



ATS

АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ

ATS-PA 01

RULES OF ACCREDITATION

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1 GENERAL BACKGROUND

1.1 Purpose

The Rules of Accreditation (hereinafter referred to as: Rules) are the rules of the Accreditation Body of Serbia (hereinafter referred to as: ATS) and they specify in detail the following:

- the accreditation procedure,
- requirements to be met by a conformity assessment body,
- rights and obligations of those participating in accreditation granting and maintenance.

1.2 Scope

The Rules are primarily intended for the ATS employees, members of the ATS organs and bodies, ATS assessors and conformity assessment bodies (CABs).

1.3 Definitions

The definitions given in the following documents shall apply in the Rules:

- Law on Accreditation ("Official Gazette of the RS", No. 73/2010 and 47/2021);
- Regulation of the European Parliament and the Council No. 765/2008 setting out requirements for accreditation and market surveillance relating to the marketing of products (Regulation 765/2008);
- SRPS ISO 9000:2015 - Quality Management System – Fundamentals and Vocabulary;
- SRPS ISO/IEC 17011:2018 - Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies;
- SRPS EN ISO/IEC 17000:2020 - Conformity Assessment – Vocabulary and General Principles.

1.3.1 Accreditation

In accordance with the standard SRPS ISO/IEC 17011:2018, accreditation is third party attestation related to CAB, conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

In accordance with the Law on accreditation ("Official Gazette of the RS", No. 73/2010 and 47/2021), accreditation is the attestation by a national accreditation body that a conformity assessment body meets the requirements of the relevant Serbian standards that transpose the harmonized standards and, where applicable, any additional requirements defined for sectoral schemes, to carry out specific conformity assessment activities.

1.3.2 Accreditation Body

Authoritative body that performs accreditation.

The national accreditation body in charge of accreditation in the Republic of Serbia is ATS.

1.3.3 Mark (logo) of the Accreditation Body

Mark (logo) is used by an accreditation body to identify itself.

1.3.4 Conformity Assessment Body - CAB

A body that performs conformity assessment activities and that can be the object of accreditation.

Note: Whenever the word "CAB" is used in these Rules, it applies to both the "applicant and accredited CAB" unless otherwise specified.

1.3.5 Conformity Assessment Activity

Activity conducted by a CAB when assessing conformity.

1.3.6 Scope of Accreditation

Specific conformity assessment activities for which accreditation is sought or has been granted. The scope of accreditation can be fixed and flexible.

1.3.7 Flexible scope of accreditation

The flexible scope of accreditation is the scope of accreditation expressed to allow the conformity assessment body to make changes in methodology and other parameters which fall within the competence of the CAB, as confirmed by ATS.

1.3.8 Accreditation scheme

Rules and processes related to the accreditation of CABs to which the same requirements apply.

Note: Accreditation scheme requirements include, but are not limited to, standards ISO/IEC 17020, ISO/IEC 17021, ISO/IEC 17025, ISO/IEC 17024, ISO 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189 and ISO 14065.

1.3.9 Accreditation activity

Individual operational tasks of the accreditation process.

1.3.10 Impartiality

The presence of objectivity

Note: Objectivity means that conflicts of interest do not exist or are resolved so as not to adversely influence subsequent activities of the accreditation body.

Note: Other terms that are useful in conveying the element of impartiality include "independence", "freedom from conflict of interests", "freedom of bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handedness", "detachment", "balance".

1.3.11 Accreditation process

Activities from application to granting and maintenance of accreditation as defined by the accreditation scheme.

1.3.12 Accreditation Symbol and Reference to Accreditation

The accreditation symbol is a protected mark owned by ATS for the use of which ATS gives permission to accredited CABs to indicate their accreditation status. An accredited CAB can make a text reference to accreditation instead of using the accreditation symbol, and it can also refer to ATS status as a signatory to the multilateral agreements on mutual recognition.

1.3.13 Accreditation decision

Decision on granting, maintaining, renewing, extending, renewal, reducing, suspending and withdrawing accreditation.

1.3.14 Granting accreditation

Awarding accreditation for a defined scope of accreditation.

1.3.15 Maintaining accreditation

Confirming the continuance of accreditation for a defined scope.

1.3.16 Extending accreditation

Adding conformity assessment activities to the scope of accreditation.

1.3.17 Reducing accreditation

Cancelling part of the scope of accreditation.

1.3.18 Suspending accreditation

Putting temporary restrictions in place for all or part of the scope of accreditation.

1.3.19 Withdrawal of accreditation

Cancelling accreditation for the full scope.

1.3.20 Complaint

Expression of dissatisfaction, other than appeal, addressed to ATS by any person or organization, relating to the ATS activities, or of an accredited CAB where a response is expected.

1.3.21 Appeal

Request by a CAB for reconsideration of any adverse accreditation decision related to its desired accreditation status.

1.3.22 Assessment

A process undertaken by ATS to determine the competence of a CAB, based on standard(s) and/or other normative documents, and for a defined scope of accreditation.

1.3.23 Reassessment

Assessment performed to renew the accreditation cycle.

1.3.24 Assessment technique

The method used by ATS to perform the assessment. Assessment techniques can include, but are not limited to: on-site assessment, remote assessment, witnessing, document review, file review (CAB's client files), measurement audits, review of performance in proficiency testing and other interlaboratory comparisons, validation audits, unannounced visits, interviewing.

1.3.25 Witnessing

Observation by ATS of the CAB carrying out conformity assessment activities within its scope of accreditation.

1.3.26 Remote assessment

Assessment of the physical location or virtual location of CAB (an online environment allowing persons to execute processes e.g., in a cloud environment), using electronic means.

1.3.27 Assessment programme

A set of assessments consistent with a specific accreditation scheme that ATS performs on a specific CAB during the accreditation cycle.

1.3.28 Assessment plan

Description of the activities and arrangements for an assessment.

1.3.29 Accreditation body personnel

Internal or external persons conducting activities on behalf of ATS.

1.3.30 Assessor

A person assigned by ATS to perform the assessment of the CAB alone or as a part of the assessment team.

1.3.31 Team leader

An assessor who is given the overall responsibility for the management of an assessment.

1.3.32 Technical expert

The person assigned by ATS, working under the responsibility of an assessor, who provides specific knowledge or expertise with respect to the scope of accreditation to be assessed and does not assess independently.

1.3.33 Interested party

A person or organization with a direct or indirect interest in accreditation.

1.3.34 Consultancy

Participation in any of the activities of a CAB subject to accreditation.

1.3.35 Accreditation procedure

An established way to conduct the accreditation process.

1.3.36 Conformity assessment

Conformity assessment is the process of determining whether the requirements specified for a product, process, service, system, person, or body are met.

1.3.37 Assessment team

The team conducting the assessment in the process of accreditation of the CAB and shall consist, as a rule, of a team leader, one or more assessors and/or one or more technical experts.

1.3.38 Observer

A person who attends the assessment but does not participate in the assessment itself.

1.3.39 Competence

Ability to apply knowledge and skills to achieve the intended results.

1.3.40 Accreditation certificate

An accreditation certificate is a document that confirms that the conformity assessment body is competent to perform conformity assessment activities, for a certain area and scope.

1.3.41 International organizations

International organizations that ATS is a member of: European Cooperation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC).

1.3.42 Combined Marks

The marks of ILAC or IAF agreements on mutual recognition in combination with the accreditation symbol are combined marks for the use of which ATS gives permission to accredited conformity assessment bodies.

1.3.43 Certificate of Conformity

Testing report, calibration certificate/report, sampling report, inspection report or certificate, product certificate, management system certificate, person certificate, verification and validation report, proficiency testing report issued by an accredited CAB for activities from the granted scope of accreditation.

1.3.44 Renewal of accreditation

Renewal of the accreditation cycle for a defined scope of accreditation.

1.3.45 Termination of the accreditation procedure

Termination of the initiated procedure due to the withdrawal of the CAB or the impossibility to conduct the procedure in accordance with these rules.

2 INTRODUCTION

2.1 General Background on Accreditation

Accreditation is a means to establish trust in the market of products and services since it presents an independent and impartial competence attestation of bodies performing testing, calibration, certification, inspection, verification and validation or proficiency testing. Demonstration of conformity of products, processes, or services with requirements set forth in regulations, standards and contracted technical specifications is a prerequisite for attaining competitiveness on the market. In this process, it is of extreme importance to use services of professional and technically competent laboratories, inspection bodies, certification bodies, verification and validation bodies and proficiency testing providers whereby ensuring trust in testing, calibration, inspection, certification, verification and validation activities that were performed.

Quality infrastructure in the Republic of Serbia is based on four laws:

1. Law on Technical Requirements for Products and Conformity Assessment ("Official Gazette of the RS", No. 49/2021);
2. Law on Metrology ("Official Gazette of the RS", No. 15/2016);
3. Law on Standardisation ("Official Gazette of the RS", No. 36/2009 and 46/2015);
4. Law on Accreditation ("Official Gazette of the RS", No. 73/2010, 47/2021).

Active ATS participation in the European and international organizations for accreditation and harmonization of the rules and procedure of accreditation with international standards, policy and

principles of EA, IAF and ILAC ensures recognition and acceptance of conformity assessment results performed in the Republic of Serbia at an international level, previously accredited by ATS.

2.2 Accreditation Body of Serbia

2.2.1 General Data:

Full name: Акредитационо тело Србије (Accreditation Body of Serbia)

Abbreviated name: ATC (ATS)

English version of the name: Accreditation Body of Serbia

Abbreviated name in English: ATS

Head Office: Vojkovićeveva 3, 11000 Belgrade 6, PO Box 92, Serbia

E- mail: office@ats.rs

Web address: www.ats.rs

2.2.2 Legal Status

ATS is the sole body delegated, by means of the Law on Accreditation to perform accreditation activities. ATS was established by the Republic of Serbia, whereas the Government of the Republic of Serbia, under statutory powers, exercises the rights of the Republic of Serbia.

ATS is an institution that shall be registered as such in accordance with the Law.

The legal acts on which the work of ATS is based are: Law on Accreditation ("Official Gazette of RS", No. 73/2010 and 47/2021), Decision on Amendments to the Decision on Establishment of the Accreditation Body of Serbia ("Official Gazette of RS", No. 79/2021) (hereinafter referred to as: Act on Establishment) and the Statute of the Accreditation Body of Serbia.

ATS was established by the Decision on the Establishment of the Accreditation Body of Serbia ("Official Gazette of RS" No. 96/2006) and as a legal entity entered in the court register of the Commercial Court in Belgrade, registration file No. 5-978-00 of 8 December 2006.

2.2.3 Competences and Obligations

The Law on Accreditation lays down the following: status and operation of ATS, organs and bodies of ATS, financial resources, accreditation procedure, cross-frontier accreditation, and surveillance of the ATS operation.

Pursuant to the Law on Accreditation, ATS shall:

1. determine the competence of conformity assessment bodies performing testing, calibration, inspection, certification of products, certification of management systems and certification of persons, proficiency testing, verification and validation;
2. determine the competence to perform other conformity assessment activities in accordance with specific laws;
3. set forth and publish the Rules of Accreditation that shall be based on the relevant Serbian, international and European standards and documents of the international and European organizations for accreditation;
4. keep a public Register of Accredited Conformity Assessment Bodies;
5. keep a public Register of externally engaged assessors and technical experts according to the type of accreditation and experts engaged for the accreditation decision-making process, respecting the principles of regulations governing the protection of personal data.

6. participates, i.e. represents the Republic of Serbia in the work of international and European accreditation organizations and maintains membership in the European Cooperation for Accreditation (EA);
7. perform other activities in the field of accreditation in accordance with the Law on Accreditation, Act on Establishment, and Statute.

ATS shall perform its activities by using state owned assets.

ATS shall not perform profit-making activities.

For obligations in legal transactions with third parties, ATS is liable for all its assets.

2.2.4 ATS Mark (logo) and Accreditation Symbol

ATS has its logo that is used for the identification thereof and it is the intellectual property of the ATS. It shall be used in accordance with the *Rules for the Use of ATS Logo, ATS-PA07*. Based on the license agreement signed with IAF, ATS shall use the IAF MLA mark in combination with its mark (logo) to indicate its status as a signatory to IAF MLA, i.e., based on ILAC approval ATS shall use ILAC MRA mark in combination with its mark (logo).

ATS shall deliver, in addition to the accreditation certificate, an accredited CAB the accreditation symbol to indicate its status as an accredited CAB. The conformity assessment body shall use the said symbol in accordance with the *ATS Rules for the Use of the Accreditation Symbol, Reference to Accreditation and ATS Status as a Signatory to the EA MLA, ILAC MRA and IAF MLA, ATS-PA04*, that is available on website www.ats.rs.

Based on the signed contract on the use of the IAF MLA mark, the ATS shall entitle accredited certification bodies to use the IAF MLA mark in combination with the accreditation symbol (combined IAF MLA mark), thus recognizing that their accredited activities are within the IAF MLA agreement i.e., accredited laboratories and inspection bodies to use the ILAC MRA mark (combined ILAC MRA mark).

ILAC MRA and IAF MLA signs shall be used by CAB only as combined signs, in accordance with *ATS-PA04*.

The rights to use the combined ILAC MRA mark by an accredited CAB, as well as the obligations arising from that right, shall be defined in *ATS-PA04*, while the rights to use the combined IAF MLA mark by the accredited CAB, as well as the obligations arising from that right, shall be regulated by a special contract that ATS signs with CAB after the accreditation is granted.

2.2.5 ATS Organs and Bodies

ATS is organized and managed in such a manner to provide objectivity and impartiality of its activities, i.e., activities in the scope of its competence.

ATS organs are: Management Board, Director and Supervisory Board. The scope of the ATS organs, the conditions for the appointment of the Chair and members of the body, the manner of decision-making and other issues important for the work of the organs are regulated by the ATS Statute and relevant rules of procedure.

The expert bodies of ATS are: the Accreditation Council and Technical Committees. The Accreditation Council is an advisory body that provides expert opinions regarding the development of the accreditation system, establishes criteria for assessors, gives initiatives for expanding the scope of ATS, gives opinions on issues of safeguarding of impartiality and takes positions on other professional issues. Technical committees are expert bodies that perform expertise for certain areas of accreditation.

Mode of the establishment of the ATS organs and bodies, their activities, appointment of organs and body members, decision-making and other issues of importance to the work of the organs and bodies shall be stipulated by the ATS Statute.

The Appeals Committee is the permanent body of ATS that makes decisions on appeals. The mode of establishment and work of the Appeals Committee is regulated by the Rulebook on the mode of establishment and work of the Appeals Committee of the Accreditation Body of Serbia (Official Gazette of RS, No. 74/2021).

2.2.6 Internal Organisation

The internal organizational structure of ATS shall set forth in the Regulation on Organisation and Functional Titles and Job Descriptions that shall be passed by the ATS Director and agreed by the Management Board.

2.2.7 Management system

The ATS management system shall be based on the requirements of SRPS ISO/IEC 17011, the requirements of Regulation of the European Parliament and Council No. 765/2008, i.e., the Law on Accreditation, and the relevant mandatory EA/IAF/ILAC documents.

2.2.8 Human resources

ATS has at its disposal a sufficient number of competent personnel for the proper performance of duties within its competence. ATS human resources include: permanently employed staff and externally engaged assessors and technical experts, as well as engaged experts for the accreditation decision-making process. The duties, responsibilities and authorities of all ATS personnel are set out in internal documents.

2.2.9 Financing

In accordance with the Law on Accreditation, it is envisaged that funds for the operation of ATS are provided from the budget of the Republic of Serbia and other sources, provided that these provisions of the law enter into force on the day of application of the law governing republican administrative fees (taxes) which will prescribe the amount of fees for the costs of the accreditation procedure. In this regard, funds for the operation of ATS are still provided: by charging the accreditation fees, from the budget of the Republic of Serbia and from other sources, in accordance with the law.

Charging the accreditation fees shall mean obtaining financial resources from the revenue being realized by providing services to clients in accordance with the Charging Policy Document.

The amount of financial resources necessary for the operation of ATS to be provided from the budget of the Republic of Serbia shall be determined in the ATS Annual Work Programme, and are approved based on Financial Plan.

Financial resources from other sources shall mean other revenues made in accordance with the law. ATS shall not receive gifts (donations) made by those using the services of ATS.

The fees as regards the ATS membership in international and European organizations for accreditation shall be determined in the Annual Work Programme and provided from the budget of the Republic of Serbia.

2.3 International Cooperation

In 2002, ATS became an associate member of the European co-operation for Accreditation (EA), and on 24th May 2012, it became its full member. On 24th May 2012 ATS signed EA MLA for the following schemes of accreditation: testing laboratories, including medical laboratories, calibration laboratories, inspection bodies and certification bodies providing certification of products. On 27th May 2014 ATS signed a new EA MLA which included certification of management systems and certification of persons, in addition to testing including medical laboratories, calibration, inspection and certification of products. The agreement was, to the same extent, confirmed by the Decision of the Multilateral Agreement Council (EA MAC) in 2018.

In 2009, ATS became an associate member of the International Laboratory Accreditation Cooperation (ILAC), and in December 2011 it became a member of the International Accreditation Forum (IAF) by signing the Memorandum of Understanding. In 2012, ATS became a signatory to the ILAC MRA for calibration, testing and inspection, and to the IAF MLA for the field of product certification, whereas on 6th October 2014 ATS signed IAF MLA in the field of management systems certification (sub-scopes: Level 4: ISO/IEC 17021-3, ISO/IEC 17021-2; Level 5: ISO 9001, ISO 14001). The IAF MLA was extended on 5th April 2018 in the field of management systems certification (Sub-scopes: Level 4: ISO/TS 22003, ISO/IEC 27006; Level 5: ISO 22000 (FSMS), ISO/IEC 27001 (ISMS), ISO 13485 (MDMS)). Based on the extension of the scope of the EA agreement with the IAF, the scope of ATS agreement for the field of management systems certification was expanded on 5th February 2020 to the following areas: Level 4: ISO/IEC 17021-10; Level 5: ISO 45001 (OH & SMS). As of 20th October 2016, ATS is a signatory of the IAF MLA in the field of certification of persons.

ATS concluded agreements on bilateral cooperation in the field of accreditation with accreditation bodies from neighbouring countries and countries that have mutual interest in bilateral cooperation between both accreditation bodies. The updated information about the concluded agreements is posted on the ATS internet portal www.ats.rs.

3 ACCREDITATION OF CONFORMITY ASSESSMENT BODIES

3.1 Criteria and requirements for accreditation

The criteria for granting and maintaining accreditation are set forth in the following documents:

- Law on accreditation;
- Serbian standards transposing international or European harmonized standards, that contain general criteria or requirements that need to be met by CABs for certain types of accreditation;
- technical regulations containing requirements for designated (notified)/authorised CABs (accreditation for the purpose of designation (notification)/authorisation);
- mandatory documents such as guidelines for the implementation of European and international standards, and guides in the field of accreditation and conformity assessment published by EA, IAF, and ILAC;
- the documents containing criteria that supplement the criteria contained in documents containing general criteria, i.e., requirements to be met by CABs for certain types of accreditation, where applicable;
- rules of accreditation and other ATS rules and mandatory application guidelines established by ATS.

The list of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body, ATS-UP01 is publicly available on the ATS website <http://www.ats.rs>, and can also be submitted upon request.

In case of need for the development of new and extension of existing areas of activities implemented by ATS, the procedure *Development, establishment and extension of accreditation schemes, ATS-PR13*, which defines the procedure implemented by ATS during development, establishment and extension of accreditation schemes/types based on the needs of interested parties, shall be applied.

If the accreditation requirements are changed, ATS shall inform the CABs, as well as the transitional period in which they are obliged to comply with the changed requirements and consequences in case the necessary changes are not implemented and applied in the defined transitional period. In case that the accredited CAB does not implement and apply the changes that must be assessed by ATS, ATS shall make a decision on the suspension or withdrawal of accreditation after the end of the transitional period.

3.2 Interpretations of requirements and guidelines for the application of reference documents

ATS conducts the accreditation procedure and other activities in the accreditation cycle in whole, according to the criteria, requirements, and rules from the reference documents, as stated in point 3.1 of these rules.

When performing accreditation activities from its scope of work, ATS shall adhere to documents and guidelines for the implementation of European and international standards and guides in the field of accreditation and conformity assessment published by EA, IAF and ILAC.

If an interpretation of certain requirements from reference accreditation documents, for which there are no guidelines for use, ATS shall provide adequate interpretation by engaging expert bodies in cooperation with interested parties.

3.3 Impartiality

ATS is an independent and non-profit institution that performs the activities of the national accreditation body in the Republic of Serbia.

Respecting the legal regulations, according to which ATS receives and resolves accreditation applications, and in accordance with its policy, rules, and procedures, ATS shall ensure that all CABs have the same treatment in the accreditation process, without discrimination or restrictions upon size, legal status, or the number of already accredited CABs.

ATS has and implements documented processes, regulated by the Law on Accreditation, the Act on Establishment, and the Statute of ATS, which enable interested parties to be effectively included in the structure of ATS in order to safeguard impartiality. The law and the mentioned acts ensure, through the Accreditation Council, which is also a mechanism for safeguarding impartiality, a balanced representation of interested parties with no single party predominating.

Impartiality of accreditation is the foundation of the trust that interested parties expect from ATS. The status of the signatory of international agreements on mutual recognition of the accreditation systems is a confirmation of the impartial implementation of the accreditation procedure.

The ATS's impartiality policy encompasses the importance of impartiality in performing accreditation activities, managing conflicts of interest, and ensuring the objectivity of its accreditation activities.

ATS is responsible for the impartiality of its accreditation activities and does not allow commercial, financial, or other pressures to compromise impartiality. All those who perform activities on behalf of ATS shall act objectively and must not be under any inappropriate commercial, financial, or any other pressure that could compromise impartiality, and undertake to do so in writing by signing

appropriate declarations of the absence of conflict of interest and confidentiality. ATS requires its personnel (ATS staff, including externally engaged personnel and committee members) to report any potential conflict of interest.

The ATS management has documented its commitment and impartiality policies in detail in the ATS Impartiality Policy (including impartiality risk analysis). The statement of impartiality attached to the said policy is also publicly available on the ATS website. Members of ATS organs and expert bodies have also committed themselves to impartiality in their work, by signing appropriate declarations.

3.4 Confidentiality

The ATS employees, members of the ATS organs and expert bodies, and persons contracted to perform certain activities on behalf of ATS are under obligation to ensure confidentiality of data and information obtained when performing activities on behalf of ATS.

All data and information obtained by ATS during the accreditation procedure shall be kept in accordance with ATS rules that apply to the confidentiality of the information and may be used exclusively within the ATS system for procedures conducted in accordance with the Rules of Accreditation. Acting in accordance with the law, i.e., acting in accordance with a court decision, is not considered unauthorized disclosure of confidential information.

Where there is a legal basis for the release of confidential data of a CAB, ATS shall notify the conformity assessment body thereof, except where prohibited by law.

All data and information on CABs are considered confidential, except for accreditation decisions and information on accreditation of accredited CABs which are published in the public register of accredited CABs, in compliance with the relevant legal regulations.

Through its documents, ATS applies the provisions of the Law on Personal Data Protection ("Official Gazette of RS", No. 87/2018) which protects the personal data of employees and external assessors/experts).

Documents and data that ATS considers as confidential, methods to maintain confidentiality status and procedures to be implemented in case of breach of confidentiality rule are determined.

The ATS policy regarding confidentiality management is defined by the Rulebook on Confidentiality available on the ATS website.

3.5 Accreditation Procedure

The accreditation procedure is initiated by an application submitted by the CAB.

Pursuant to its non-discriminatory policy, ATS shall accept and review all the applications for accreditation submitted by CABs interested in accreditation if the accreditation of the said conformity assessment activities is within the scope of the ATS activities (*ATS Scope of Activities, ATS-PA08*). In other cases, before submitting the application for accreditation, it is necessary for the CAB to send a letter of intent to ATS, so that ATS, carries out the procedure set out in the document *Development, Establishment and Extension of Accreditation Schemes, ATS-PR13*, if applicable. The CAB will be notified of the outcome.

For all applications for accreditation submitted by the CAB from abroad and the CAB from the Republic of Serbia that have locations where they perform conformity assessment activities abroad, ATS shall apply the policy set out in *the Rules of Cross-frontier Accreditation, ATS-PA05*.

The initial accreditation procedure shall last, in accordance with the Law on Accreditation ("Official Gazette of RS", No. 73/2010, 47/2021), for a maximum of eight months from the date of submission of the application for accreditation. Exceptionally, the period of eight months may be

extended at the written request of the applicant, for a maximum of four months from the date of expiry of the period of eight months.

The accreditation procedure implies a series of activities defined by these rules, and in order to comply with the deadlines set by the Law on Accreditation ("Official Gazette of RS", No. 73/2010, 47/2021), these rules shall define the maximum time allowed for CAB to submit the documentation/required information at the request of ATS or enable the implementation of activities in the accreditation process, in order for the accreditation procedure to last for a maximum of eight months from the day of submitting the application for accreditation.

Exceptionally, the CAB may request in writing an extension of the time limits defined by these rules, provided that in such cases, the prescribed duration of the initial accreditation procedure may be extended in accordance with the Law on Accreditation, for a maximum of four months in total. ATS shall consider any request from the CAB relating to the extension of time limits defined by these rules and approve it if it allows for the smooth implementation of all remaining activities in the accreditation process and their completion within the deadline for the accreditation process allowed by the Law on Accreditation ("Official Gazette of RS", No. 73/2010, 47/2021). The CAB shall be notified in writing of the acceptance/non-acceptance of the request, whereby any non-acceptance of the request must be rationale.

In case the CAB does not follow the accreditation procedure defined by these rules, does not submit documentation/required information at the request of ATS, does not enable the implementation of activities in the accreditation process, does not comply with deadlines and other obligations defined by these rules, ATS shall make a decision on termination of the accreditation procedure. The CAB has the right to appeal if it is dissatisfied with the decision of ATS.

The CAB may at any time withdraw from the accreditation procedure initiated by submitting an application for accreditation, of which it shall inform ATS in writing. Pursuant to the submitted request, ATS shall make an appropriate decision to terminate the procedure. The CAB that has withdrawn from the application for accreditation is not entitled to a refund of the amount paid for accreditation costs.

A representative of the body or organization responsible for the preparation or adoption of certain technical regulations may participate in the accreditation procedure of the CAB for the purpose of designation (notification) or authorisation, as an observer, and respecting the rules of confidentiality and other general acts of ATS.

If there is evidence of fraudulent behavior, intentional providing of false information or concealment of information by the CAB, during the application process or at any other time in the accreditation process, ATS shall reject the application for accreditation or terminate the accreditation process and in both cases decide on the termination of the accreditation procedure. The CAB has the right to appeal if it is dissatisfied with the decision of ATS.

In case ATS does not complete the accreditation procedure by making a decision on accreditation within 8 months, i.e., 12 months in the manner defined by these rules, ATS will make a decision to terminate the procedure and refund the amount paid for accreditation costs to the applicant's account, in accordance with the Law on accreditation ("Official Gazette of RS", No. 73/2010, 47/2021) within 30 days from the date of 8 months expiration, i.e. 12 months. The CAB has the right to appeal the decision made.

3.6 Accreditation Scope

A CAB submits application of accreditation for the scope that it deems it is competent for. This scope of accreditation shall be harmonized in the initial phase of the accreditation procedure and shall be finally determined during the assessment procedure and accreditation decision-making.

Guideline for expressing the scope of accreditation of CABs are available on the ATS website www.ats.rs.

3.7 Language of the accreditation procedure

ATS shall conduct the accreditation procedure in the Serbian language. In cases of cross-frontier accreditation or engagement of a foreign assessor in the assessment team, the assessment procedure or part of thereof is conducted in English or another agreed language, with the engagement of a translator, if necessary. If it is necessary to translate certain documents for the purposes of assessment, the CAB is responsible for the content of the translation. The scope of translation of documents (only the necessary part of the documentation/parts of the documentation shall be translated) is decided by ATS based on the needs of the foreign assessor/expert.

3.8 Mode of communication

ATS communicates with CABs by mail and e-mail. Communication by e-mail is preferred even in situations where communication by mail is used. Any request from ATS to the CAB to which response is required must be submitted by e-mail and the date of sending the e-mail is considered the date of delivery, but also the receipt of the same. The same applies to e-mails sent to the ATS by the CAB.

3.9 Accreditation Fees

The CAB has to pay adequate accreditation fees in accordance with the signed contract stipulating mutual rights and obligations, and in accordance with *the Charging Policy Document* that is available on the ATS internet portal.

3.10 Transfer of Accreditation

If the legal status of an accredited CAB is changed, ATS shall transfer accreditation to the legal successor, which shall follow:

- accept the policy and management system procedures of the CAB;
- keep the key personnel of the CAB;
- keep and implement conformity assessment methods and procedures used by previously accredited CAB;
- keep equipment and appliances, and facilities of the CAB that are needed and sufficient for competent performance of conformity assessment activities.

If it is necessary to transfer accreditation, the accredited CAB i.e., his legal successor shall make a formal request to ATS. The mentioned request shall contain the following:

- rationale behind the request for accreditation transfer;
- a clear and precise description of the new legal status, and all relevant documents confirming the new legal status;
- description of possible changes in the management system;
- declaration made by the new owner/management to confirm that they shall meet the accreditation criteria;
- planned activities with the defined deadline for updating the internal documents, in accordance with the changes that were made, including, but not limited to management system document in accordance with the changes occurred;

- Information about updating necessary contracts with employees, contracts with subcontractors, etc, if relevant.

In order to make an appropriate decision, ATS reserves the right to request additional documentation.

Depending on the changes, ATS will decide whether to make a decision on the transfer of accreditation based on the submitted documents, or for the purposes of making decision on accreditation transfer to perform an extraordinary assessment using one or more different assessment techniques, where CAB shall be notified by ATS.

A special type of accreditation transfer is also possible within the same legal entity, e.g., in the case of a merger of two or more accredited CABs within the same legal entity. In this case, the period of validity of the accreditation is the shortest period of accreditation of the merging bodies.

As a rule, the request for transfer of accreditation shall not move the previously planned activities of surveillance assessment and reassessment.

3.11 Accreditation for the purpose of designation (notification)/authorization of CABs

ATS, as a signatory to the EA MLA, adheres to the EA policy related to accreditation for the purpose of notification, which is contained in *EA Document on Accreditation for Notification Purposes (EA-2/17 M)*.

ATS shall use the established requirements in the said document when accrediting the CABs that will request, based on ATS accreditation, to apply for notification for conformity assessment activities in accordance with the harmonized EU legislation. Until the conditions for notification of CABs are met in the Republic of Serbia, ATS shall use the requirements of the said document and apply procedure *Accreditation for designation (notification) purposes ATS-PR18* when accrediting CABs that will require, on the basis of ATS accreditation, the designation/authorization to carry out conformity assessment activities in accordance with the regulations of the Republic of Serbia, transposing the legislation of harmonized European Union legislation (earlier directives of the new approach).

ATS, in cooperation with the competent ministry for the designation (notification)/authorization of CABs, may identify standards that are suitable for accreditation, taking into account the conformity assessment activities for which the CAB seeks accreditation, as well as the requirements given in the ATS document *ATS-PR18*.

4 INITIAL ACCREDITATION

4.1 Information about accreditation

The ATS internet portal <https://www.ats.rs/> contains information on accreditation rules, accreditation procedure, accreditation fees, necessary documentation for starting the accreditation procedure and the Accreditation Application form. In case of impossibility of access to the Internet portal, at the written request of the CAB, ATS shall submit all relevant publicly available information and documents.

4.2 Submitting and Reviewing the Application for Accreditation

4.2.1 Submitting the Application for Accreditation

Accreditation can be applied for by a CAB that has established and maintains a management system in accordance with the appropriate accreditation scheme, and which has the resources and performs conformity assessment activities from the requested scope of accreditation.

In addition to the completed *Accreditation Application Form*, available on the ATS website <https://www.ats.rs/>, the CAB shall submit the relevant documents/information specified in *the*

Accreditation Application Form for each type/scheme of accreditation, which shall be submitted in electronic form (on an appropriate removable medium or by e-mail) uniquely identified in accordance with the identification given in the application form (e-mail address is: office@ats.rs). Along with the completed *Accreditation Application* form, two copies of the completed and signed *Accreditation Contract ATS-PR11-007* shall be submitted as an attachment (the Accreditation Contract form can be downloaded from the ATS website <https://www.ats.rs/>).

ATS shall acknowledge receipt of the accreditation application to CAB in writing.

4.2.2 Reviewing of the Application for Accreditation

The completeness of each submitted application for accreditation and accompanying documentation is reviewed and, in case of the incompleteness of the application, ATS shall ask the CAB to complete the application within 5 working days. To add accreditation application can be requested only once.

The procedure for reviewing the application for accreditation determines the ability of ATS to perform the assessment, in terms of its policies and procedures, the competence and availability of appropriate personnel for assessment and decision-making activities. Also, the review includes determining the ability of ATS to perform the initial assessment in a timely manner and make an appropriate decision on accreditation.

In case that during the review of the accreditation application is determined that ATS is not able to perform the assessment in a timely manner (for example if all necessary assessment resources are not currently available or due to the need for additional time to evaluate conformity assessment schemes, etc.), CAB shall be provided with an explanation that the activities can be continued only after the necessary conditions have been met, as well as the estimated deadline for the continuation of activities. In such situations, it is necessary to obtain the written consent of the CAB.

If, after reviewing the application, ATS concludes that it cannot accept the application for accreditation (e.g. the CAB has not declared that it is ready to wait until the conditions for further activities are met, or for any other justified reason), the accreditation procedure is terminated and a decision on termination of the accreditation procedure is made, which contains a detailed explanation of the reasons for non-acceptance of the application and which is submitted to CAB no later than 30 days from the day of submitting the application for accreditation. The CAB has the right to appeal if it is dissatisfied with the decision of ATS.

4.2.3 Contracting

ATS and the CAB enter into an agreement (*Accreditation Contract ATS-PR11-007*, previously submitted by the CAB in accordance with cl. 4.2.1 of these rules). The contract specifies the rights and obligations of the contracting parties and other issues related to accreditation.

The content of the contract is the same for all CABs.

The contract has legal effect and is considered valid on the day of signing by both parties. After the contract is signed by ATS, one copy is submitted to the CAB, and the other copy is kept by ATS.

4.2.4 Preliminary Visit

Applicant for accreditation may wish for a preliminary visit to take place during which its readiness to continue with the assessment procedure shall be assessed, while the CAB shall bear the prescribed fees.

If the applicant for accreditation declares for the realization of the preliminary visit it shall enable its realization no longer than 5 working days from the signing of the contract by both contracting parties.

A preliminary visit shall be performed with the aim of:

- gaining an insight into the CABs organizational structure, locations, and resources to comply with the scope of accreditation it applied for;
- evaluating its general readiness to proceed with the accreditation procedure;
- gaining an insight into the level of documentary capacities of the management system as regards the requirements of reference documents for the accreditation of CABs;
- evaluating the duration, scope, and necessary resources for performing the assessment.

Minutes on the preliminary visit shall be produced and submitted to the applicant.

The accreditation process continues with the appointment of an assessment team.

If during the preliminary visit ATS and the applicant agree that the accreditation procedure cannot be continued, in accordance with the written request of the CAB, a decision shall be made to terminate the accreditation procedure.

4.3 Preparation for the Assessment

4.3.1 Appointment of the Assessment Team

The assessment team is appointed in such a way that its composition (number of team members and structure) corresponds to the scope and diversity of conformity assessment activities for which accreditation is sought. The assessment team shall be composed of a team leader, the relevant number of assessors/technical assessors, and/or technical experts for each of the conformity assessment fields.

ATS shall promptly notify the CAB of the names of the assessment team members and potential observers e.g. representatives of the Committee for the Selection and Monitoring of Performance of Assessors and Technical Experts, representatives of bodies or organizations responsible for preparing or adopting certain technical regulations, representatives of international organizations for accreditation with which ATS has signed international agreements, representatives of international projects to support the development of the accreditation system) and the organization in which they are employed in order to give the CAB the opportunity to object to the appointment of any particular team member or observer it supports. In case that an objection is sent to the appointed team or observers, which must be explained in detail and with arguments, the CAB shall be notified in writing of the results of the objection review, i.e., its acceptance or non-acceptance, once more shall be sought consent to a changed/assessed team composition, including the presence of an observer.

If the objection to the composition/change of the team, including the presence of observers, is assessed as unjustified, and the applicant does not withdraw from it, the procedure is terminated, and a decision is made to terminate the accreditation procedure.

Recruitment of assessors/technical experts from other accreditation bodies signatories to the EA MLA is also possible in the situation when ATS assesses, on the occasion of reviewing its resources to perform the accreditation procedure, when it is evaluated that it does not have sufficient competence, i.e., that it does not have human resources to competently and impartially perform the said assessment or in the case of cross-frontier accreditation.

The presence of observers regulated by the Law on Accreditation or resulting from the obligations of ATS as a signatory to international agreements cannot be objected to.

Objections relating to a conflict of interest may be accepted as justified.

The CAB is obliged to declare in writing, no later than 3 working days from the delivery of the notification on the composition of the team, regarding the proposed team and the presence of observers (consent/objection), and then, no later than the same time limit and in relation to ATS response to any objections to the assessment team made by the CAB.

4.4 Assessment

The assessment procedure is carried out in accordance with the *Assessment of CABs, ATS-PR12*. The assessment is carried out by an appointed assessment team and includes a review of documentation and on-site assessment.

4.4.1 Documentary review

The review of the documentation determines the compliance of the submitted documentation with the requirements of the reference documents for accreditation. Report on the review of documentation containing information on identified non-conformities and/or deficiencies shall be submitted to the applicant for accreditation, and the CAB is obliged to submit a response to that report, i.e. to eliminate non-conformities and/or deficiencies identified during the review of documentation no longer than 15 working days for the initial assessment and assessment for the purpose of extending the scope of accreditation, or within a period not longer than 5 working days for reassessment (for situations when it does not include the extension of the scope of accreditation).

If the assessment team assesses that the evidence of non-conformities is inadequate, the same findings will be repeated in the next assessment phase. ATS may, having in mind the nature of the unresolved non-conformities, make a decision to terminate the accreditation procedure to which the CAB has the right to appeal.

4.4.2 On-site assessment

For the realization of the assessment, ATS primarily uses the on-site assessment technique. In situations when it is defined by the Assessment Programme or when due to extraordinary circumstances (e.g. extremely unfavorable epidemiological situation) it is not planned or possible to directly access the location of the CAB and/or locations where conformity assessment activities are carried out), based on risk analysis, ATS uses one or a combination of other assessment techniques such as: remote assessment, interview, document review and file review, to achieve the same goal as the assessment at the location being replaced.

The ATS policy is that for initial assessments and assessments to expand the scope of accreditation to include new sites and/or new conformity assessment activities that are significantly different from those for which accreditation has been granted, an on-site assessment is mandatory.

Regardless of the choice of assessment technique, each assessment has the same elements, but with the specifics described in detail in the procedure *Assessment of CABs, ATS-PR12*.

For each assessment, an Assessment Plan is prepared and the deadline for conducting the assessment is harmonized with the CAB, in such a way that the previously determined dynamics of the sequence of activities determined by these rules is met. The CAB is obliged to enable assessment no later than 10 working days from the receipt of the Report on the review of documentation (if no nonconformities/deficiencies were found during the document review), or from the submission of evidence relating to the findings from the the Report on the review of documentation.

The initial assessment shall be assessed the locations where one or more of the following activities are performed, which relate to the requested scope of accreditation: policy establishment, development of processes and/or procedures, contract review, conformity assessment planning, conformity assessment, review and approving the results of conformity assessment and decisions of these results.

The selection of representative samples of conformity assessment activities, which will be the subject of witnessing is done in compliance with the witnessing criteria described in the guidance

Determining locations, number of assessment days and necessary witnessing during CAB assessment, ATS-UP38.

At the opening meeting, the representatives of the CAB shall be provided with all relevant information regarding the assessment procedure and the further course of the accreditation procedure, including the obligations regarding confidentiality. The opening meeting, among other things, confirms the plan and scope of assessment.

During the assessment, the CAB shall provide the ATS assessment team with access to all relevant documents and to all areas related to the conformity assessment activities for which accreditation is sought, as well as interviews with personnel involved in the activities covered by the assessment.

At the closing meeting, the assessment team shall inform the representatives of the CAB about the assessment findings, including any non-conformities and/or concerns identified, if any.

Categorization of findings is performed as follows:

Conformity is a finding when CAB meets the requirements of the accreditation reference documents, EA, ILAC, IAF documents containing mandatory requirements for CAB, rules of accreditation or other ATS rules containing requirements for CAB, or its own management system.

Non-conformity is a finding when CAB does not meet the requirements of the reference documents for accreditation, EA, ILAC, IAF documents, or rules of accreditation or its own management system. The assessed CAB is required to perform a cause analysis of non-conformity and to submit to ATS within a specified period (1 or 3 months depending on the type of assessment) evidence of the implementation of specified actions to eliminate identified nonconformities so they can be assessed by the assessment team. Elimination of identified nonconformities represents one of the basis for giving a recommendation on accreditation.

A concern is a finding of the activities, management system or resources of CAB that can escalate into non-conformity if adequate actions are not taken. The assessed CAB is expected to determine the cause of the concern and to define the actions for the elimination of the concern and the deadline within which it will implement the proposed actions. The assessment team is obliged to send written consent to the actions after the analysis of the proposed actions (if applicable), and ATS shall be obliged to assess their implementation during the next assessment. If during the next assessment it is established that the identified concern has not been eliminated, then non-conformity may be determined regarding that request.

Comment is a finding regarding the activities or documents of CAB that should be considered as a place for improvement. Comments are expressed in the Assessment Report.

The conclusions of the closing meeting are entered in the List of Findings which is left to the CAB. The CAB shall be given the opportunity to ask questions or request clarifications regarding the findings of the assessment team. Representatives of the CAB state their opinion on the assessment findings and in case of disagreement with the findings of the assessment team, information on this is recorded in the List of Findings, with a detailed statement of the reasons for the expressed disagreement. If necessary, a more detailed explanation of the disagreement, the CAB may forward to ATS no later than 2 working days after the realization of the closing meeting. The CAB shall be informed of the conclusions regarding the disagreement expressed. The disagreement expressed cannot prolong the deadline for submission of evidence.

Proposals for actions to eliminate non-conformities and/or concerns defined in the List of Findings, which include cause analysis of non-conformities and/or concerns, as well as the proposed deadline for elimination of concerns, CAB is obliged to submit to ATS no later than 5 working days after closing meeting, i.e., findings for which disagreement was expressed, from informing about the conclusions regarding the expressed disagreement. Exceptionally, at the request of the CAB, this time limit may be extended for a maximum of 5 working days from the date of the originally established time limit. In case the need for supplementing the proposal is determined, the requested

supplement must be submitted within no longer than 2 working days. At the written request of the CAB, this deadline may be extended for a maximum of 5 working days from the date of the originally set deadline.

The CAB is obliged to analyze the cause of the non-conformity and propose actions, even in case when the CAB decides to withdraw from the accreditation of conformity assessment activities in relation to which the non-conformity has been determined.

During the initial assessment, the deadline for elimination of non-conformities may not be longer than three months from the day when the proposal of actions for their elimination was accepted. In all other cases, the deadline for resolving the non-conformities is one month. At the written request of the CAB, this period may be extended for another month from the date of expiry of the previously established period.

Within the defined deadlines, the CAB shall notify ATS, in writing, of the elimination of the identified non-conformities and submit evidence of the implemented actions, i.e., elimination of non-conformities.

The assessment team shall confirm that the identified non-conformities have been resolved satisfactorily. Confirmation of the elimination of non-conformities may be done by reviewing and assessing the submitted written evidence and/or follow-up assessment, of which the CAB is informed during the assessment of the proposed corrective actions.

If it is assessed that the submitted evidence is not adequate, the CAB has a period of 5 working days to submit additional information - supplemented evidence and/or enable the implementation of follow-up assessment. At the written request of the CAB, this deadline may be extended for another 5 days from the expiration of the previously determined deadline.

After verification of the implementation of corrective actions to eliminate identified non-conformities, including, if necessary, verification of the implementation of corrective actions through the follow-up assessment procedure and/or improvement with actions and proposed time for resolving concerns, ATS submits to CAB an Assessment Report containing accreditation recommendation and proposed scope of accreditation, i.e. change of the scope of accreditation when it comes to surveillance assessment. The CAB is required to confirm the correctness of the proposed scope of accreditation or to point out possible errors within no more than 2 working days. ATS shall accept additional harmonization of the scope/scope change proposal only if it is confirmed that there was an omission during the verification by the assessment team and in relation to the results of the assessment itself, which must be confirmed by the assessment team itself.

If changes occur in the period before the preparation of the file for decision on accreditation that can affect the given recommendation of the assessment team (e.g., change of key personnel, change of location where conformity assessment activities are performed), additional assessment can be realized. The CAB is obliged to enable the realization of additional assessment without delay. If during this assessment non-conformities/concerns are identified, the deadline for elimination of non-conformities in accordance with the actions whose adequacy is assessed at the assessment itself, cannot be longer than 5 working days from the day of assessment.

4.5 Granting Accreditation

4.5.1 Accreditation Decision-making

Decisions on accreditation shall be made by the ATS Director following the proposals made by the Accreditation Committee.

The Accreditation Committee shall be composed of ATS permanent employees that did not take part in the assessment for which the findings shall be decided and external engaged experts

providing the needed technical expertise in keeping with fields of conformity assessment subject to accreditation decision-making.

The Accreditation Committee considers the information from the file that has been decided, determines the completeness, evaluate the clarity, comprehensibility, and sufficiency of the of the information on the proposal of the decision on accreditation. If the Committee finds that the information is insufficient to make an appropriate proposal for a decision, additional information shall be requested from the assessment team or the CAB, which may include the conduct of a supplementary assessment. The CAB is obliged to submit additional information and/or enable the realization of the supplementary assessment within 5 days at the latest.

The decision on accreditation, which is adverse for him, the CAB has the right to appeal.

4.5.2 Accreditation Certificate and Reference to Accreditation

If it is determined after the completed accreditation procedure that the CAB meets the accreditation criteria, ATS shall make a Decision on accreditation and issue an Accreditation certificate accompanied by the Scope of accreditation (list of accredited conformity assessment activities) to CAB. In addition to the Accreditation certificate, ATS shall give CABs right to use the accreditation symbol and/or combined mark in accordance with the *Rules for the Use of the Accreditation Symbol, Reference to Accreditation and ATS Status as a Signatory to the EA MLA, ILAC MRA and IAF MLA agreement, ATS-PA04*. The Accreditation certificate shall be valid for four years.

An accredited CAB may use, instead of the accreditation symbol, text accreditation or reference to the status of ATS as a signatory to multilateral agreements or to use combined marks in accordance with *Rules for the Use of the Accreditation Symbol, Reference to Accreditation and ATS Status as a Signatory to the EA MLA, ILAC MRA and IAF MLA agreement, ATS-PA04*.

Accredited CABs shall be entered in the Register of Accredited Conformity Assessment Bodies.

4.6 Register of Accredited CABs

Register of Accredited CABs shall contain the following data:

1. accreditation number;
2. name and address of an accredited CAB, including its locations wherein it performs accredited activities;
3. basic information about the accredited CAB;
4. information about the accreditation status and the changes of the status, if any;
5. date of the first and last accreditation, and expiry of the accreditation validity period;
6. contact data;
7. valid scope of accreditation.

The Register shall be made publicly available on the ATS internet portal www.ats.rs and shall contain information regarding valid accreditations, withdrawn accreditations and the current status of suspended accreditations.

The status/status changes of accreditations are kept permanently in ATS. The ATS maintains a list of all accreditation decisions made. Archived information on status/status change can be obtained by contacting the official e-mail address of ATS.

4.7 Register of externally engaged assessors and technical experts and experts engaged for the accreditation decision-making

In accordance with the Law on Accreditation ("Official Gazette of RS", No. 73/2010 and 47/2021), ATS shall keep a Register of externally engaged assessors and technical experts and experts engaged for the accreditation decision-making process.

The register is public and available on the ATS internet portal www.ats.rs.

4.8 Documents of Accredited CABs kept by ATS

ATS shall keep the documentation of accredited CABs that was submitted together with the application for accreditation and all the records relating to assessment procedure and accreditation decision-making, for a period of at least two accreditation cycles, respecting the confidentiality policy.

5 ACTIVITIES IN THE ACCREDITATION CYCLE

5.1 General background

ATS conducts activities in the accreditation cycle in order to ensure that the accredited CAB continuously meets the accreditation requirements for the activities for which accreditation has been granted.

These activities include assessment and surveillance activities. Surveillance activities include the collection and analysis of all information relevant to maintaining the status of an accredited CAB and communicating with the CAB in this regard, which, taking into account risk analysis, may involve a request for action or an extraordinary assessment.

5.2 Assessment in the accreditation cycle (surveillance assessments)

5.2.1 Regular assessments in the accreditation cycle

The first assessment in the accreditation cycle is conducted in the interval of 6 to 9 months from the date of granting accreditation unless otherwise decided in the accreditation decision-making process, and exceptionally 12 months if accreditation is a prerequisite for designation (notification)/authorization.

Regular assessments are carried out in accordance with the Assessment Programme, as a rule, every calendar year, using applicable assessment techniques, taking into account that the period between two assessments at the client's location cannot be longer than two years.

The interval between assessments in the accreditation cycle, as well as the applicable assessment techniques, depend on the results of conducted assessments, the nature of non-conformities, the effectiveness of actions implemented in the previous period, the results of internal audits, management reviews, participation in PT activities and interlaboratory comparisons, results of solving complaints, frequencies of changes in the accredited CAB that may affect the accreditation status, etc.

The CAB is obliged to submit the necessary documentation for the implementation of the regular surveillance assessment no later than 1 month before the planned implementation date. In case when the CAB intends to be carried out the assessment in order to expand the scope of accreditation together with the surveillance assessment the application for accreditation shall be submitted no later than 3 months before the planned implementation of the surveillance assessment. As a rule, the assessment team remains the same in the period from the granting of accreditation to the

reassessment but is engaged in the composition that corresponds to the planned assessment activities in accordance with the Assessment Programme.

ATS applies an Assessment Programme that ensures that during the accreditation cycle, by applying appropriate assessment techniques, those conformity assessment activities that are representative of the scope of accreditation are assessed.

5.2.2 Extraordinary assessment

If needed, the extraordinary assessment shall be conducted when:

- complaints to the work of an accredited CAB were raised;
- changes took place in an accredited CAB that may affect the meeting of conditions under which the accreditation was granted and requirements (change in the legal status, inner organization, managerial structure, conformity assessment procedures, technical and human resources, etc.);
- after the suspension, it is necessary to assess and verify whether an accredited CAB meets the accreditation criteria and requirements again;
- based on information on the status of the accredited CAB, which may affect the status of the granted accreditation.

A decision on the performance of an extraordinary assessment shall be made by the ATS Director.

6 ACCREDITATION RENEWAL

6.1 Reassessment

Accreditation may be renewed at the request of an accredited CAB.

Pursuant to the Law on Accreditation (“Official Gazette of the RS”, No. 73/2010, 47/2021), the procedure for renewal of accreditation (reassessment) lasts a maximum of four months from the date of submission of the application for accreditation. In exceptional cases, the deadline of four months can be extended at the written request of the applicant, and to the maximum of four months from the day of the expiration of four months.

Reassessment activities start at least 5 months before the expiration of the valid accreditation, by submitting application for renewal of accreditation by the CAB, with the accompanying documentation specified in the *Accreditation Application form*.

All phases of the reassessment are realized as in the initial assessment, except for the realization of the preliminary visit, provided that the time limits defined for individual activities are adjusted to the type of assessment (assessment in the accreditation cycle) and the maximum allowed period for the duration of the procedure.

Reassessment is a special type of assessment in the accreditation cycle.

Reassessment shall be conducted during the validity of accreditation. In case the accredited CAB does not follow the accreditation procedure defined by these rules, does not submit documentation/required information at the request of ATS and does not enable reassessment in the accreditation cycle, ATS shall decide to terminate the accreditation procedure. With the decision to terminate the accreditation renewal procedure, the accredited CAB does not automatically lose the accredited status (which is valid until the expiration of the validity of the accreditation certificate) but loses the possibility of renewing the accreditation. In that case, after the expiration of the accreditation, the CAB has the right to submit a new application for initial accreditation. The CAB has the right to appeal the decision to terminate the procedure.

Any request for extension of the valid scope during the implementation of the reassessment shall be treated in such a way that the procedure can be extended as defined by the Law on Accreditation ("Official Gazette of RS", No. 73/2010, 47/2021), having in mind the scope of activities required by that expansion of scope.

In case the CAB requests that the renewal of accreditation includes the extension of the valid scope, the application must be submitted no later than 8 months before the expiration of the valid accreditation, in order to complete the procedure by the end of accreditation, and no later than 8 months. Delivery of the application for accreditation within the specified period is necessary if there is a need for the CAB to use additional time in the procedure, i.e., at the request of the CAB, the maximum allowed time in which the CAB must submit documentation/requested information at the request of ATS and/or in which it must enable the implementation of activities in the process of renewal of accreditation could be extended.

As a rule, a different assessment team is appointed for reassessment, in relation to the team that carried out previous assessments in the valid accreditation cycle. The exception is the need for reassessment to be carried out through a combination of other assessment techniques (other than on-site assessment) when a team that has carried out previous assessments may be appointed to manage the assessment risk.

For the purposes of reassessment, the CAB shall submit the required scope of accreditation with, if applicable, clearly indicated changes in relation to the valid scope of accreditation (extension, reduction, other changes in the scope of accreditation).

ATS reserves the right not to accept the assessment in order to expand the scope of accreditation, which would be carried out together with the reassessment if the application is not submitted within the defined deadlines and/or if during the review of the application for accreditation determined that ATS is not capable of performing assessment in timely manner.

6.2 Extension of validity of accreditation

If due to extraordinary circumstances there is a delay in the accreditation renewal procedure caused by ATS and the decision on accreditation is not made until the expiration of valid accreditation, the Director may decide to extend validity of accreditation, until the decision on renewal of accreditation, up to 3 months from the expiration of the previous accreditation, provided that it cannot have an impact on the duration of the procedure prescribed by these rules, i.e. the decision on extension of validity of accreditation cannot extend the duration of the procedure prescribed by the Law on Accreditation.

7 CHANGES IN THE ACCREDITATION SCOPE

7.1 Extending the Accreditation Scope

In order to extend the scope of accreditation, an accredited CAB may submit an application at any point in time during the accreditation validity period, which also includes the extension of the accreditation scope in the accreditation renewal process, but in this case the special application for extension of the scope of accreditation is not submitted (an application for renewal of accreditation is submitted) i.e. the requested scope of accreditation shall identify the conformity assessment activities for which the CAB is requesting an extension. Assessment for the purpose of extending the scope of accreditation can be realized through an independent procedure or together with regular assessment in the accreditation cycle. All stages in the procedure are realized as in the initial assessment, except for the realization of the preliminary visit.

Extension to accreditation scope does not affect the accreditation validity period.

7.2 Reducing the Accreditation Scope

The accreditation scope of an accredited CAB can be reduced at the request of CAB, after finishing the assessment procedure, and made relevant decision on accreditation.

The CAB has the right to appeal if it is not pleased with the ATS decision to reduce the accreditation scope.

7.3 Other changes of accreditation scope

At any time in the accreditation cycle, the CAB may request a change in the valid scope of accreditation, and due to changes in the reference document for conformity assessment (standard, rulebook, etc.), changes in location, etc. The CAB is obliged to submit with the request an explanation regarding the required changes, which includes an analysis of the impact on his work and the established management system, as well as relevant documentation/records confirming this.

Depending on the changes, ATS shall decide whether to make a decision to change the scope based on the submitted documents, or for the purpose of decision-making on changes of the scope of accreditation, to carry out the extraordinary assessment using one or more different assessment techniques, and the CAB shall be notified in writing.

8 SUSPENSION OF ACCREDITATION

8.1 Accreditation Suspension on Request

An accredited CAB may, during the accreditation validity period, ask ATS to suspend accreditation either for part or the entire scope of accreditation that was granted due to temporary inability to perform accredited conformity assessment activities with observance of accreditation criteria. The requested suspension can be granted for up to 6 months maximum. An accredited CAB should, in the form of a written request, ask, at least two months before the accreditation suspension period expires, for the suspension to be lifted.

Accreditation suspension may be lifted on the basis of the results of an assessment that was carried out or on the basis of submitted evidence confirming the elimination of circumstances that caused the suspension.

If no conditions allowing the lifting of suspension are met, ATS shall reduce the scope of accreditation to match the suspension level that was approved or withdraw accreditation if a decision to suspend accreditation in full was made.

The CAB has the right to appeal if it is not pleased with the ATS decision on suspension.

The duration of the suspension does not affect the accreditation validity period.

8.2 Compulsory Suspension

ATS may suspend the accreditation on the basis of surveillance activities, or not meeting accreditation criteria and non-observance of contractual obligations and other obligations considering CAB, assessment results or from the proposal of the Accreditation Committee. This suspension may last for up to 6 months maximum and can include part or the entire scope of accreditation. An accredited CAB should, in the form of a written request, ask for the suspension to be lifted at least two months before the accreditation suspension period expires. Compulsory suspension can be lifted on the basis of the results of an extraordinary surveillance assessment or on the basis of adequate evidence that was submitted confirming the elimination of circumstances that caused the suspension.

If the conditions for lifting of the suspension are not met, ATS will reduce the scope of accreditation to the extent to which the decision on suspension was made or withdraw the accreditation if the decision to suspend the accreditation as a whole was made.

The CAB has the right to appeal if it is not pleased with the ATS decision on compulsory suspension.

The duration of the suspension does not affect the accreditation validity period.

9 WITHDRAWAL OF ACCREDITATION

9.1 Dropping Accreditation

An accredited CAB may drop the accreditation that was granted for any reason and make a written request to ATS to withdraw accreditation at any time.

9.2 Accreditation Withdrawal

ATS shall withdraw accreditation that was granted on the basis of surveillance activities, not meeting accreditation criteria and non-observance of contractual and other obligations of the CAB, or from the proposal of the Accreditation Committee. In particular, ATS shall initiate the process of withdrawing accreditation if during surveillance activities it becomes known that the CAB had fraudulent behaviour, intentionally providing false information about its accreditation, or misuses accreditation or deliberately violates accreditation rules. After accreditation withdrawal an accredited CAB is obliged to send back to ATS the Accreditation certificate and Scope of accreditation that ATS issued thereto, and undertake, by means of a written declaration, to carry out all actions preventing the use of the accreditation symbol or combined marks or making text reference to accreditation or ATS status as a signatory to the EA MLA, ILAC MRA and/or IAF MLA.

The accredited CAB has the right to appeal if it is not pleased with the ATS decision on accreditation withdrawal.

The CAB which accreditation was withdrawn can submit a new application for accreditation after the withdrawal of accreditation, i.e., after 12 months from the date of withdrawal of accreditation, if the withdrawal of accreditation followed due to abuse of accreditation.

10 COMPLAINTS AND APPEALS

10.1 Complaints

The Director of ATS shall decide on complaints by any person or organization regarding the activities of ATS or the CAB, in accordance with the procedure for *Resolution of Complaints and Appeals*, *ATS-PR16*, which are available on the Internet portal <http://www.ats.rs/>.

ATS shall:

- review whether a complaint is justified;
- ensure, where appropriate, that a complaint is first reviewed by the CAB in the light of the complaint related thereto;
- reply to a person filing a complaint;
- undertake appropriate actions and assess their effects.

Complaints that ATS receives and that pertain to CABs accredited by another accreditation body shall be forwarded to the competent accreditation body.

10.2 Appeals

An appeal can be lodged to ATS against accreditation decisions within 15 days after the decision has been delivered, in accordance with the procedure *Resolution of Complaints and Appeals, ATS-PR16* which is available at the Internet portal www.ats.rs. The Appeals Committee shall make decisions on the appeals within 30 days following the receipt of appeals. The Appeals Committee shall be established by the ATS Management Board.

The decision of Appeals Committee shall be final, whereas an administrative dispute can be brought against it.

11 OBLIGATIONS

11.1 Obligations of Accredited CABs

It is the obligation of an accredited CAB, when performing its activities, to adhere to the established organization, its own rules, and procedures on the basis of which ATS granted accreditation thereto, and to provide conformity assessment services to its clients by observing the rules of accreditation and accreditation criteria.

It is an obligation of an accredited CAB to enable ATS and its representatives to monitor compliance with the rules of accreditation and relevant accreditation criteria including, but not limited to:

- cooperation to the extent necessary for ATS to assess the fulfillment of accreditation requirements;
- ensuring that ATS personnel, during their presence on-site of the CAB or the location of its clients for assessment purposes, are accommodated in adequate conditions and equipped with adequate personal protective equipment, if necessary, in order to reduce health and safety risks at an acceptable level and to meet legal requirements;
- providing access to all relevant areas of work of the CAB, which includes the necessary arrangements at all locations where conformity assessment and witnessing activities are performed by clients of the CAB, when required by ATS, to the extent necessary to assess compliance with accreditation requirements;
- providing a legally valid agreement with its clients obliging them to ensure the realization of the witnessing, where applicable. In particular, in case of management system certification bodies, the legally valid agreement must include information on the presence of ATS during the auditing activities if the client is selected for witnessing, that the refusal to witness must be justified and accepted by the certification body and ATS, as well as that refusal may lead to withdrawal of accreditation if the reasons for refusal, are not accepted;
- making available documents and records related to conformity assessment activities when required by ATS, in order to enable the implementation of assessment and surveillance activities, to the extent necessary to assess the fulfillment of accreditation requirements;
- start reassessment activities within the deadlines set by ATS assessment programme before the expiration of the valid accreditation, by submitting an application for renewal of accreditation with accompanying documentation;
- payment of accreditation fees within the prescribed deadlines, in accordance with the Charging Policy Document;
- maintaining the confidentiality of information and data obtained in the accreditation process;

- the obligation to timely inform ATS of all changes (including plans in case of already planned activities), which have an impact on the status of accreditation, i.e.:
 - changes in legal, ownership or organizational status;
 - changes in organizational structure, management and key personnel;
 - changes of persons authorized to sign certificates of conformity where applicable;
 - changes in policies, resources and locations;
 - changes in the content of the conformity assessment scheme (e.g., certification schemes);
 - changes of members of the certification committee and other organs exerting influence of the parties interested in certification where applicable, and
 - other changes affecting fulfillment of the accreditation criteria.

After analyzing the possible effects on accreditation status arising from the changes made, ATS shall decide on the method of verification thereof, which may also involve on-site assessments.

Furthermore, an accredited CAB shall:

- not use the accreditation that was granted thereto in order to jeopardize the reputation of ATS by taking special care not to be misleading as regards the scope and subject of accreditation that was granted or make any statements about its accreditation that may, according to these Rules, be considered as misuse of granted accreditation;
- to claim that it is accredited only for the scope for which the accreditation was granted;
- in case of any doubts about the use of the accreditation granted to CAB, contact ATS for an authentic interpretation;
- does not include in the contracts with service users or in its documents on conformity any determinants that lead to the conclusion that by accreditation, the subject of conformity assessment has been confirmed by ATS;
- does not use the term "accreditation" or any similar term in connection with its business name or otherwise presents itself as a provider of accreditation services as defined in the Law on Accreditation or refers to any other conformity assessment services called "accreditation", which fall within the scope of ATS accreditation activities;
- in case of accreditation suspension in full or for part of the scope of accreditation, immediately stop issuing certificates of conformity (including labels), and other documents containing the accreditation symbol or combined marks or reference to accreditation or ATS status as a signatory to the multilateral agreements in accordance with the Rules for the Use of the Accreditation Symbol, Reference to Accreditation and ATS Status as a Signatory to the EA MLA, ILAC MRA and IAF MLA and that pertains to the activities that led to accreditation suspension, and on the web page;
- return, after the accreditation has been withdrawn, the accreditation certificate and scope of accreditation to ATS; after the expiry of the accreditation validity period or accreditation withdrawal, it shall immediately stop stating that it is still accredited and it shall stop distributing documents/items containing the accreditation symbol or combined marks or text reference to accreditation or ATS status as a signatory to the multilateral agreements in accordance with the ATS Rules for the Use of the Accreditation Symbol, Reference to Accreditation and ATS Status as a Signatory to the EA MLA, ILAC MRA and IAF MLA and this also implies their removal from the web page;
- inform its clients in writing that accreditation was withdrawn and ask them to stop using the accreditation symbol if applicable and inform ATS thereof in writing;
- to assist in the investigation and resolution of all complaints addressed to ATS to the CAB;

- ensure the storage of certificates of conformity and associated records during one accreditation cycle;
- immediately notify ATS and ensure the keeping of records related to incidents related to the safety of products covered by the scope of accreditation, as well as records by users of its services or third parties (for example records of judicial authorities) and information on actions taken in connection with incidents;
- submit to ATS the details on the actions that judicial bodies undertook against it as regards the accreditation services rendered;
- report regularly, in case of authorized/designated bodies by the competent authorities based on accreditation, to ATS about their current authorized/designated status (when this status is to be granted or denied, etc.).

An accredited certification body, i.e., a body that has submitted an application for accreditation, is obliged to submit to ATS every year, upon request:

- updated list of certified clients;
- list of consultants recruited to put in place management systems for their certified clients;
- updated list of auditors/assessors containing the following information: name and surname, qualifications, work experience, technical competence (e.g., IAF code, the field of certification) and the list of audited clients;
- list of countries into which accredited certificates are issued and the number of certificates issued in each country;
- list of countries in which the certification body operates from fixed locations (permanent premises of the certification body where the certification activities are performed and/or managed for the CAB, regardless of location and relationship with the certification body) that performs any certification activities;
- list of countries in which the certification body has remote personnel (individuals who may be internal or external that perform certification activities for a CAB and do not work at a fixed office location) that perform any certification activities;
- to present the mechanisms by which it manages all activities that take place at locations abroad or performed by engaged personnel to perform conformity assessment activities.

Accredited certification body for management system certification, in addition to the above lists, are obliged to submit to ATS by the end of January each year the following data (by country and according to the standard by which it performs certification): number of accredited certificates valid at the end of December, number of auditors/assessors, number of completed certification transfers, number of late audits and number of completed audit days, based on the instructions they will receive from ATS on that occasion.

Before applying for accreditation, the certification or inspection body shall have realized at least one certification, i.e. inspection for each registered certification scheme or inspection area.

Accreditation bodies for certification of management system certification can be granted only for IAF codes/categories of food chain/technical areas, for which the certification body has made a decision on certification - granted certification.

If accreditation is a prerequisite for designation (notification)/authorisation, it can also be granted by witnessing the work of CABs under simulated conditions. A designated/authorised accredited CAB is obliged to inform ATS about its first conformity assessment so that ATS can witness the work thereof under real conditions. If witnessing is not performed before the first regular surveillance assessment, ATS shall suspend the accreditation that was granted.

Accredited CABs may be faced with the situation (for technical or economic reasons) that they do not perform certain conformity assessment activities for which they are accredited in a certain period of time. These activities are called "dormant activities".

ATS will enable the maintenance of these activities to the extent of accreditation and provide them to users of CABs through external procurement of services (subcontracting), provided that all documents necessary for business management are maintained, that resources (staff and equipment) are maintained to perform these businesses and to monitor standards/regulations/other relevant documents related to these activities, to maintain contracts with external suppliers, to determine the actions to be taken in case the activities continue. The activity is declared "dormant" one year after the last performance of the activity, i.e., when the activity is not performed for a year, about which it is necessary to submit information to ATS. This activity, i.e., conformity assessment activities, may be part of the scope of accreditation for a maximum of two years. The CAB is obliged to inform ATS about the first reactivation of "dormant activities", which will decide on the activities it will undertake in order to verify the new situation. These activities may include extraordinary assessment, which includes witnessing of the work of the CAB.

If not, ATS shall reduce or withdraw the granted accreditation for conformity assessment activities that have not been performed for more than two years.

The certification body certifying management systems under accreditation must not offer and provide management system certification services in accordance with standards ATS uses for the accreditation of the CABs (e.g., ISO/IEC 17025, ISO 15189, etc.).

The details as regards the reference to accreditation status and use of accreditation symbol are set forth in the rules for the use of accreditation symbol and reference to accreditation. ATS will, in case of incorrect reference to accreditation and use of the accreditation symbol, undertake actions that may include a request to undertake corrective actions, extraordinary surveillance assessments, suspension or withdrawal of accreditation.

A CAB is obliged to adhere to *the Rules of Cross-frontier Accreditation ATS-PA05*, which are publicly available at www.ats.rs, in cases of its accredited activities abroad and the existence of locations of the conformity assessment body in other countries.

In case of need for witnessing ATS performance by EA or other international accreditation organizations that ATS has signed multilateral arrangements on mutual recognition, a CAB is obliged to host, during assessment by ATS, members of evaluation team from EA or other international accreditation organizations, which will monitor and observe the work of ATS assessment team.

The CAB is obliged to agree with the presence of representatives of bodies, i.e., organizations responsible for the preparation or adoption of certain technical regulations, which may participate in the accreditation procedure of the conformity assessment body for the purpose of designation (notification) or authorization while respecting confidentiality rules and other general acts of ATS.

A CAB is obliged to participate in inter-laboratory comparisons (inter-laboratory comparisons-ILC) and proficiency testing programs (proficiency testing - PT) schemes in accordance with *the Rules on participation in interlaboratory comparisons and proficiency testing schemes, ATS-PA02*, which are publicly available at www.ats.rs.

11.2 Obligations of ATS

11.2.1 Obligations towards CABs

ATS shall:

- limit assessment procedures to the assessment of conformance with the accreditation criteria;

- provide participation of competent, independent and impartial personnel in the accreditation procedure;
- that the personnel participating in the on-site assessments of the CAB complies with the prescribed actions for the protection of health and safety at work;
- ensure confidentiality of data and information obtained during the accreditation procedure;
- provide public access to up-to-date information about accreditations that were granted;
- inform about changes in accreditation criteria on time having in mind, if need be, opinions of the interested parties, and of methods to be used to verify whether each accredited CAB made the necessary adjustments;
- timely information on the activities that the CAB should carry out in order to maintain the status of the granted accreditation to ensure compliance with the provisions given in the accreditation agreement, as well as the deadlines for fulfilling these requirements and the consequences that may follow if the CAB fails to comply with the requirements within the prescribed period;
- provide information relating to the provision of acceptable traceability of measurement;
- provide information relating to international arrangements it is involved in.

11.2.2 Obligations towards international organizations for accreditation

As a signatory to multilateral arrangements on mutual recognition (EA MLA, ILAC MRA and IAF MLA) ATS abides all relevant and mandatory guidelines of EA, ILAC and IAF referring to accreditation procedure or accreditation bodies and CABs.

The list of mandatory and informative documents issued by international organizations for accreditations is presented in EA-INF/01, the valid edition of which is available at <http://www.european-accreditation.org>.

As a signatory to EA MLA, ATS abides requirements from the EA-1/06 that contains criteria for signing and maintaining EA MLA.

12. CROSS-FRONTIER ACCREDITATION

The policy applied by ATS when accreditation is provided to a CAB with the head office outside the Republic of Serbia or to a CAB established in the Republic of Serbia, but that performs conformity assessment activities abroad, is prescribed in the *Rules of Cross-frontier Accreditation, ATS-PA05*.

13. TRANSITIONAL PROVISION

These Rules shall enter into force and apply from 01.11.2021. Until then, the Rules of Accreditation ATS-PA01, edition 12 of July 2019, is in force.

ACTING DIRECTOR

Prof. Aco Janićijević, PhD