Entry into force

This Law shall enter into force fifteen days (15) after its publication in the Official Gazette of Kosovo.

Law No.05/L - 117
20 December 2016

Promulgated by Decree No.DL-001-2017, dated 05.01.2017, President of the Republic of Kosovo Hashim Thaçi.