

**DEVELOPMENT, ESTABLISHMENT AND  
EXTENSION OF ACCREDITATION SCHEMES**

Any differences between the Serbian and English versions of this document are not intended, but if in doubt, the Serbian version should be consulted.

## 1. SCOPE

This document shall lay down the procedure to be undertaken by the Accreditation Body of Serbia (ATS) for development, establishment and extension of accreditation scheme/type of accreditation, depending on the needs of the interested parties.

The procedure shall be implemented when:

- develop/establish of new scheme/type of accreditation (*level 2 and 3*);
- extend ATS activities to new standards or sectoral schemes containing additional criteria, for existing schemes/types of accreditation (*level 4*);
- extend accreditation under existing schemes/types of accreditation for specific conformity assessment schemes (*level 5*).

## 2. REFERENCE DOCUMENTS, TERMS AND DEFINITIONS AND ACRONYMS

Reference documents:

- SRPS ISO/IEC 17011:2018 – Conformity Assessment- Conformity Assessment – General Requirements for Bodies Accrediting Conformity Assessment Bodies;
- REGULATION (EC) No 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;
- EA-1/06 A-AB:2020- EA Multilateral Agreement. Criteria for signing. Policy and procedures for development;
- EA-1/22 A-AB:2020, EA Procedure and Criteria For the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members;
- Statute of the Accreditation Body of Serbia;
- Rules of Accreditation, ATS-PA01;
- Quality Manual, ATS-PK01.

Terms and definitions:

For the purposes of this Procedure, the terms defined in the reference documents shall be used.

**CAB:** Conformity Assessment Body

**ATS:** Accreditation Body of Serbia

**EA:** European Co-operation for Accreditation

**ILAC:** International Laboratory Accreditation Cooperation

**IAF:** International Accreditation Forum

**EA MLA:** Multilateral agreement within EA (laboratories, PT providers, producers of reference materials, inspection, certification bodies, and verifiers and validation bodies)

**ILAC MRA:** Mutual recognition arrangement within ILAC (laboratories, PT providers, producers of reference materials, inspection bodies)

**IAF MLA:** Multilateral recognition arrangement within IAF (certification bodies and validation and verification bodies)

**Scheme/type of accreditation:** unique combination of conformity assessment activities (EA MLA - level 2) and standard containing the requirements for CABs which perform the said activities (EA MLA - level 3) e.g.: testing / EN ISO/IEC 17025.

**Conformity assessment activities (level 2 EA MLA):** conformity assessment activities performed by CABs accredited by ATS, in accordance with the standards, such as: calibration, testing (including medical testing), inspection, certification of products, certification of management systems, certification of persons, proficiency testing, verification and validation.

**Standards which contain general requirements for CABs which perform conformity assessment activities (level 3 EA MLA):** Serbian standards transposing harmonised standards, which contain general requirements for CABs performing conformity assessment activities included in level 2: SRPS ISO/IEC 17025 (EN ISO/IEC 17025), SRPS EN ISO 15189 (EN ISO 15189), SRPS ISO/IEC 17020 (EN ISO/IEC 17020), SRPS EN ISO/IEC 17065 (EN ISO/IEC 17065), SRPS ISO/IEC 17021-1 (EN ISO/IEC 17021-1), SRPS ISO/IEC 17024 (EN ISO/IEC 17024), SRPS ISO/IEC 17043 (EN ISO/IEC 17043) and SRPS EN ISO/IEC 17029 (EN ISO/IEC 17029), SRPS ISO 14065 (EN ISO 14065).

**Sector standards or other recognised normative documents (level 4 EA MLA):** documents containing the criteria which amend the criteria contained in standards level 3. These documents are: sector specific standards (sector standards) or other recognized normative documents e.g.: ISO 15195, CEN/TS 15675, ISO 22870, ISO/TS 22003, ISO/IEC 27006; **sectoral schemes** as referred to in Regulation (EC) No. 765/2008, Articles 2 (10) and 13, which contain criteria that complement the criteria contained in the EA MLA Level 3 standards, e.g.: Regulation (EC) No., **2018/2067 and conformity assessment schemes** in accordance with EA-1/22.

*Note:* level 4 is only applied when there are documents that supplement the requirements for level 3 (which means that level 5 is usually directly related to level 3 - standard).

**Scope of accreditation (level 5 EA MLA)** or standards or other normative documents used by accredited CAB when performing conformity assessment activities.

### 3. DESCRIPTION OF THE PROCEDURE

#### 3.1 ATS policy regarding the development, establishment, and extension of accreditation schemes/types

ATS provides services of assessing competence and is a signatory to EA MLA agreement on mutual recognition for the following schemes/types of accreditation (level 2 and 3):

- Accreditation of testing laboratories according to EN ISO/IEC 17025,
- Accreditation of medical laboratories according to EN ISO/IEC 15189,
- Accreditation of calibration laboratories according to EN ISO/IEC 17025,
- Accreditation of inspection bodies according to EN ISO/IEC 17020,
- Accreditation of certification bodies providing certification of products according to EN ISO/IEC 17065,
- Accreditation of certification bodies providing certification of management systems according to EN ISO/IEC 17021-1 and
- Accreditation of certification bodies providing certification of persons according to EN ISO/IEC 17024.

Furthermore, ATS is able to provide services of assessing competence of the proficiency testing bodies of CABs (PT providers) against EN ISO/IEC 17043.

Based on the signed EA MLA, ATS signed ILAC MRA for the fields of testing, calibration and inspection and IAF MLA for the fields of certification of products and the field of certification of management systems and certification of persons.

The list of adopted standards of levels 3 and 4, which constitute the criteria for accreditation, is contained in the document *List of Documents containing requirements to be met by Applicants for accreditation and accredited bodies CAB, ATS-UP01*.

The general criteria for evaluation whether the new accreditation scheme/type of accreditation (level 2 and 3) and/or the extension of the accreditation scheme/type (level 4) will be within the scope of ATS are:

- Fulfilling of appropriate and clearly expressed needs of the market of the Republic of Serbia,
- Enabling the principle that the activity of accreditation activities as serving the public interest,
- Sufficient substance to contribute to recognition of competence CABs and/or conformity assessment activities done by CABs, including the notification/designation of CABs,
- Complementary to or supportive of for any other standard currently in use,
- The new accreditation scheme/type does not contradict with or have a negative impact of the outcome of any Level 2 and 3 schemes,
- Conformity assessment standards, sectoral standards and schemes must be produced by recognisable consensus process with involvement of relevant interested parties.

ATS shall include in its scope of work a new accreditation scheme/type, which is not specified in the document *List of Documents containing requirements to be met by Applicants for accreditation and accredited bodies CAB, ATS-UP01*, if it is within the EA MLA and/or if there is a need for such a scheme/type of accreditation on the market of the Republic of Serbia, i.e. if it is a precondition for designation (notification)/authorization of CABs.

### **3.2 ATS policy regarding determination of the suitability of conformity assessment schemes and standards for the purpose of accreditation**

The areas of conformity assessment in which ATS performs accreditation are defined in the document *ATS Scope of Activities, ATS-PA08*.

If accreditation is sought in the areas contained in this document, ATS shall immediately accept the application for accreditation. In other cases, ATS shall implement the procedure set out in this document for the development/establishment/extension of accreditation schemes/types in the case of a new accreditation scheme/type (levels 2 and 3), or an extension for an existing accreditation scheme/type within which new reference documents containing additional criteria are applied (level 4). In the case of a new conformity assessment scheme (level 5) within the existing developed levels 2/3/4, the appropriate cl. 3.3 - 3.7 of this procedure shall be applied.

For the evaluation of conformity assessment schemes with the aim of determining their suitability for the intended use and accreditation, the procedure *Evaluation of CASs, ATS PR19* and *Guide for the procedure of evaluation of the conformity assessment schemes, ATS-UP41* is used.

### **3.3 Activities before deciding on development, establishment, and extension accreditation schemes/types**

#### **3.3.1 Feasibility of initiating development, establishment, and extension accreditation schemes/types**

Before making a decision on the development, establishment and extension of accreditation schemes/types, the necessary analysis of the existing ATS competence, the expediency of the listed activities, resources, etc. shall be performed.

#### **3.3.2 Analysis of existing competencies and resources**

As part of its regular work, participation in meetings of task groups and committees in ministries, the Serbian Chamber of Commerce, exchange of information with authorities and bodies and other interested parties for accreditation, as well as participation in the work of bodies and expert bodies EA, ILAC and IAF, there is information about the need for ATS to introduce a new accreditation scheme/type (levels 2 and 3) in the scope of work or to start providing services for the existing accreditation scheme/type in areas for which there are normative documents that contain additional criteria (level 4), which shall be used in the accreditation of CAB.

The initiative to develop, establish and extend accreditation schemes/types can be referred to the Assistant Director for Development and Quality (QM) by any ATS employee, the ATS Board of Directors, CAB through the application for accreditation, assessors/experts and other interested parties. Based on the obtained information, QM shall analyse the existing ATS competence, the expediency of expansion, existing resources, the need and possibility of using expertise from other external sources and other things that are needed for the decision in question.

### **3.4 Decision on development, establishment and extension of accreditation scheme/types**

At the meeting of the Board of Directors, the analysis made by the QM shall be considered and if accepted, the director shall submit the proposal together with the analysis to the Accreditation Council to consider it and give an expert opinion on the expediency of developing, establishing, and expanding ATS accreditation schemes/ types.

After reviewing the proposal, taking into account the criteria for introducing a new accreditation scheme/type in the scope of work of ATS and giving a positive expert opinion, the Accreditation Council, with the participation of interested parties, shall send an initiative - proposal to the Management Board.

The decision on the introduction of a new/extension of the scheme/type of accreditation in the scope of work of ATS shall be made by the Management Board at the initiative of the Accreditation Council.

### **3.5 Planning and realisation of the decision on the development, establishment and extension of accreditation schemes/types**

After the decision made by the Management Board, it is necessary to make the necessary changes and additions to the existing documents of the ATS management system, to compile and adopt, if necessary, new documents, to recruit and train the missing assessors/decision experts, as well as to train all employees who will participate in the procedure, for a new scheme/ type of accreditation or for an existing scheme/type of accreditation in the field for which there are normative documents that contain additional criteria that shall be used in accreditation of CAB.

#### **3.5.1 Accessing and employing expertise**

When drafting new or supplementing existing documents, ATS shall use resources (which may be external) to ensure that all guidance/implementation documents or normative documents used are

developed by working groups or persons with the necessary competence and with the participation of relevant interested parties. These documents shall not contradict with, or exclude any requirement included in the relevant international standards and/or other normative documents.

For the purposes of implementing the assessment and decision-making process for the new accreditation scheme/type, i.e. for the existing accreditation scheme/type within which new reference documents containing additional criteria are applied, ATS will use, based on the conducted analysis (cl. 3.3.2) the existing ATS competence and existing human resources, if necessary, externally engaged persons (assessors/experts/decision-making experts, members of the task group, trainers, representatives of bodies or organizations responsible for the preparation or adoption of technical regulations, etc.).

### **3.5.2 Establishment of the Working group**

Based on the decision of the Management Board, the QM, within its competencies, forms a working group, from among the employees, for the development of the accreditation system, i.e. for the introduction of a new accreditation scheme/type (level 2 and 3) or for the existing scheme/ type of accreditation in the field for which there are normative documents that contain additional criteria (level 4) that shall be used in the accreditation of CAB. The working group may include representatives of interested parties and/or the relevant Technical Committee and the Accreditation Council and/or assessors/experts and/or experts from international projects in which ATS is involved and/or representatives of bodies or organizations responsible for preparation or adoption of technical regulations.

### **3.5.3 Planning realisation of activities**

Working group chaired by QM shall make a Plan of preparation of ATS (implementation of activities) for development/establishment/extension of activities (introduction of new type of accreditation/scheme in the scope of ATS activities or extension of existing type of accreditation/scheme to the field wherein there are normative documents containing additional criteria which have to be used while accrediting CABs (level 4)). The Plan shall contain a list of activities which need to be performed, responsibilities for implementation of these activities, i.e. particular assignments within activities, deadlines for implementation of each activity, as a manner of verification of the implementation of every activity.

If it is necessary to allocate financial resources for the implementation of certain activities, it is planned, keeping in mind the annual Work program incorporating the financial plan of ATS and approved by the Director under the approval of the entire Plan.

As a rule, the plan includes activities related to procurement of the missing documents, amendments to the existing ATS documents and creation of new documents, provision and training of necessary assessors/experts and training of ATS staff.

At this stage, the Working group shall assess whether it is necessary to draft specific guidelines - instruction or a document for the implementation of the reference document containing the general requirements for CABs performing conformity assessment activities. If it is estimated that documents are needed, it is obligatory to plan participation of interested parties in their development by engaging relevant technical committee and the Accreditation Council and/or experts against cl. 3.4.2. of this procedure.

The completed plan shall be reviewed and adopted at the meeting of the Board of Directors and approved by the Director.

### **3.5.4 Amendments to existing documents and creation of the new documents**

The Working group shall analyse the needs, availability and assess the list of standards (primarily referent standard containing requirements for the accreditation of CAB for new type of

accreditation/scheme (level 3) and standards containing additional criteria (level 4)) and other normative documents (primarily documents containing sectoral schemes, conformity assessment schemes and relevant documents of EA, ILAC and IAF) which need to be obtained in order to extend the scope of ATS activities and use these documents in the accreditation procedure. Obtaining missing documents shall be performed according to routine procedure applicable in ATS.

The Working group shall establish the need for amendments to existing ATS management system documents so as to render them applicable for a new/extension scheme/type of accreditation and/or existing type in new fields as well as for creating new ATS management system documents. The drafts of new documents and changes to the existing documents from the established list are made by the Working group, which are then reviewed, adopted, and approved according to the procedure *Document Control (ATS-PR01)* taking into account that requirements related to the new accreditation scheme/type shall not contradict, or exclude any requirements included in the relevant international standards and/or other normative documents.

### **3.5.5 Provision of human resources and training(s) of assessors/staff of ATS**

Based on the analysis of the existing ATS competence and existing human resources, needs and possibilities of using expertise of external persons engaged for a new type of accreditation/extension of scheme which has been carried out by the QM, the Working Group shall determine the manner in which to reach the required expertise or competence, especially in the processes of assessment and decision-making for a new type of accreditation/extension of scheme, or for an existing type of accreditation/scheme within which new reference documents containing additional criteria are applied.

The Working group shall assess the need for assessors and the need for the implementation of appropriate training to ensure competent assessors, by engaging existing and/or new assessors/technical experts for a new type of accreditation/scheme.

If there are mandatory guidelines of EA, ILAC and IAF for the competence of assessors of accreditation bodies for a new type of accreditation/scheme or an existing type of accreditation/scheme within which the new reference documents containing additional criteria are applied, the Working Group shall take them into account in the implementation of activities relating to the provision of the necessary human resources – assessors.

If there is a possibility, the Working Group shall assess the appropriateness of engaging assessors from abroad, either based on bilateral cooperation agreements that ATS has with the accreditation bodies in the region, or in the context of projects involving ATS, which are related to the strengthening of quality infrastructure in the Republic of Serbia.

The selection of candidates for assessors for a new type of accreditation/scheme is carried out according to the procedure *Selection of Persons Participating in the Accreditation Process and Performance Monitoring (ATS-PR02)*, provided that the criteria which need to be met for a new type of accreditation/scheme as regards education and professional experience in the relevant fields are pre-defined. Planning training sessions for assessors and technical experts, as well as the organization and implementation thereof are carried out according to the procedure *Trainings (ATS-PR03)*.

If there are mandatory guidelines of EA, ILAC and IAF for the competence of the accreditation bodies' staff for a new type of accreditation/scheme or an existing type of accreditation/scheme within which the new reference documents containing additional criteria are applied, the Working Group shall take them into account in the implementation of activities relating to the training sessions of ATS staff.

Notwithstanding the existence of mandatory guidelines, all ATS employees involved in the accreditation process for a new type of accreditation/scheme or an existing type of

accreditation/scheme within which new reference documents containing additional criteria are applied, shall be acquainted with:

- amendments to existing ATS management system documents,
- content and implementation of new ATS management system documents,
- the content of the documents (standards) containing general requirements for CABs performing conformity assessment activities covered by the new type of accreditation/scheme,
- requirements of conformity assessment schemes, other procedures and methods used by CAB,
- principles of risk-based assessment,
- general regulatory requirements related to conformity assessment activities,

and depending on what role they have in the accreditation procedure and what activities they perform from the procedure.

### **3.6 Implementation arrangements and end of activities**

The ATS preparation plan shall include arrangements for the implementation of a new accreditation scheme/type or for an existing accreditation scheme/type within which new reference documents containing additional criteria are applied, taking into account the views of interested parties, timeframes prescribed by decisions of international organizations for accreditation/standardization/owners of conformity assessment schemes/competent ministries, etc.

After each activity from the ATS Plan of preparation is verified to be completed, in the manner provided for in the plan, including the last activity related to the publication of information on the Internet ATS website <http://www.ats.rs/> on the readiness of the ATS to accept applications for accreditation and informing interested parties and CABs, if applicable, for a new accreditation scheme/type or for accreditation for an area for which there are normative documents containing additional criteria that shall be used in CAB accreditation, all ATS development activities have been completed, establishing and expanding accreditation schemes/types.

By deciding on and accepting the Application for accreditation in the field that was the subject of development/extension of the ATS activities, it is considered that ATS has extended the scope of its activities in accordance with the requirements of clause 4.6 of ISO/IEC 17011.

### **3.7 Views of interested parties**

The ATS shall take into account views of interested parties at all stages of the accreditation scheme/development/extension process. The manner of communication with them is achieved by participating in the Working group, submitting opinions through public hearings, submitting opinions through representatives of the Serbian Chamber of Commerce and other professional association, etc., and is not limited to these ways.

### **3.8 Discontinuation of certain scheme/type of accreditation, i.e., transition to new versions of level 3 and/or 4 standards**

In case of the need to discontinue, in whole or in part, certain accreditation schemes/types (levels 2 and 3, including 4, if applicable), the QM shall conduct an analysis that takes into account at least the following: views of interested parties, contractual duties, transition arrangements, external communication regarding discontinuation of accreditation activities, information for publication, etc.

After the proposal of the decision on the discontinuation of the use of a certain scheme/type of accreditation by the director, and on the proposal of the QM, it is sent for consideration to the Accreditation Council. After receiving a positive opinion from the Accreditation Council, which represents views of interested parties, the decision becomes final and is published with transitional arrangements on the ATS website, <http://www.ats.rs/> and all accredited CABs, etc. are notified.



In case of transition to a new version of the level 3 and/or 4 standards, it is necessary to implement the relevant steps from cl. 3.3 -3.6, including the publication of transitional arrangements on the ATS website.

#### **4. DISTRIBUTION**

This document shall be used by all employees of ATS.

#### **5. ANNEXES**

None.

#### **6. FORMS**

None.

#### **7. ATS-PR13 DOCUMENT AMENDMENT HISTORY**

Issue/revision	Date of issue/revision
1/0	6.05.2009
1/1	12.12.2009
1/2	21.03.2011
1/3	11.07.2012
1/4	08.05.2013
2/0	04.02.2016
2/1	07.07.2017
3/0	23.08.2021