



АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ

ATS-PA 01

RULES OF ACCREDITATION

Eleventh edition

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

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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:

- accreditation procedure,
- requirements to be met by a conformity assessment body (CAB),
- 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 those working in conformity assessment bodies.

1.3 Definitions

Definitions set forth in the following documents shall be used in the Rules:

- Regulation setting out requirements for accreditation and market surveillance (765/2008/EC)
- SRPS ISO 9000:2015 – Quality Management System – Fundamentals and Vocabulary
- SRPS ISO/IEC 17011:2007 – Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies
- SRPS ISO/IEC 17000:2008 – Conformity Assessment – Vocabulary and General Principles.

1.3.1 Accreditation

Accreditation is the determination by a national accreditation body whether the conformity assessment body meets the requirements for performance of certain conformity assessment activities, which are set out in the relevant Serbian, or international and European harmonized standards, and, where applicable, all additional requirements defined for particular areas, including the requirements set out in the relevant sectoral conformity assessment schemes.

1.3.2 Accreditation Body

National accreditation body in charge of accreditation.

1.3.3 Appeal

Request by a CAB/applicant for accreditation for reconsideration of any decision made by the accreditation body that has adverse effect on a conformity assessment body and that is related to its desired accreditation status.

1.3.4 Interested Parties

Parties with a direct or indirect interest in accreditation.

Note: Direct interest refers to the interest of those who **undergo accreditation**; indirect interest refers to bodies and **other organisations** who use or rely on accredited conformity assessment services.

1.3.5 Logo of the Accreditation Body

Logo used by an accreditation body to identify itself.

1.3.6 Surveillance

Set of activities, except reassessment, **which are undertaken** to monitor the continued fulfilment by accredited CABs of requirements for accreditation.

Note: Surveillance includes both on-site assessments and other surveillance activities such as the following:

- enquiries from the accreditation body to the CAB on aspects concerning the accreditation,
- requests to the CAB to provide documents and records (e.g. results of internal audits, management reviews, records, complaints/appeals records, **copies of conformity certificates issued under certification**, updated list of personnel – in laboratory; inspectors; auditors/assessors, updated list of certified clients, list of consultants, updated list of those inspecting results of internal quality control);
- monitoring the performance of CABs (such as results of participating in inter-laboratory comparisons, PT schemes, etc.),
- **reviewing correctness of the use of the accreditation symbol and reference to accreditation.**

1.3.7 Assessment

Process **undertaken** by an accreditation body to assess the competence of a CAB on the basis of specific standard(s) and/or other normative documents for the defined scope of accreditation.

Note: Conformity assessment of a CAB involves competence assessment of the entire operations of the CAB, including competence of the personnel, validity of the conformity assessment methodology and validity of the conformity assessment results.

1.3.8 Accreditation Withdrawal

Process of cancelling accreditation in full.

1.3.9 Witnessing

Observation of the conformity assessment body **carrying out** conformity assessment **activities** within requested/**granted** scope of accreditation.

1.3.10 Scope of Accreditation

Specific conformity assessment services for which accreditation is sought or has been granted.

1.3.11 Complaint

Expression of dissatisfaction, other than appeal, by any person or organisation, to an accreditation body, relating to the activities of that accreditation body or of an accredited CAB where a response is expected.

1.3.12 Extending Accreditation

Process of enlarging the scope of accreditation.

1.3.13 Accreditation Certificate

A set of documents stating that accreditation is granted for the **defined scope of accreditation (list of accredited conformity assessment activities)**.

1.3.14 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 text reference to accreditation and it can also refer to ATS status as a signatory to the multilateral agreements on **mutual recognition** instead of using the accreditation symbol.

1.3.15 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.

1.3.16 Reducing Accreditation

Process of cancelling accreditation for part of the scope of accreditation.

1.3.17 Suspending Accreditation

Process of temporarily making accreditation invalid, in full or for part of the scope of accreditation.

1.3.18 Conformity Assessment Body (CAB)

Legal entity **holding legal responsibility** or part thereof, which performs conformity assessment services, including testing, calibration, certification, inspection, **verification and validation or proficiency testing**.

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

1.3.19 Certificate of Conformity

Test report, calibration certificate, certificate, inspection report **or** certificate, **verification/validation report, proficiency testing report** issued by an accredited conformity assessment body for the activities covered by the scope of accreditation that was granted.

1.3.20 International Organisations

International organisations that ATS is a member of: European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation cooperation (ILAC).

2 INTRODUCTION

2.1 General Background on Accreditation

Accreditation is a means to establish trust on the market of products and services since it presents an independent and impartial competence evaluation 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 providers for proficiency testing of laboratories** whereby ensuring trust in testing, calibration, inspection, certification, **verification and validation** activities that were performed.

Active ATS participation in the European and **international** organisations for accreditation and harmonisation 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**.

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

1. Law on Technical Requirements for Products and Assessment of Product Conformity with the Prescribed Requirements (“Official Gazette of the RS”, No. 36/09)
2. Law on Metrology (“Official Journal of the RS”, No. **15/2016**)
3. Law on Standardisation (“Official Journal of the RS”, No. 36/09 **and 46/15**)
4. Law on Accreditation (“Official Journal of RS”, No. 73/10).

ATS is one of four components of quality infrastructure in the Republic of Serbia.

2.2 Accreditation Body of Serbia

2.2.1 General Data:

Full name: Akreditaciono telo Srbije

Abbreviated name: ATS

English version of the name: Accreditation Body of Serbia

Legal status: institution

Head Office: **Vlajkovićeve 3, 11000 Beograd 6, PO Box 92, Srbija**

Phone No: +381 11 3130-373

Fax No: +381 11 3130-374

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 (“Official Journal of the RS”, No. 73/10), to perform accreditation activities. ATS was established by the Republic of Serbia, whereas the Government of the Republic of Serbia, under statutory powers, exercise the rights of the Republic of Serbia.

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

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;
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 organisations for accreditation;
4. keep a public Register of Accredited Conformity Assessment Bodies;
5. participate in the work of international and European organisations for accreditation;
6. organise and deliver training to assessors in the field of accreditation;
7. organise seminars and training courses, and promote the importance and role of accreditation;
8. perform other activities in the field of accreditation in accordance with the Law on Accreditation, Act on Establishment and Statute.

The Founder shall be held responsible for the obligations of ATS should ATS fail to meet its obligations by using its assets or if the work of ATS would be seriously jeopardised by using its assets to meet its obligations.

2.2.4 ATS Logo and Accreditation Symbol

ATS has its own logo that is used for the identification thereof and it is the intellectual property of the ATS. It is used in accordance with the *Rules for the Use of ATS Logo*.

ATS delivers, in addition to the accreditation certificate, **an accredited conformity assessment body** the accreditation symbol to indicate its status of accredited conformity assessment body. 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*.

2.2.5 ATS Organs and Bodies

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

Organs of the Accreditation Body of Serbia are as follows: Management Board, Director and Supervisory Board.

The Management Board has a president and four members appointed and dismissed by the founder, i.e. the Government of the Republic of Serbia. Two members of the Board of Directors are proposed by the founder, two members are proposed by the Association of Accredited Bodies for Conformity Assessment, from the accredited conformity assessment bodies, and one member is selected from the employees of the ATS. The Supervisory Board is the body of control over the legality of work and financial operations of the ATS, which reports for its work to the Management Board, in accordance with the law and the Act on the Establishment of ATS. The chairman and members of the Supervisory board are appointed and dismissed by the founder.

ATS expert bodies are Accreditation Council and technical committees.

Prominent experts and scientific workers in areas of importance for the performance of tasks within the competence of the ATS are selected as members of the Accreditation Council, as representatives of stakeholders. Members of the Council are appointed and dismissed by the Management Board.

Technical committees are technical bodies that carry out expert tasks for certain areas of accreditation, ie conformity assessment. Technical committees as standing or temporary professional bodies shall be established by the Director upon the proposal of the Council. Standing Technical Committees are formed for certain types of accreditation. Temporary Technical Committees shall be formed, if necessary, to work on specific and professional issues from particular fields of accreditation.

Mode of the establishment of the ATS organs and bodies, their activities, selection of organ 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.

2.2.6 Internal Organisation

Internal organisational structure of ATS is set forth in the By-Law on Internal Organisation and Functional Titles and Job Descriptions that is passed by the ATS Director and agreed by the Management Board.

2.2.7 Management system

The ATS management system is based on the requirements of SRPS ISO / IEC 17011, the requirements of Regulation 765/2008 / EC, or the Law on Accreditation, and the corresponding binding EA / IAF / ILAC documents.

In accordance with the competences defined by the ATS Statute, the Director defines and documents the policies and objectives of the ATS, including the quality policy. ATS establishes, applies and maintains a management system and continuously improves its efficiency in accordance with the requirements of SRPS ISO / IEC 17011.

Quality Manager is responsible for establishing and maintaining ATS management system and for reporting to ATS top management on the performance of the management system, and on any need for improvement, in accordance with the requirements of SRPS ISO / IEC 17011. Quality Manager the responsibility and authority to ensure that the management system documents are established and report to the top management on the performance of the management system and any need for its improvement.

2.2.8 Human resources

ATS has at its disposal a sufficient number of competent staff for the proper performance of duties within its competence. ATS human resources include: permanently employed staff and external engaged assessors and technical experts, as well as engaged experts for the accreditation decision-making process.

ATS documented the duties, responsibilities and authorisation of staff that could affect the quality of assessment and confirmation of competence of the conformity assessment bodies.

ATS has established, implemented and maintained procedures for monitoring the work and competence of the relevant staff involved in the accreditation process, by applying the procedure for selection and monitoring the performance of persons participating in the accreditation process.

2.2.9 Financing

Financial resources used for the operation of ATS shall be provided by:

1. charging accreditation fees;
2. using budget assets of the Republic of Serbia;
3. using the assets coming from other sources as stipulated in the law.

Charging the accreditation fees shall mean obtaining financial resources from the revenue being realised 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 on the basis of activities defined in the ATS Annual Work Programme.

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 organisations 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 Cooperation for Accreditation (EA, www.european-accreditation.org) and on 24th May 2012 it became its full member. On 24th May 2012 ATS signed the multilateral agreement (EA MLA) of EA 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 agreement which included, in addition to testing including medical laboratories, calibration, inspection certification of products, certification of management systems and certification of persons.

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 (Mutual Recognition Agreement) for calibration, testing and inspection, and to the Multilateral Agreement (IAF MLA) for the field of product certification, whereas on 6th October 2014 ATS signed IAF MLA for the field of certification of management systems, (Sub-scopes: Level 4: Nil, Level 5: ISO 9001, ISO 14001), and on 20th October 2016 it became a signatory of IAF MLA for the field of certification of persons sub-scope “-“.

The ATS representatives, as a signatory to multilateral agreements on mutual recognition, participate in the work of international organisations for accreditation (EA, ILAC and IAF), General Assembly meetings, Technical Committee meetings and Working Group meetings.

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 Accreditation Criteria

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

- Law on Accreditation;
- Serbian standards **transposing international or European harmonised standards**, that contain general criteria or requirements that need to be met by conformity assessment bodies for certain types/fields of accreditation;
- 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;
- rules of accreditation.

The List of Documents Containing Requirements to Be Met by Accredited Conformity Assessment Bodies is also available on request and on the ATS internet **portal** www.ats.rs.

In addition to these Rules, ATS shall keep all relevant information about accreditation criteria up to date on ATS internet **portal** and they shall also be available on request.

In case of any changes in the accreditation criteria, ATS shall inform conformity assessment bodies thereof, and of a transitional period during which the bodies are obliged to make necessary adjustments to conform to the changed criteria.

3.2 Interpretations and Guidelines

Accreditation and surveillance activities are fully performed in line with the requirements laid down in the documents referred to in point 3.1 of these Rules.

When performing accreditation activities from its scope of work, ATS adheres 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 instructions for use, is required, ATS will provide adequate interpretation **by engaging expert bodies** in cooperation with interested parties.

3.3 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 they come in contact with when performing activities on behalf of ATS. In case of legal obligation to publish those data, ATS shall inform in writing the interested parties thereof.

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 laid down by ATS.

3.4 Accreditation Procedure

Pursuant to its non-discriminatory policy, ATS shall accept and review all the applications for accreditation submitted by conformity assessment bodies interested in accreditation if the said process is within the scope of the ATS activities. ATS shall, as a rule, perform the accreditation procedure within 12 months from the date on which the contract was signed with a conformity assessment body.

A conformity assessment body can, at any point in time, drop the accreditation procedure. **If a CAB drops accreditation before on-site assessment, ATS shall make a decision on termination of accreditation procedure.**

3.5 Accreditation Scope

A conformity assessment body submits the application for accreditation for **conformity assessment activities** (the scope of accreditation) that it deems it is competent for. This scope of accreditation shall be harmonised in the initial phase of accreditation procedure and shall be finally determined during the assessment procedure **and accreditation decision-making** which includes mandatory witnessing as laid down in the rules.

Guidelines for the formulation of scopes of accreditation for conformity assessment bodies are available on the ATS internet **portal** www.ats.rs and on request.

3.6 Locations

During initial assessments and reassessments all other sites belonging to **conformity assessment bodies** performing one or more key activities included in the scope of accreditation shall be **visited** apart from the CAB head office.

The key activities for different types of conformity assessment bodies are stipulated in line with the document entitled IAF/ILAC A5:11/2013, Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004.

Among other things, the key activities performed by conformity assessment bodies include: policy formulation, process and/or procedure development and, as appropriate, contract review, conformity assessment planning, review and approval of and decision on the results of conformity assessments.

In case of surveillance assessment of a conformity assessment body performing its **accredited conformity assessment activities** at different locations, ATS shall, **in line with** the established planning procedure for surveillance activities, **assess** all locations at least once again during the accreditation validity period.

3.7 Accreditation Procedure-related Terminology

ATS shall conduct the accreditation procedure in Serbian. In case of cross-frontier accreditation, i.e. in case of recruitment of a foreign assessor in **the assessment team**, the assessment or part of the assessment shall be carried out in English **language** or in the language agreed in advance of the assessment.

3.8 Accreditation Fees

Conformity assessment bodies have 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.

3.9 Transfer of Accreditation

If the status of an accredited conformity assessment body is changed, ATS shall transfer accreditation to the legal successor to the conformity assessment body provided that the former:

- accepted the policy and management system procedures of the conformity assessment body;
- kept the key personnel of the conformity assessment body;
- kept conformity assessment methods and procedures used by previously accredited conformity assessment body and that it implements the said methods and procedures;
- kept equipment and appliances, and facilities of the conformity assessment body that are needed and sufficient for a competent performance of conformity assessment activities.

If it is necessary to transfer accreditation, the accredited conformity assessment body shall make a formal request to ATS. The said request shall contain the following:

- rationale behind the request for accreditation transfer;
- clear and precise description of the new legal status, and of all relevant document 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 defined deadline for updating quality manual, documented procedures and other documents in accordance with the changes that were made;
- where applicable information about updating necessary contracts with employees, contracts with subcontractors, etc.

ATS shall, depending on the changes that were made, decide whether to make a decision on the transfer of accreditation on the basis of submitted documents or whether to make an adequate decision after obtaining additional information or after a surveillance assessment has been carried out.

3.10 Accreditation for the purpose of designation/authorization of conformity assessment bodies

ATS as a signatory to the EA MLA, observes the policy agreed in the EA for the accreditation of conformity assessment bodies, by the national accreditation bodies which is the basis for notification by the Notifying Authorities, that should perform activities within EU regulations for harmonization and which is contained in the document entitled *EA Document on Accreditation for Notification Purposes (EA-2/17 M: 2016)*.

ATS will use the established requirements in the specified document when accrediting the CABs that will request, based on ATS accreditation, to apply for notification for conformity assessment activities in accordance with the harmonised EU legislation, and until the conditions for CAB notification are met in the Republic of Serbia ATS shall use the requirements of the said document when accrediting CABs that will require, on the basis of ATS accreditation, the designation/authorisation to carry out conformity assessment activities in accordance with the regulations of the Republic of Serbia, transposing the legislation of harmonised European Union legislation (earlier directives of the new approach).



Namely, the Law on Technical Requirements for Products and Conformity Assessment ("Official Gazette of the Republic of Serbia" No. 36/09), on the basis of which the regulations of the harmonised legislation of the European Union are adopted, defines regulation of the technical requirements for products as well as conformity assessment of products with proscribed technical requirements. When a technical regulation establishes that conformity assessment is conducted by a designated CAB or an authorized CAB for the needs of state administration bodies, the Law stipulates that in assessing the fulfilment of proscribed requirements for the designation/authorization of CABs, the responsible Minister shall also take into account the Accreditation Certificate that the CAB obtained in the accreditation procedure.

The basic objective of accreditation, when used as a means of supporting the notification of CABs for performance of conformity assessment activities in accordance with harmonized EU legislation, i.e., for carrying out conformity assessment activities in accordance with the regulations adopted on the basis of the Law on Technical Requirements for Products and Conformity Assessment, is to create confidence that relates to: competence, impartiality and consistency of the CAB, as well as the fulfilment of the requirements by the CABs prescribed in every technical regulation of the Republic of Serbia transposing the regulation of harmonized EU legislation.

In order to achieve the said objective, ATS shall, based on *EA Document on Accreditation for Notification Purposes (EA-2/17 M: 2016)*, and in cooperation with the ministry relevant for designation/authorization of CABs, identify standards which are appropriate to be used for accreditation, taking into consideration conformity assessment activities which a CAB is seeking accreditation for. In addition to requirements from the standard for accreditation, in the accreditation procedure ATS will evaluate meeting requirements for CABs, stated in the relevant technical regulation for which the applicant is seeking accreditation. Accreditation Certificate shall solely refer to relevant accreditation standard, and accreditation scope shall be described in accordance with the document entitled *EA Document on Accreditation for Notification Purposes (EA-2/17 M: 2016)* and relevant guides for the formulation of scopes of accreditation.

4 INITIAL ACCREDITATION

4.1 Getting Informed about the Accreditation Procedure

All the information about the rules of accreditation, **accreditation procedure**, **accreditation fee**, documentation necessary for the commencement of the accreditation procedure, and accreditation Application form can be found on the ATS internet **portal**.

ATS shall provide a conformity assessment body with the documentation necessary for the commencement of the accreditation procedure and the accreditation Application form at the written request of the conformity assessment body.

A briefing meeting may be organised **in ATS premises** at the request of a conformity assessment body to determine whether an activity performed by the conformity assessment body may be subject to accreditation **or** whether the applicant for accreditation's intention is in accordance with the ATS scope of work and policy.



4.2 Submitting and Reviewing the Application for Accreditation

4.2.1 Submitting the Application for Accreditation

The accreditation procedure is initiated when a conformity assessment body submits the application in paper and electronic format.

The following documents/information shall be submitted by a conformity assessment body together with the completed accreditation Application form: clearly formulated scope of sought accreditation, description of conformity assessment services that a conformity assessment body performs and the list of standards, methods or procedures a conformity assessment body seeks accreditation for, copy of the Quality Manual and relevant accompanying documents and records such as information about participation in inter-laboratory comparisons and PT schemes if any. For each type of accreditation documents/information that are **mandatory** to be submitted **together with the Application for accreditation** shall be specified **in detail** in the Application for accreditation form.

4.2.2 Reviewing the Accreditation Application and ATS Resources

An application for accreditation with accompanying documentation shall be filed by the ATS employees in an appropriate manner. Completeness and adequacy of each application for accreditation that was submitted and the accompanying documentation shall be reviewed. In case of submission of incomplete documentation, ATS will ask the conformity assessment body to complete the application. The missing documentation can be added only twice. If the conformity assessment body fails to submit fully completed application after **two completions**, ATS shall not accept the application and in that case the conformity assessment body has the right to appeal.

After the application for accreditation has been fully completed, it shall be reviewed when the adequacy and clarity of information submitted by the applicant for accreditation shall be determined, including the legal status of the applicant for accreditation, adequacy of the activity performed by the conformity assessment body that **the accreditation is sought for** and if **accreditation** for the activity for which the **accreditation** is sought is in the scope of the ATS activities. ATS shall assess its own competence-**capacity** to perform the assessment of the conformity assessment body in terms of its policy, competence and availability of adequate assessors and experts **and other necessary resources**, and its capacity to perform the initial assessment **and grant accreditation** on time.

If after the review, ATS cannot accept an accreditation application (e.g. if the scope of accreditation is outside the scope of the ATS activities or for any other justifiable reason), the conformity assessment body shall be informed thereof in writing with an adequate explanation of the reasons for **refusal of application**.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision to refuse the application.

4.2.3 Contracting

After the application for accreditation has been accepted by ATS, mutual queries related to the accreditation procedure, issuance of the accreditation certificate, accreditation maintenance, and accreditation fees shall be stipulated in a contract concluded between ATS and a conformity assessment body. The Contract shall stipulate rights and obligations of the Contracting Parties **and other issues related to accreditation, accreditation procedure, granting accreditation act, maintenance of accreditation, accreditation costs**. **The accreditation contract is concluded with the**



conformity assessment body - the legal entity that submitted the Application for accreditation, and the contract can state, when needed, the organisational unit of the applicant for accreditation wherein accredited activities will be performed. The Contract shall, on behalf of the conformity assessment body, be signed by the authorised representative of the legal entity. The Contract shall be legally binding from the date on which the contract was signed by the ATS Director. In case when the authorised representative of the legal entity fails to sign the Contract, ATS shall make a decision on accreditation procedure termination.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision to terminate the accreditation procedure.

4.2.4 Preliminary Visit

When completing an Application for accreditation, a conformity assessment body may wish for a preliminary visit to take place during which its readiness to continue with the assessment procedure shall be assessed, while the conformity assessment body shall bear the prescribed costs.

A preliminary visit shall be performed with the aim of:

- gaining an insight into the conformity assessment body's organisational 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 quality of documentary capacities of the management system as regards the requirements of reference documents for the accreditation of conformity assessment bodies;
- evaluating the duration, scope and necessary resources for performing the assessment.

Minutes on the preliminary visit shall be produced and submitted to the conformity assessment body.

The deadline for commencing the performance of the follow-up activity related to the accreditation procedure shall not be longer than 3 months from the date of the preliminary visit. If the conformity assessment body fails to inform ATS about its willingness to continue with the accreditation procedure, it shall be deemed that it is no longer interested in continuing the accreditation procedure and ATS shall make a decision to terminate the accreditation procedure.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision to terminate the accreditation procedure.

4.3 Preparation for the Assessment

4.3.1 Appointment of the Assessment Team

The ATS assessment team shall be appointed according to the size of the conformity assessment body and diversity of fields and scopes of the conformity assessment activities the accreditation is sought for. The assessment team is composed of a lead assessor, relevant number of assessors/technical assessors and/or technical experts for each of the conformity assessment field.

ATS shall notify, in a timely manner, the conformity assessment body of the names of the assessment team members and organization in which they are employed, in order to enable the conformity assessment body to send a remark to the appointment of a specific team member. In case of written objections to certain members, those objections will be reviewed and if it is determined that the objection was justifiably raised, the new assessment team/Team Leader/team

member will be appointed. If the conformity assessment body does not approve the newly appointed assessment team, ATS shall propose appointment of assessors/experts from accreditation bodies that are signatories to the multilateral agreements instead of the team member whose appointment was objected to. If the conformity assessment body does not even approve the newly appointed assessment team composed of foreign assessors/experts, ATS will make a decision on the termination of the accreditation procedure.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision 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 own resources to perform the accreditation procedure, 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.

4.4 Assessment

The assessment procedure shall be performed by the appointed assessment team by means of a phased approach: documentary review and on-site assessment that also includes witnessing the implementation of the conformity assessment procedures.

4.4.1 Documentary Review

Documentary review shall be performed by the assessment team. Documentary reviews show whether the documentation is in conformity with the requirements of reference documents relating to the type/field and scope of accreditation that was sought. Nonconformities and/or shortcomings identified in this phase shall be eliminated within the defined deadline. If the conformity assessment body fails to submit evidence on time that the said nonconformities and/or shortcomings were eliminated, ATS shall ask the conformity assessment body to submit a written explanation of its intention to proceed with the accreditation procedure.

If the conformity assessment body fails to submit the explanation on the continuation of the accreditation procedure within the defined deadline, i.e. if it fails to submit evidence, it shall be considered that it gave up further accreditation procedure and ATS shall make a decision to terminate the accreditation procedure.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision to terminate the accreditation procedure.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision to terminate the accreditation procedure.

4.4.2 On-site Assessment

An assessment plan shall be drafted for each assessment and the date of an on-site assessment shall be agreed with the conformity assessment body. The plan of assessment shall, in addition to other elements, contain clearly listed conformity assessment procedures from the sought accreditation scope that will be subjected to witnessing by the ATS assessment team.

Witnessing may be performed at the location of the conformity assessment body and/or locations where it performs the conformity assessment activities it sought the accreditation for. When witnessing of planned and arranged conformity assessment activities cannot be performed during on-site assessment, it shall be planned separately – before or after the assessment at a location. Selection of representative samples of conformity assessment activities that shall be subjected to witnessing shall be made in accordance with the witnessing criteria laid down in the guide



determining locations where assessment will be performed, number of assessment days, and the selection of representative sample of conformity assessment activities falling in the accreditation scope that will be subject to witnessing.

An on-site assessment shall be performed in accordance with the ATS assessment procedure for conformity assessment bodies which includes an opening meeting, assessment and a closing meeting. At the opening meeting all data relevant to the assessment procedure and further direction of the accreditation procedure shall be explained to the conformity assessment body's representatives, including the obligations related to confidentiality safeguarding. Furthermore, the assessment plan and scope shall be confirmed at this meeting.

During the assessment the conformity assessment body shall enable the ATS assessment team to gain an insight into all relevant documents, access to all facilities connected to conformity assessment activities the accreditation is sought for, and it shall provide **interview** with all members of the staff involved in the assessment activities.

At the closing meeting the assessment team shall inform the conformity assessment body's representatives about the assessment findings, including the findings relating to identified nonconformities **and/or concerns**, if any, procedure related to the elimination of identified nonconformities **and/or concerns**, and recommendations of the assessment team **as regards decision on accreditation**. The conformity assessment body shall be able to ask questions or request the **assessment team** findings to be explained. The Team Leader shall **produce** the Closing meeting minutes that shall **contain** basic information about the on-site assessment, **reference to** the list of identified nonconformities **and/or concerns (List of findings)** and recommendation of the assessment team. The minutes shall be signed by the Team Leader and the conformity assessment body's representative. If both parties cannot find a mutually acceptable understanding or come to an agreement as regards the identified nonconformities **and/or concerns** or recommendation of the assessment team **as regards decision on accreditation**, the Team Leader shall record that in the minutes. Representatives of the conformity assessment body shall put forward their opinion on the assessment findings, and in case of any disagreement between their findings and those of the assessment team, the conformity assessment body can forward the rationale for their disagreements to ATS.

After an on-site assessment has been performed, the assessment team shall produce the assessment report to be submitted to the conformity assessment body that was assessed.

4.4.3 Elimination of Nonconformities

When nonconformities are identified during an assessment, a conformity assessment body shall, within the defined deadline, submit the proposed corrective actions that will eliminate the identified nonconformities and those will include the analysis of the cause of nonconformities. If the Team Leader and assessment team members find that the proposed corrective actions are not adequate, the conformity assessment body shall define the new corrective actions within the new deadline. The deadline for the elimination of nonconformities shall not be longer than four months in case of initial assessments, starting from the date of the approval of the proposed corrective actions as regards the elimination thereof. In all other cases the deadline for elimination of all nonconformities shall not be longer than two months.

A conformity assessment body shall, within the defined deadline, inform ATS in writing about the elimination of identified nonconformities and it shall submit evidence to confirm that corrective actions **or elimination of nonconformities** were undertaken.

The assessment team shall confirm whether the identified nonconformities were eliminated in an appropriate manner. A procedure to confirm the elimination of nonconformities may **be performed** either by **reviewing and assessing** submitted written evidence and/or follow-up assessment.



If the corrective actions **for the elimination of nonconformities** cannot be defined within the defined deadline, i.e. if the nonconformities cannot be eliminated within the defined deadline or if these are considered as inadequate, ATS shall make a decision not to grant accreditation, while the procedure can be re-instigated by submitting a new application for accreditation.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision not to grant accreditation.

When concerns are identified during assessment, the conformity assessment body is obligated to submit within the defined deadline the proposal of actions and deadlines for elimination of the established concerns, which includes an root cause analysis of concerns. If the team leader and members of the assessment team do not evaluate the proposed actions and deadlines as adequate, conformity assessment body shall have an additional deadline to define a new proposal for actions.

The assessment team shall confirm whether the identified concerns have been eliminated to a satisfactory level, during the subsequent assessment of the conformity assessment body. If it finds then that the identified concern has not been eliminated, then in relation to that requirement nonconformity can be established.

4.5 Granting Accreditation

4.5.1 Assessment Team's Recommendations

After the assessment activities have been carried out and after it has been verified that the nonconformities were eliminated, **or after it has been confirmed that proposed actions and deadlines for elimination of established concerns are appropriate**, the assessment team shall make a recommendation on accreditation in the *Summary Assessment Report and/or Annex to the Summary Assessment Report*.

4.5.2 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 the ATS permanent employees that did not take part in the **assessment the findings of which is being decided** and external experts providing the needed technical expertise in keeping **with fields of** conformity assessment subject to accreditation decision-making.

The Accreditation Committee shall review the information from the file prepared for decision-making process, determine whether it is complete, and evaluate its clarity, comprehensiveness and sufficiency of information on the basis of which a decision on accreditation shall be made in accordance with the **written** procedure governing accreditation decision-making and granting. If the Committee finds that there is not sufficient information to make an adequate proposal for the decision to be made, it will ask for additional information **from assessment team or assessed conformity assessment body** which may include an additional assessment.

The conformity assessment body has the right to appeal **to the adverse** decision on accreditation.

The accreditation procedure can be re-instigated after the new application for accreditation has been submitted.

4.5.3 Accreditation Certificate and Reference to Accreditation

If it is determined after the accreditation procedure that the conformity assessment body 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 a conformity assessment body**. In addition to the Accreditation certificate, ATS shall give conformity assessment bodies the permission 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*. The Accreditation certificate shall be valid for four years.

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

4.6 Register of Accredited Conformity Assessment Bodies

ATS shall keep the public Register of Accredited Conformity Assessment Bodies which contains the following data:

1. accreditation number;
2. name and address of an accredited conformity assessment body, including its locations **wherein it performs accredited activities or wherein it performs key activities**;
3. basic information about the accredited conformity assessment body;
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. name of the contact person;
7. valid scope of accreditation.

The Register shall be made publicly available on the ATS internet **portal** www.ats.rs.

4.7 Documents of Accredited Conformity Assessment Bodies Kept by ATS

During the accreditation validity period ATS shall keep the documentation of accredited conformity assessment bodies that was submitted together with the application for accreditation and all the records relating to assessment procedure **and accreditation decision-making** performed during the accreditation validity period, **or during accreditation cycle**.

5 SURVEILLANCE

5.1 General Background

ATS shall carry out surveillance of accredited conformity assessment bodies to ensure that defined requirements relating to the activities the accreditation was granted for are regularly fulfilled.



Surveillance of accredited conformity assessment bodies shall include surveillance assessments and other surveillance activities.

Surveillance assessments shall be performed on-site or at the head office(s) of an accredited conformity assessment body and/or locations where accredited activities are performed in order to confirm that an accredited conformity assessment body performs its activities in accordance with the accreditation criteria.

Surveillance activities shall be carried out by ATS on a continuous basis throughout the accreditation validity period - **cycle**, and they shall include the collection and analysis of all the information of relevance to the accreditation status maintenance or work of an accredited conformity assessment body **relating to observance of criteria and requirements for accreditation and rules of accreditation**.

5.2 Surveillance Assessment Types

There are two types of surveillance assessments - regular and extraordinary ones.

5.2.1 Regular Surveillance Assessments

Regular surveillance assessments shall be performed in accordance with the accredited conformity assessment body surveillance assessment plan. An accredited conformity assessment body shall **enable implementation of surveillance activities within planned deadlines and** provide conditions for the performance of surveillance assessments. If not, ATS can undertake actions to suspend or withdraw accreditation.

During each surveillance assessment observance of requirements of the rules of accreditation shall be verified, as well as the results of management reviews, internal audit reports, results of corrective and preventive actions that were undertaken, resolution of appeals and complaints, results of the participation in inter-laboratory comparisons and PT schemes, and issued certificates of conformity **under accreditation**. During the accreditation validity period regular surveillance assessments shall serve as a means to assess the entire scope of accreditation and whether all requirements were met. During the accreditation validity period the fulfillment of all requirements is being assessed by regular surveillance assessments and **representative conformity assessment activities are being witnessed** for the entire scope of accreditation.

5.2.2 Extraordinary Surveillance Assessment

If need be, extraordinary surveillance assessments shall be conducted when:

- complaints or written objections to the work of an accredited conformity assessment body were raised;
- changes take place in an accredited conformity assessment body that may affect the **meeting of conditions** under which the accreditation was granted **and requirements from referent standards for accreditation** (change in the legal status, **inner** organisation, managerial structure, conformity assessment procedures, technical and human resources, etc.);
- after the suspension, it is necessary to assess **and verify** whether an accredited **suspended** conformity assessment body can meet the accreditation criteria **and requirements** again;
- **when** ATS obtains, **during performance of regular surveillance activities**, certain information and **knowledge** about an accredited conformity assessment body that can affect the status of granted accreditation or observance of the ATS rules by a conformity assessment body.



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

5.3 Regular Surveillance Assessments

5.3.1 Timeframe of Regular Surveillance Assessments

First regular surveillance assessment shall be carried out 6 to 9 months after the accreditation has been granted and, by exception, 12 months if accreditation is a prerequisite for designation/authorisation, second regular surveillance assessment shall be carried out 18 to 21 months after the accreditation has been granted, while the third one shall be carried out 30 to 33 months after **the date** the accreditation has been granted.

5.3.2 Preparation for Surveillance Assessments

An accredited conformity assessment body shall be informed about regular surveillance assessments at least three months before the planned date of assessment.

ATS shall appoint an assessment team to perform regular surveillance assessment depending on the activities set forth in the Surveillance Activity Plan. When possible, the Team Leader shall remain the same throughout the accreditation validity period.

5.3.3 Documentation Analysis

After gaining an insight into documentation needed for regular surveillance visits, the following shall be analysed:

- reports from previous assessments with accompanying records;
- potentially submitted management system documentation in case of any changes **in documentation**;
- records on participation in PT schemes and inter-laboratory testing;
- records on internal audits and management reviews;
- records on complaint and appeal resolution, **if there were any**;
- communications submitted by an accredited conformity assessment body as regards changes affecting the conditions under which the accreditation was granted.
-

5.3.4 Surveillance Assessment

Every time when an on-site surveillance assessment is performed, the following shall be performed:

- assessment of the efficiency of corrective actions that were undertaken to eliminate nonconformities identified during previous assessments;
- assessment of the results of performance of internal audits and management reviews;
- confirmation of the members in the team and status of the staff involved in conformity assessment procedure;
- assessment of equipment condition and application of policy relating to traceability of measurement, results of the participation in inter-laboratory comparisons and PT schemes;



- assessment of the activities such as document control, purchasing, training programme, control of certificates of conformity, etc. in accordance with a defined plan;
- witnessing of conformity assessment activities in accordance with a defined plan.

5.3.5 Reporting

After a surveillance assessment has been carried out, an assessment report shall be produced.

5.3.6 Accreditation Maintenance Decision-making

Following the recommendation of the assessment team, i.e. proposal made by the Accreditation Committee, and in accordance with the **written** procedure for accreditation decision-making and granting accreditation, the adequate decision shall be made on accreditation maintenance, change in the scope **of accreditation**, accreditation suspension or withdrawal.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision.

6 ACCREDITATION RENEWAL

6.1 General Background

An accredited conformity assessment body wishing to renew its accreditation shall inform ATS in writing thereof at least 9 months prior to the expiry of the current accreditation and it shall submit the application for accreditation with accompanying documentation. As a general rule, reassessment performed during accreditation renewal shall be performed at least 6 months before the expiry of accreditation validity period.

If, for justified reasons, the accredited conformity assessment body does not submit the Application for renewal of accreditation with accompanying documentation 3 months before the expiration of the valid accreditation, the ATS will not implement the accreditation renewal process, and the conformity assessment body can file an Application for Accreditation, which will be settled in accordance with Chapter 4 of these Rules.

Reassessment shall be carried out in the same manner as the initial assessment, whereas preliminary visit will not be performed.

6.2 Decision on Accreditation Renewal

Accreditation renewal decision-making shall be performed in the same manner as accreditation granting decision-making.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision not to renew accreditation.

6.3 Extension of the Accreditation Validity Period

If an accredited conformity assessment body submitted an application to ATS to renew accreditation within the defined deadline, and a decision on accreditation renewal was not made before the expiry of the current accreditation and when the delay was caused by ATS, the ATS Director can make a decision on extending the accreditation validity period **until the decision-making on accreditation renewal** and that shall not be longer than 3 months from the expiry of the current accreditation.



7 CHANGES IN THE ACCREDITATION SCOPE

7.1 Extending the Accreditation Scope

In order to extend the scope of accreditation, an accredited conformity assessment body can submit an application at any point in time during the accreditation validity period, **which also includes extension of the accreditation scope in the accreditation renewal process, but in this case the application for extension of the scope of accreditation is not submitted. Instead, the conformity assessment activities for which the conformity assessment body has not been accredited are identified in the requested scope of accreditation.** ATS shall review the application relating to the extension of scope the conformity assessment body applied for and shall make a decision on whether the assessment for the purpose of extending the scope of accreditation shall be performed during a regular surveillance assessment/**reassessment** or as a separate procedure, **at the request of a conformity assessment body.**

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

7.2 Reducing the Accreditation Scope

Accreditation scope of an accredited conformity assessment body can be reduced at the request of a conformity assessment body or on the recommendation of the assessment team, **after finishing** the assessment procedure **or** on the basis of the proposal made by the Accreditation Committee.

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

8 SUSPENSION OF ACCREDITATION

8.1 Accreditation Suspension on Request

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

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

If no conditions allowing the termination 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 conformity assessment body has the right to appeal if it is not pleased with the ATS decision to reduce the accreditation scope or withdraw accreditation.

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

8.2 Compulsory Suspension

ATS can suspend the accreditation on the basis of surveillance activities, nonobservance of contractual obligations, 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 entire scope of accreditation. Exceptionally, if accreditation is a prerequisite for designation/ authorization, and there is a change in the regulations governing the subject area of conformity assessment, ATS can issue a new decision on the suspension of accreditation for more. For a maximum of six months, **until the conformity assessment body adapts to the altered regulations**. An accredited conformity assessment body should, in the form of a written request, request, at least two months before the accreditation suspension period expiry, the suspension to be terminated. Compulsory suspension can be withdrawn on the basis of the results of an extraordinary surveillance assessment or on the basis of adequate evidence that was submitted confirming elimination of circumstances that caused the suspension.

The conformity assessment body 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 TERMINATION OF ACCREDITATION

9.1 Dropping Accreditation

An accredited conformity assessment body 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 can withdraw accreditation that was granted on the basis of surveillance activities, nonobservance of contractual obligations, assessment results or from the proposal of the Accreditation Committee. **In particular, ATS will initiate the process of withdrawing accreditation if during surveillance activities it becomes known that the conformity assessment body intentionally provides false information about its accreditation, or misuses accreditation or arbitrarily violates accreditation rules**. A conformity assessment body the accreditation of which was withdrawn shall, immediately after the accreditation withdrawal, 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 **after accreditation withdrawal**.

The conformity assessment body has the right to appeal if it is not pleased with the ATS decision on accreditation withdrawal.

The conformity assessment body the accreditation of which was withdrawn can submit new application for accreditation thereafter.



10 COMPLAINTS AND APPEALS

10.1 Complaints

Complaints made by any person or organisation that are related to the ATS activities or activities of an accredited conformity assessment body shall be dealt with by the ATS Director in accordance with **the written** procedure for the resolution thereof.

ATS shall:

- review whether a complaint is justified;
- ensure, where appropriate, that a complaint is first reviewed by an accredited conformity assessment body in the light of the complaint related thereto;
- undertake appropriate actions and assess their effects;
- keep records of all complaints and actions that were undertaken, and
- reply to a person filing a complaint.

Complaints that ATS receives and that pertain to conformity assessment bodies accredited by another accreditation body shall be forwarded to the respective accreditation body.

10.2 Appeals

An appeal can be lodged to ATS against accreditation decisions within 15 days after the decision has been delivered. 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 Conformity Assessment Bodies

It is the obligation of an accredited conformity assessment body, when performing its activities, to adhere to the established organisation, 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 conformity assessment body to enable ATS and its representatives to monitor compliance with the rules of accreditation and relevant accreditation criteria including, but not limited to:

- access to all relevant areas of work of an accredited conformity assessment body including the necessary arrangements **for evaluation of conformity with accreditation rules** at all locations where accredited activities are performed;
- make the documents and records pertaining to the conformity assessment activities **under accreditation** available at the request of ATS. This will aim at making the assessment process possible in order to confirm accreditation maintenance;



- pay the accreditation fees **within defined deadlines** in accordance with the Charging Policy Document;
- immediately inform ATS about all the changes affecting the accreditation status, such as:
 - changes in legal, ownership or organisational status;
 - changes in organisational, management and key staff structure;
 - new persons authorised to sign certificates of conformity where applicable;
 - changes in policies, resources and locations;
 - changes in the certification scheme;
 - new members of the certification committee and other organs exerting influence of the parties interested in certification where applicable; and
 - other changes affecting fulfilment of the accreditation criteria.

After analysing possible effect on accreditation status arising from the changes made, ATS shall decide on the method of verification thereof, which may also **involve** extraordinary surveillance assessments.

Furthermore, an accredited conformity assessment body shall:

- not use the accreditation that was granted thereto in order to jeopardise 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;
- contact ATS to obtain authentic interpretation if it is in doubt as to whether it can use the accreditation that was granted;
- not include in the contracts with its clients or certificates of conformity any provisions leading to a conclusion that products or services were approved by ATS by means of accreditation;
- 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.



- ensure record keeping of the incidents pertaining to the safety of products falling within the scope of accreditation, and records made by clients or by third parties (e.g. judicial bodies records) and of data on the relevant corrective actions that were undertaken to rectify the incidents;
- submit to ATS the details on the actions that judicial bodies undertook against it as regards the accreditation services rendered;
- report, in case of bodies authorised/ designated by the competent authorities on the basis of accreditation, to ATS on a regular basis about their current authorised/designated status (when this status is to be granted or denied, etc.).

Every year an accredited certification body **or body that applied Accreditation application** is obliged to submit the following to ATS prior to a surveillance assessment/**initial assessment/reassessment**:

- 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. EA code, field of certification) and the list of assessed 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 conformity assessment body, 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 conformity assessment body and do not work at a fixed office location) that perform any certification activities;**
- **To indicate which fixed office location/s is/are responsible for performing and/or managing key activities as defined in IAF/ILAC A5 or from where remote personnel performing key activities are managed; and**
- **to present the conformity assessment body's arrangements for managing all activities that are performed from a foreign fixed office locations abroad or by remote personnel.**

An accredited certification body for the certification of the management systems is also obliged to submit, other than the stated lists, the following data to ATS each year by the end of January every year (according to the country and according to the standard for which it performs certification): number of accredited certificates valid at the end of December, the number of auditors / assessors, the number of transfers accepted, number of overdue audits, and the number of auditor days delivered, on the basis of the instructions that will be provided by ATS on that occasion.

Certification or inspection bodies shall, before applying for accreditation, perform at least one certification or inspection for each certification scheme or field of inspection they applied for.

Accreditation can be granted to a certification body providing certification of management systems only by means of EA codes/food chain/**technical area** categories for which the certification body made decisions on certification - **granted certification**.

If accreditation is a prerequisite for **designation**/authorisation, it can also be granted by witnessing the work of conformity assessment bodies under simulated conditions. A **designated**/authorised accredited conformity assessment body 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 reduce or withdraw the accreditation that was granted.

An accredited conformity assessment body shall, at least once every two years, perform conformity assessment activities it was accredited for. 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 conformity assessment bodies (eg 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 conformity assessment body is obliged to adhere to the Rules of Cross-frontier Accreditation (ATS-PA05), which are publicly available at www.ats.rs, in the cases of its own accredited activities abroad and 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 with, a conformity assessment body is obliged to host, during assessment by ATS, members of assessment team from EA or other international accreditation organizations, which will monitor and observe the work of ATS assessment team.

A conformity assessment body is obliged to participate in inter-laboratory training comparisons-ILC comparisons and proficiency testing (PT) schemes in accordance with the Rules on participation in inter-laboratory 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 conformity assessment bodies

ATS shall:

- limit assessment procedures to the assessment of conformance with the accreditation criteria;
- provide participation of competent, independent and impartial staff in the accreditation procedure;
- 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 conformity assessment body made the necessary adjustments;
- provide information relating to the provision of acceptable traceability of measurement;
- provide information relating to PT schemes recommended by EA, and
- 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 binding guidelines of EA, ILAC referring to accreditation procedure or accreditation bodies and conformity assessment bodies.

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 conformity assessment body with the head office outside the Republic of Serbia or to a conformity assessment body established in the Republic of Serbia, but that performs conformity assessment activities abroad, is prescribed in the *Rules of Cross-frontier Accreditation (ATS PA05)*.

ACTING DIRECTOR

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