



ATC

АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ

ATS-PR02

SELECTION OF PERSONS PARTICIPATING IN THE ACCREDITATION PROCESS AND PERFORMANCE MONITORING

Reviewed by: **Radivoje Nikoličić,**
Quality Manager (QM)

Approved by: **Prof Aco Janićijević, PhD,**
Acting Director

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 SCOPE

This document shall lay down the following: functions of assessment team members **and other participants in the accreditation process**, selection criteria, job application process and training of assessors, technical experts **and accreditation decision-making experts**; selection criteria fulfilment assessment, appointment and entry in the **relevant Registers**; monitoring of their performance when carrying out assessment activities and making decisions in the accreditation process; professional development and advancement; records on assessors, technical experts **and decision-making experts**; mode of their removal from the Register, relationship between the ATS and assessors, technical experts **and decision-making experts**, and requirements as regards conflict of interests.

Selection method **and performance monitoring** in case of assessors, technical experts and **decision-making experts** shall be carried out by the ATS with the aim of ensuring adequate resources needed for the assessment of conformity assessment bodies (hereinafter referred to as: CABs) and **decision-making on granting accreditation to CABs**.

2 REFERENCE DOCUMENTS, DEFINITIONS AND ACRONYMS

- SRPS ISO/IEC 17000:2008, Conformity Assessment – Vocabulary and General Principles;
- SRPS ISO/IEC 17011: 2007, Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (CABs);
- SRPS ISO 19011: 2011, Guidelines for Auditing Management Systems;
- ILAC-G11:07/2006, ILAC Guidelines on Qualifications and Competence of Assessors and Technical Experts;
- EA 3/12M:2013, EA Policy for the Accreditation of Organic Production Certification;
- **IAF MD 16:2015, Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies;**
- **IAF MD 13:2014, Knowledge Requirements for Accreditation Body Personnel for Information Security Management Systems (ISO/IEC 27001);**
- **IAF MD 8:2015 Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485);**
- **IAF MD14: 2014, Application of ISO/IEC 17011 in Greenhouse Gas Validation and Verification Bodies (ISO 14065:2013).**

For the purposes of this document, terms defined in the said reference documents shall be used. Furthermore, the following terms shall have the following meanings:

Assessment team:	Assessment team performs assessment as part of CAB accreditation process or accreditation maintenance and, as a rule, is composed of a lead assessor, one or more technical assessors or one or more technical experts.
Assessor:	Person assigned by the ATS to perform an assessment as part of accreditation process either alone or as part of an assessment team.
Lead assessor:	Assessor having adequate knowledge and experience in order to perform the assessment of management system for certain scheme and field of accreditation and is given responsibility for specified assessment activities such as: preparation of assessment plan aimed at effective use of resources,



offer guidance to assessment team throughout assessment process, prevention and rectification of all possible conflicts, adoption of decisions and provision of assistance to the assessment team to reach conclusions and make assessment findings, presentation of the team to a body being assessed, direction for and guidance to technical experts and assessors that are being trained, drafting and distribution of assessment reports to the ATS whereby enabling both a body being assessed and the ATS to take appropriate actions and decisions.

As a general rule, lead assessors are assessment team leaders, if the team includes two or more assessors.

Lead assessors can act as technical assessors during the same assessment process in case of those accreditation fields they are competent in.

Technical Assessor:

Assessor having necessary knowledge and experience on order to perform the assessment of technical competence of CABs for a specific scheme or field of accreditation.

Technical assessors can, if need be, act as technical experts in their assessment teams.

Technical Expert:

Professional having necessary knowledge and experience in specific field of conformity assessment subject to assessment and is appointed by the ATS to provide technical expertise in case of a specific assessment and technical advice, but is not considered as an assessor.

As a general rule, during assessment or witnessing of performance of conformity assessment activities, a technical expert must be escorted by an assessor.

Technical experts can perform witnessing independently, if the witnessing involves solely observance of performance of conformity assessment activities performed by a conformity assessment body and does not involve interviewing observed personnel.

Accreditation File Manager:

Permanent ATS employee, assigned by ATS to manage a particular accreditation file, which, in addition to the coordination of activities in certain phases of the accreditation process, involves communication and cooperation with the assessment team and the CAB being assessed on matters of observance of ATS policy, procedures and accreditation rules, **in coordination with the Head of Section / Head of Department**. Furthermore, it involves **participation in reviewing applications for accreditation, assembling an assessment team and review of the documentation submitted following the assessment**, as well as possible participation in the assessment team as a lead assessor, technical assessor or a technical expert, depending on his/her qualification and competence, or code from the Register. **Accreditation File Manager shall, if need be, participate in accreditation decision-making for accreditation scheme wherein he/she is the lead assessor, in the file, the assessment of which he/she has not participated in as an assessor/technical expert.**

**Head of Section/
Head of
Department for
Accreditation:**

Permanent ATS employee, assigned by ATS to, among other activities in line with the By-law on Internal Organisation and Functional Titles and Job Descriptions of the Accreditation Body of Serbia, review applications for accreditation, alongside AFM in charge, as well as assemble an assessment



team, review-evaluate the assessment report and other documentation submitted following the assessment. Head of Section/Head of Department shall, if need be, participate in accreditation decision-making for type of accreditation wherein he/she is the lead assessor, in the file, the assessment of which he/she has not participated in as an assessor/technical expert.

Accreditation Committee:

Committee formed by the ATS Director in order to propose the decision on the accreditation of CABs, on the basis of evaluation of information obtained in the process(es) before the decision-making and other relevant information for each accreditation file which was submitted for decision-making. The Committee consists of permanent ATS staff, who did not participate in the process of CAB assessment, which preceded the decision-making and external decision-making experts who provide the necessary technical expertise for the type of accreditation and conformity assessment in the field wherein a CAB performs its activities.

Decision-making Expert:

Professional having necessary knowledge and experience in specific field of conformity assessment subject to assessment and is appointed by the ATS to perform evaluation of information from the CAB assessment process and establish adequacy of information for decision-making on fulfilment of accreditation requirements.

Performance Monitoring:

Assessment of the **participants in assessment and participants in decision-making's** traits pertaining to their competence and personality traits displayed during the assessment and/or decision-making in the accreditation procedure.

Applicant for the position of assessor /technical expert /decision-making expert:

Person interested in performing the activities of an assessor or technical expert for the purpose of accreditation **or an accreditation decision-making expert** and he/she submitted the application to the ATS for the position of **assessor /technical expert/decision-making expert**.

Candidate to be trained as an ATS assessor and candidate for briefing seminar:

Applicant meeting the selection criteria for assessors and technical experts as referred to in Section 3.3 of this procedure and that is invited by the Committee for the Selection and Performance Monitoring of Assessors and Technical Experts (hereinafter referred to as Committee) to the assessor training or briefing seminar for technical experts.

Candidate for an assessor:

Applicant meeting the criteria for the selection of assessors referred to in Section 5 of this Procedure that attended the training for the ATS assessors (hereinafter referred to as training). He/she successfully passed the test.

Candidate for a technical expert /decision-making expert:

Applicant meeting the criteria for the selection of technical experts and **decision-making experts referred to in Section 3.3 and 3.4** of this Procedure, respectively, and who attended the briefing seminar for technical experts/**decision-making experts** or attended ATS briefing meeting.

Proposal for the appointment of assessors and

Proposal forwarded by the Committee to the ATS Director informing the Director that an applicant meets the criteria for the selection of assessors referred to in Section 3.3 of this Procedure. The Committee shall witness the



their entry in the Register: competence thereof during the assessment and if awarded a pass mark for all the phases of the selection process described in Section 3.8 of this Procedure, the applicant will be appointed as an ATS assessor and entered in the Register.

Proposal for the appointment of technical experts and their entry in the Register: Proposal forwarded by the Committee to the ATS Director informing the Director that an applicant meets criteria for the selection of technical experts referred to in Section 3.2 of this Procedure. The applicant shall attend the briefing seminar for technical experts or attend ATS briefing meeting and will therefore be appointed as an ATS technical expert and entered in the Register.

Proposal for the appointment of accreditation decision-making experts and their entry in the Register: Proposal forwarded by the Accreditation Council to the ATS Director informing the Director that an applicant meets criteria for the selection of decision-making experts referred to in Section 3.3 of this Procedure. The applicant shall attend the briefing seminar for decision-making experts or attend ATS briefing meeting and will therefore be appointed as an ATS decision-making expert and entered in the Register of decision-making experts.

Acronyms:

ATS:	Accreditation Body of Serbia
CAB	Conformity Assessment Body
EA:	European co-operation for Accreditation
ILAC:	International Laboratory Accreditation Cooperation
IAF:	International Accreditation Forum
ISO:	International Organization for Standardization
MLA:	Multilateral Agreement within EA or IAF
MRA:	Mutual Recognition Arrangement within ILAC
AFM:	Accreditation File Manager
HS:	Head of Section in Accreditation Department
HD:	Head of Accreditation Department
AC:	Accreditation Committee
FSMS:	Food Safety Management Systems
ISMS:	Information Security Management Systems

3 SELECTION OF PERSONS PARTICIPATING IN THE ACCREDITATION PROCESS AND PERFORMANCE MONITORING

3.1 Functions of the Assessment Team Members

The ATS shall appoint an assessment team for each assessment in accreditation process and/or accreditation maintenance. On the occasion of the establishment of assessment teams the ATS shall use assessors (lead and technical ones) with relevant educational background, experience and



training, and technical experts with relevant knowledge and experience in specific fields of conformity assessment. In addition to the assessors working at the ATS, the ATS shall, during selection process for the purpose of witnessing their competence, hire external assessors and technical experts that were entered in the Register of **assessors and technical experts**, and candidates for assessors, in the process of their selection, during witnessing of their competence. Communication and cooperation with the assessment team before, during and after assessment shall be performed by the AFM in charge of the subject assessment, **together with, if need be, HS or HD.**

Functions and roles of assessment team members (lead and technical assessors, technical experts and accreditation file manager, **or the Head of relevant section and/or Head of relevant department, who, if it is necessary to interpret ATS policy, procedures or accreditation rules, mutually cover necessary knowledge and skills**) are shown in Table 1.

If ATS hires assessors and technical experts entered in the Register of other accreditation body, which is a signatory to MLA/MRA agreements which ATS has signed, that are not fluent in Serbian, the ATS shall provide translator/interpreter for the assessment purposes if need be. As a rule, the organization being assessed is responsible for providing translation of the CAB documentation.

Function	Lead Assessor	Technical Assessor	Technical Expert	AFM/HS/HD
Performs conformity assessment for certain scheme and field of accreditation	secondary	primary		secondary
Performs assessment in the field of management systems	primary	secondary		secondary
Manages and coordinates activities between assessment team members	primary			secondary
Provides technical expertise	secondary	primary	primary	secondary
Interprets ATS policy, procedures and accreditation rules	primary	secondary		primary

Table 1: Functions and Roles of Assessment Team Members

3.2 FUNCTIONS OF THE PERSONS PARTICIPATING IN THE DECISION-MAKING PROCESS

Pursuant to Article 28 of the Statute of the ATS (Official Gazette RS no. 97/11), it is stipulated that ATS Director shall make decisions on accreditation, whereas the manner of decision on accreditation is laid down in Article 61. It is prescribed that the Director shall make decisions on the accreditation at the proposal of the Accreditation Committee.



The Accreditation Committees consist of: the Adviser to the Director (organises and manages the work of the Accreditation Committee), the Assistant Director of Development and Quality (proposes to the Director the composition of the committees and participates in their work in the field of his/her competence as an assessor, or to check conformance with the ATS rules and procedures in the assessment process) and, if necessary, the Head of Department / Head of Section and/or Accreditation File Manager who has the competence of the assessor/technical expert for the file (conformity assessment activities) within which the accreditation decision-making is conducted and, obligatorily, one or more experts from the Register of Decision-making Experts on Accreditation (Sectoral Committees), whose task is to carry out evaluation of the information from the CAB assessment process and to establish, together with other members of the Committee, the adequacy of information for decision-making that the accreditation requirements have been met.

As a rule, for each decision, the Committee shall have a different composition, due to the need to meet the requirements of the reference documents for the work of accreditation bodies, which relates to technical competence in decision-making.

The Accreditation Committee reviews information from the file which has reached the decision-making stage, determines its completeness, evaluates the clarity, comprehensibility and sufficiency of the information on the basis of which the decision on accreditation is made in accordance with the procedure for decision making and granting accreditation.

The necessary knowledge and skills for the review of the assessment reports and other information that has come to the decision-making and proposing the decision on accreditation, in each particular decision-making file, is covered by the committee as a whole.

The Director, pursuant to the prescribed procedure Decision-making and Granting Accreditation (ATS PR15) shall review and, should he accept the proposal, make the decision on accreditation or he can ask the Accreditation Committee for additional information/explanation or ask for additional assessment. Additional assessment shall be carried out in line with the said procedure whereafter the Accreditation Committee shall again provide the Director with the proposal of decision on accreditation.

3.3 SELECTION CRITERIA FOR ASSESSORS AND TECHNICAL EXPERTS

Criteria for the selection of the ATS assessors and technical experts are as follows:

- **educational background:** assessors (lead and technical ones) and technical experts shall hold university degrees in natural sciences and mathematics, humanities, medical and technical and technological sciences. Furthermore, technical assessors and technical experts who assess certification bodies which provide certification in the field of organic products must have a college degree corresponding to the category or group of products from the scope of accreditation e.g. Agricultural Engineer, Food Technology Engineer, Doctor of Veterinary Medicine, etc .;
- **professional experience:**
 - technical assessors and technical experts should have:
 - a) at least four years of work experience in the field subject to accreditation, at least two years of which should pertain to certain scheme of accreditation and gained within a period not dated back longer than five years at the time of the application; additionally, technical assessors and technical experts assessing certification bodies which provide certification in the field of organic production in line with the referent documents and control measures equivalent with EU regulations, must possess

adequate knowledge of EU regulations governing organic production and Codex Alimentarius CAC/GL 32-1999, and have experience in surveillance and/or assessment in third countries;

- lead assessors should have:
 - a) at least four years of work experience in the field subject to accreditation, at least two years of which should pertain to management systems for certain scheme of accreditation if they are not ATS employees;
 - b) ATS employees should have at least **three** years of relevant work experience gained at the ATS, i.e. at least **three** years of previously gained work experience in the field subject to accreditation, at least two years of which should pertain to management systems for certain scheme of accreditation;
- candidates for assessors in the field of assessment of certification bodies operating certification of quality management systems and environmental management systems shall have work experience in the field of quality management (e.g. quality manager, production planning, services) or work experience in the field of environmental management (e.g. quality manager, emergency response team member, experience in pollution prevention).
- **personality traits:** assessors and technical experts must be, as per the requirements of SRPS ISO/IEC 19011, communicative, honest, sincere, discrete, tactful, analytical, capable of making the difference between essential and important issues and those less important, capable of collecting objective evidence and performing correct and objective assessment thereof, persistent, impartial, reliable, trustworthy, etc.;
- **knowledge of relevant standards, regulations and accreditation procedures:**
 - assessors shall know, understand and adequately implement criteria and standards used for the accreditation of CABs, regulations governing accreditation, rules of accreditation, ATS procedures and guides, relevant EA, ILAC and IAF guides, and of other international and national organisations, assessment practice and techniques;
 - technical experts should understand the basics of accreditation standards and the ATS policy;
 - lead assessors shall have extensive knowledge, understanding and ability to apply the requirements of management systems for certain schemes of accreditation and be in the possession of a training certificate for courses or other training sessions;
 - furthermore, lead assessors should have expertise in and be capable of preparing and planning assessments, organising and managing the assessment team, making assessment-related decisions and conclusions, and drafting assessment reports;
 - technical assessors shall have extensive knowledge, understanding and ability to apply technical requirements for certain schemes of accreditation; while technical assessors and technical experts shall have technical knowledge of specific field of conformity assessment.
 - candidates for technical experts in the field of assessment of certification bodies operating certification of quality management systems and environmental management systems shall complete training in the application of quality management methods or training in evaluation of environmental performance or internal training in storing, mixing, using and disposing of materials and their impact on the environment (waste management) or training in emergency response planning.
 - candidates for assessors in the field of assessment of certification bodies operating certification of quality management systems and environmental management systems shall



complete assessor/internal assessor training or quality manager training, and four complete audits performed with a total of 20 audit days in the last three years.

In addition to the fulfilment of the said criteria referred to in this Section, candidates for assessors and technical experts must be able to efficiently communicate in both written and spoken Serbian. Candidates for assessors must successfully pass the knowledge test (hereinafter referred to as: test) after they have attended the training delivered as per the procedure entitled *Training of Assessors, Briefing Seminar for the AT5 Technical Experts, Decision-making Experts and Training of the AT5 Employees (AT5-PR03)*.

During the selection process candidates for technical experts shall attend a briefing seminar for technical experts or attend a briefing meeting.

3.4 SELECTION CRITERIA FOR DECISION-MAKING EXPERTS

- education: decision-making experts shall hold university degrees in natural sciences and mathematics, humanities, medical and technical and technological sciences,
- decision-making experts shall have extensive knowledge, understanding and assessment of the requirements for certain types of accreditation and shall have technical knowledge in the field of conformity assessment,
- personality traits: decision-making experts must be communicative, honest, sincere, discrete, tactful, analytical, capable of making the difference between essential and important issues and those less important, impartial, reliable, trustworthy, diplomatic, open, independent, etc.

3.5 SELECTION CRITERIA FOR AT5 PERSONNEL

In addition to the criteria they have to fulfill in order to be assigned to the appropriate post, which are defined in the By-law on Internal Organisation and Functional Titles and Job Descriptions of the Accreditation Body of Serbia, persons employed in the AT5 participating in the process of assessment and decision-making on the CABs accreditation should also have additional knowledge and skills to perform the tasks in the process in which they participate.

3.5.1 Necessary (additional) knowledge and skills

For performing activities of reviewing accreditation application and assembling an assessment team (AFM and HS/HD and other participants, if needed, as a team)

- Extensive knowledge of AT5 rules and procedures,
- General knowledge of accreditation in general and knowledge of requirements for the types of accreditation (e.g. ISO/IEC 17020, ISO/IEC 17021-1, ISO/IEC 17025, ISO/IEC 17024, ISO/IEC 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189 and ISO 14065) for which accreditation application was submitted and requirements from the documents, if there are any,
- Knowledge of the requirements for the conformity assessment scheme (ISO 9001, ISO 14001, reference documents for testing/inspection methods, for example), procedures and methods used by the CAB that submitted the application for accreditation.

For carrying out the tasks of reviewing the documentation from the assessment and making the decision on accreditation (AFM and HS / HD, as a team and AC)

- Good knowledge of AT5 rules and procedures,
- Knowledge principles, practices and techniques of CAB assessment,
- Knowledge of the general principles of the management system and tools used in the management system,



- The skill of giving observations - notes and writing reports,
- General knowledge of accreditation in general and knowledge of requirements for the types of accreditation (e.g. ISO/IEC 17020, ISO/IEC 17021-1, 1019 ISO/IEC 17025, ISO/IEC 17024, ISO/IEC 17034, ISO/IEC 17043, ISO/IEC 17065, ISO 15189 and ISO 14065) for which accreditation application was submitted and requirements from the documents for application, if there are any,
- Knowledge of requirements of conformity assessment scheme (ISO 9001, ISO 14001, reference documents for testing/inspection methods, for example), procedures and methods that the CAB which applied for accreditation uses.
- Knowledge of the principles of risk-based assessment,
- Knowledge of the function and relevance of the tasks of conformity assessment for CAB clients,
- Knowledge of general requirements from regulations related to conformity assessment activities,
- The ability to evaluate the outcome of the assessment process, including the appropriate recommendations of the assessment team.

Knowledge and skills ATS should possess to accredit certification bodies certifying management systems – Annex 3

- The knowledge and skills that the Accreditation Body should possess for specific activities in accreditation of certification bodies for FSMS are listed in IAF MD 16:2015, Application of ISO / IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies;

- The knowledge and skills that the Accreditation Body should possess for specific activities in accreditation of certification bodies for ISMS are listed in IAF MD 13:2014, Knowledge Requirements for Accreditation Body Personnel for the Information Security Management Systems (ISO/IEC 27001);

- The knowledge and skills that the Accreditation Body should possess for specific activities in accreditation of certification bodies for QMS in the field of medical devices are listed in IAF MD 8:2015, Application ISO/IEC 17011:2004 in the field of Medical Device Quality Management Systems (ISO 13485);

- The knowledge and skills that the Accreditation Body should possess for specific activities in accreditation of verification and validation bodies for greenhouse gases are listed in IAF MD14:2014, Application ISO/IEC 17011 in Greenhouse Gas Validation and Verification (ISO 14065:2013)

3.6 Candidacy for assessors and technical experts

3.6.1 Submitting application

Applicants for assessors and technical experts apply to the ATS, based on a permanently open public invitation to the ATS Internet portal, at www.ats.rs . If necessary, the ATS may publish a public invitation for assessors and technical experts in the media. A Form entitled Application for



Assessors and Technical Experts (hereinafter: Application) (ATS-PR02-O01) can be downloaded from the ATS Internet Portal.

The completed Application (Part A) and the required documentation shall be submitted to the ATS in written and electronic form. The list of mandatory documents is given in part B of the Application.

The application is made for a particular type and area of accreditation, according to the Code List / Keyword Codes for the areas of testing / calibration / inspection / certification for which the applicants possess appropriate competence (Annex 1 of the Application)

Applications are registered in the director's office and submitted for further processing to the Committee.

The director of the ATS appoints the Committee, consisting of a president and two members, and that shall be selected from the ATS employees. All members of the Committee are ATS lead assessors.

3.6.2 Application Data Validity Checks and Selection of Candidates for Training/Briefing Seminar

During the entire candidate selection process, the Committee shall enter the appropriate data in the form entitled *Applicant List (ATS-PR02-O02)*. In case of a negative assessment, in any part of the procedure, the Committee shall inform the applicant / candidate in writing of the termination of the procedure for his/her selection.

The Committee shall review the application and the submitted documentation, filling in Part B of the Application and, if necessary, it shall request additional documentation.

After completing the documentation, the Committee, as a rule, shall conduct a conversation with the applicant, and make an assessment of it in part B of the Application.

The Committee may seek the opinion of the appropriate technical committee on the competence of the applicant, which shall be entered in the part G of the Application.

The final assessment of the applicant shall be included in the part D of the Application by the Committee, after which it shall make *the Preliminary List of Training Candidates and the Briefing Seminar (ATS-PR02-O03)*.

The analysis of the candidates from the Preliminary List, based on the ATS needs, is performed by the Committee in an expanded composition, together with the Head of the relevant Department and the Head of the relevant Section, after which they make *the List of Candidates for Training and the Briefing Seminar (ATS-PR02-O03)* that they submit to the Director for approval. The Committee shall send the Final List of Candidates for Training and Briefing Seminars (ATS-PR02-O03) to the Training Manager, upon the approval by the Director, in accordance with the procedure *Training of Assessors, Briefing Seminar for the ATS Technical Experts, Decision Making Experts and Training of ATS Employees (ATS-PR03)*.

Associate for Administrative, Technical and General Affairs is in charge of performing administrative affairs.

3.7 Training for assessors and briefing seminar for technical experts

Candidates for assessors shall be invited for training, and candidates for technical experts for a briefing seminar in accordance with the procedure entitled *Training of Assessors, Briefing Seminar for the ATS Technical Experts, Decision Making Experts and Training of ATS Employees (ATS-PR03)*. The Committee shall include lecturers' evaluation of the candidates for assessors, during the training, as well as the result of the performed test, in part G of the Application.

Based on the results of the knowledge test and the assessment of the candidates, during the course of the training, the Committee shall make a proposal and a *List of Candidates for Assessors (ATS-PR02-O04)*.



3.8 Assessment of the criteria fulfillment and competence of candidates for assessors, and technical experts, appointment of assessors and technical experts and registration in the Register

3.8.1 Assessment of the criteria fulfillment for selection of assessors

Assessment of the criteria for the assessor candidates shall be carried out by the Committee.

3.8.2 Assessment of competence of candidates for assessors

The task of the Committee is to witness – assess the competence of candidates for assessors during assessment (planning, assessment and reporting) and their knowledge of assessment methods and procedure by having an assessor from the ATS Register, as a representative of the Committee, monitor the work a candidate for assessor during the assessment. Their observations shall be provided in writing in the form entitled *Observations about the Work of Assessors and Technical Experts/Assessment Team Leader/Candidates for Assessors (ATS-PR02-005)*. The Committee shall complete Part G of the Application on the basis of those observations.

Candidates for lead assessors and technical assessors shall first participate in at least one assessment as observers, and their work shall then be monitored by lead assessor or technical assessor from the ATS Register during at least one assessment to be performed on their own, as a team leader or a member of assessment team. The exact number of observations and monitoring shall be proposed by the Committee depending on the experience and demonstrated knowledge and skills of the candidates in the previous part of the process. When monitoring of the work of candidates for assessors did not yield satisfactory evaluation result, the work of those candidates shall be monitored during another assessment to be performed on their own with previously undertaken measures, if need be. The selection of the assessments in which the candidate for the assessor will participate, as well as the need for a greater number of assessments in which he/she shall be monitored, shall be carried out by the Committee in cooperation with the Head of the respective Department, or the head of the respective Section.

When assessing the competence of the assessor already entered in the Register, for a new type of accreditation, the Committee shall determine, in each specific case, the method of assessing competence in terms of the number and the need for prior observation, or monitoring the performance of the assessor, taking into account his/her experience in the assessment and availability of the assessors already registered in the ATS Register for this type of accreditation.

3.8.3 Assessment of Criteria Fulfilment Assessment in case of Candidates for Technical Experts, Appointment and Entry into Register

After a briefing seminar or briefing meeting for technical experts has been organised or the candidates for technical experts attended briefing meeting in ATS, wherein representative of the Committee, Head of the respective Department and Head of the respective Section shall participate, the Committee shall complete the form entitled *List of Proposals for the Appointment of and Entering in the Register of Assessors and Technical Experts (ATS-PR02-006)* and shall forward a proposal to the ATS Director to appoint and enter technical experts in the *Register (ATS-PR02-007)*. On the occasion of the entering in the Register a technical expert shall be awarded an identification number.

3.8.4 Selection and Appointment of Assessors

If the Committee's evaluation of the candidates was positive in terms of all the sections of the Applicant List, the final interview shall be performed if need be, and the opinion shall be entered in Part H of the Application. The Committee shall then make a proposal for the ATS Director to appoint assessors by using the form (ATS-PR02-006) entitled List of Proposals for the Appointment of and Entering in the Register. After the appointment has been made by the ATS Director, an assessor shall be entered in the Register (ATS-PR02-007) as a lead assessor or technical assessor and shall be awarded an identification number.



Changes in the status of assessors and technical experts that were entered in the Register shall be made by performing the relevant activities referred to in Chapters 3.2, 3.3 and 3.4 of this Procedure. A scheme reflecting the selection process for assessors and technical experts is shown in Annex 1 of this Procedure.

3.8.5 IDs

All assessors and technical experts shall be awarded ID cards the appearance of which is shown in Annex 2, and it contains name of the assessor, Registry ID number and status of the assessor or technical expert. These ID cards can only be used when performing concrete assessments for which the assessment team was appointed.

These ID cards are the property of the ATS and shall be returned at request.

3.8.6 Reference to the Status of Assessors and Technical Experts

ATS assessors and technical experts can make reference to their status only within the scope of the task delegated by the ATS.

ATS assessors and technical experts have a right to enter the data on the participation in seminars and training delivered by the ATS in their CVs, and the data on their being entered in the Register.

It is forbidden to make references to the status of the ATS assessors and technical experts for commercial purposes.

3.9 Selection, Appointment and Entry into Register of Decision-making Experts

The candidate for the decision-making expert shall submit to the ATS, at the invitation, the application for the decision-making expert together with the biography - CV, which shall be considered by the Assistant Director of Development and Quality, and if he/she concludes that the criteria prescribed in Section 3.4 of this Guide have been met, he/she will invite the candidate at a briefing meeting, where he/she will acquaint the candidate with the tasks in the decision-making process on accreditation, or work in the Accreditation Committee.

If necessary, in case there are more candidates for decision-making experts, or ATS management's decisions to offer experienced and long-term assessors from the Register of Assessors and Technical Experts to become decision-making experts, the ATS can organise a briefing seminar for decision-making experts, wherein candidates are also introduced to tasks in the decision-making process on accreditation, or work in the Accreditation Committee.

After the meeting or the held seminar, the Assistant Director for Development and Quality, shall send an initiative to the ATS Director to forward applications for decision-making experts to the Accreditation Council for further consideration.

Accreditation Council, after reviewing the Application shall forward to ATS Director a proposal that the applicant (that fulfils the criteria for selection of decision making experts from Section 3.4 of this guide and that has attended briefing seminar for decision making experts or attended briefing meeting at ATS), be appointed as decision making experts and entered into Register of decision making experts.

Entering into Register of decision making experts shall be performed by Assistant Director of Development and Quality and Register shall be approved by ATS Director.

If the work requires, due to non-existence of appropriate decision-making expert entered in the Register, a person fulfilling requirement from Section 3.4 of this guide whose application has not been considered at the Accreditation Council, should be engaged in Accreditation Council. The



Director shall approve his/her temporary engagement, whereas Accreditation Council shall review at the first meeting the fulfillment of proscribed requirements and if they are fulfilled, it shall propose for appointment of decision-making expert.

3.10 Monitoring Performance of Persons Participating in Assessment Process

The ATS makes regular monitoring and evaluation of task performance, i.e. competence of assessors and technical experts (both externally engaged and permanent ATS employees) during: assessments, i.e. participation in the work of an assessment team, by means of announced or unannounced witnessing, review of received assessment documentation and adoption of Assessment report, accreditation decision-making, and on the basis of feedback information provided by a body being assessed, its opinions and possible complaints.

Monitoring the performance of participants in the assessment process of permanent employees (AFM, HS, HD) is carried out on a daily basis through the routine informing of the supervisors on the accomplishment of the assignments, occasionally informing on the tasks accomplished at the meetings of the Boards of directors, as well as through regular internal audits and management reviews.

3.10.1 Work Monitoring

After each assessment on behalf of the ATS, an assessment team leader shall make observations about the work of each member of the assessment team and enter those in the form entitled *Observations about the Work of Assessors and Technical Experts/Assessment Team Leader/Candidates for Assessors (ATS-PR02-O05)* and shall attach them to the Assessment Report. The original copy of the completed form shall be placed in the personal file of an assessor or technical expert, while the copy thereof shall remain in the accreditation file as an annex to the Assessment Report.

When reviewing the Assessment Report, the Head of a respective department shall, in cooperation with an Accreditation File Manager, make observations about the work of the assessment team and enter those in the form entitled *ATS Observations about the Work of Assessment Team (ATS-PR02-O09)* and shall attach it to the Assessment Report, while copies thereof shall be submitted to the Committee.

During decision-making process as laid down in the procedure entitled *ATS-PR15, Decision-making and Granting Accreditation* the work of assessors shall be evaluated by the Accreditation Committee that is composed of both assessors competent in the respective scheme of accreditation and experts competent in the field of conformity assessment that is subject to the decision-making process. The findings shall be incorporated in-as annex to the *Proposals on Accreditation Decisions (ATS-PR15-O01)*.

If the observations about the work of the team leader and members of the assessment team are negative or if there is any complaint against their work, the Committee shall review, as soon as possible, the sequence of the activities performed during the said assessment and inform the ATS Director in writing about the oversights so that adequate actions could be undertaken.

The Committee shall, at least quarterly (every three months), review the observations made, and after the analysis has been carried out, it shall inform the ATS Board of directors in writing by presenting the adequate actions to be taken in case of certain assessors and technical experts (additional training, unannounced witnessing during extraordinary monitoring, sending warning letters to the assessors as regards their work, removal from the Register, etc.).



The Committee shall monitor the assessment experience for each assessor and technical expert from the Register and on that occasion the *Assessment Lists (ATS-PR02-O08)* shall be completed.

3.10.2 Announced/Unannounced Witnessing

At least once every three years each assessor should be subjected to witnessing performed by the representatives of the Committee. The representatives of the Committee shall pay, in terms of the assessor, an announced or unannounced visit during assessment and make observations that will contain recommendations on possible upgrading of the work of assessors in the form entitled *Observations about the Work of Assessors and Technical Experts/Assessment Team Leader /Candidates for Assessors (ATS-PR02-O05)*.

The Committee shall draft a monitoring plan for the period of three years. The plan shall contain the names of assessors and general terms for the monitoring thereof, and it shall be harmonised every year with annual assessment plans and proposed actions defined to upgrade the work of assessors.

3.10.3 Revision of Opinions and Complaints

When carrying out performance monitoring in case of assessors and technical experts the Committee shall take into consideration and review opinions and possible complaints of Assessment Team Leader, Accreditation File Manager, and accredited CABs.

Formal complaints about the work of assessors and technical experts shall be resolved in accordance with the procedure entitled *Resolution of Complaints and Appeals (ATS-PR16)*.

3.11 Monitoring performance of participants in decision-making process

ATS shall constantly monitor and evaluate the performance of persons involved in the accreditation decision-making process by monitoring the work in the current year, reviewing and analyzing the given opinions of the members of the Accreditation committee and the proposal for decisions on accreditation. The following criteria for monitoring and assessment of participants' performance in the decision-making process on accreditation have been established:

- understanding reports and accompanying records that are subject to consideration in the decision-making process;
- understanding the principles and techniques of assessment conducted by ATS;
- the ability to demonstrate their own competence in the decision-making process on accreditation;
- attitude to work and
- traits (diplomacy, openness, independence, autonomy).

Monitoring and assessing participants' performance in the decision-making process are performed by the Assistant Director of Development and Quality and the Advisor to the Director, for all participants in the decision-making process, and their performance is monitored and assessed by the Director and the person whom he determines, who has experience in organizing and working in Accreditation Committees.

Once a year, the results of the monitoring are systematised, analysed, and the Report on monitoring performance of participants in the decision-making process on accreditation is being prepared, and it is considered during the management review.

3.12 Professional Development and Advancement

Pursuant to the procedure entitled *Training of Assessors, Briefing Seminar for ATS Technical Experts and Decision-making Experts and Training of ATS Employees (ATS-PR03)*, the ATS shall, at least once a year, organise for assessors and technical experts, and ATS employees



seminars/specialised conferences/round-table discussions/workshops covering specific fields, so that they can get familiar with, discuss, and solve certain issues in the domain of accreditation. These shall be organised in case of significant changes in the ATS accreditation procedure.

The ATS shall encourage its **employees**, assessors, technical experts **and decision-making experts** to regularly upgrade their knowledge and skills by means of additional education and professional development, and by means of participation in relevant conferences, seminars, workshops, courses and training sessions; and by means of participation in activities of professional associations and conferences, relevant technical committees, work bodies and committees.

3.12 Records on Assessors, Technical Experts **and Decision-making Experts**

The ATS shall keep the records on external assessors, technical experts **and decision-making experts**, their relevant qualifications, training, experience, competence, and findings relating to the monitoring of their work. These records are an integral part of personal files of assessors or technical experts **or decision-making experts** and shall be kept in accordance with the procedure entitled *Records Control (ATS-PR04)*.

The ATS shall keep the records on assessors and technical experts up-to-date by using personal files containing the following data:

- name and surname,
- address,
- status,
- original positions within their companies,
- educational background and professional status,
- work experience,
- training in management systems and assessment activities,
- competence in specific conformity assessment fields,
- assessment experience,
- observations of a Team Leader or Accreditation File Manager relating to the work of assessors or technical experts,
- observations of the Committee relating to regular work monitoring.

Part of the said personal file data shall be entered in the Register **of assessors and technical experts** that is kept by using the form entitled ATS-PR02-O07 and in electronic data base of assessors and technical experts.

The Committee shall update the data on assessor competence maintenance once every three years by collecting the updated information in order to confirm the competence for specific fields of conformity assessment that an assessor or technical expert was appointed for.

ATS keeps up-to-date records of decision-making experts through a file containing the following information:

- **name and surname,**
- **address,**
- **status,**



- original positions within their companies,
- educational background and professional status,
- work experience,
- experience in assessing CABs,
- competence in conformity assessment fields,
- observations of person monitoring performance of decision-making expert relating to the work of decision-making expert.

3.14 Removal from the Register

A decision on the removal of assessors and technical experts from the Register of assessors and technical experts shall be made by the ATS Director at the proposal of the Committee.

Criteria for the removal from the Register can be as follows:

- inadequate competence maintenance in specific field for specific scheme of accreditation,
- lead and technical assessors' failure to perform assessment activities in the previous three years,
- one observation that seriously damages the reputation of the ATS or several negative observations,
- unjustifiable refusal to perform assessment activities,
- unjustifiable failure to participate in annual seminars or courses,
- non-observance of the provisions of this Procedure.

Assessors or technical experts shall be informed in writing about the decision on their removed from the Register.

Each assessor or technical expert can be removed from the Register at their request at any point in time.

A person that was removed from the Register is obliged to immediately return the ID card to the ATS and his/her rights obtained by being in the Register shall expire automatically.

The decision to remove decision-making experts from the Register of Decision-making Experts is made by the Director of ATS, on the proposal of the Assistant Director of Development and Quality and/or the Accreditation Council.

Criteria for removal from the Register can be:

- unjustified refusal of engagement in the Accreditation Committee,
- Force Majeure,
- failure to comply with contractual obligations;
- failure to comply with the prescribed rules and procedures of the ATS.

The decision-making expert shall be informed in writing about the decision on removal from the Register.

Any decision-making expert may, at his own request, be removed from the Register at any time.

3.15 Relationship between the ATS and Engaged Persons in Accreditation Process



3.15.1 Scope and Duration of Work Activities

Mutual obligations of the ATS and assessors, technical experts and decision-making experts contracted for assessment purposes or decision-making in accreditation procedure shall be laid down in contracts that are concluded once a year, in line with the guide entitled *Conclusion and Implementation of Contracts with Persons Engaged in Accreditation Process ATS-UP10*.

If assessors or technical experts realise that they do not have adequate knowledge or experience needed for a particular accreditation type and field, but are still proposed by the ATS as assessment team members, they shall inform the ATS thereof in order to be replaced. The Committee shall perform the necessary analysis and propose changes to be made in assessor or technical expert's personal files and the Register.

The ATS shall consider the task delegated to an assessor or technical expert as completed when the last activity of the process they had been hired to perform was completed.

Assessors and technical experts are bound by a contract to perform assessment activities within the defined time frame, to act on the complaints made by the ATS, and remove identified deficiencies relating to completed activities, i.e. to perform contracted activities within the new time frame proposed by the ATS.

3.15.2 Obligations of Assessors and Technical Experts

Assessors and technical experts are obliged to (in addition to the observance of obligations as defined in the contract):

- base their assessments on objective observance, even in stressful situations;
- show the assessment results without being afraid or partial;
- be completely dedicated and committed to the assessment procedure;
- observe and promote the *ATS Assessors' Code of Practice (ATS-UP21)*;
- inform the ATS about any change in data entered in the documentation placed in personal files of the ATS assessors and technical experts and to submit the necessary evidence thereof;
- submit evidence of competence maintenance;
- attend seminars (training courses) organised for the ATS assessors and technical experts;
- maintain a good reputation of the ATS by displaying proper behaviour and attitude;
- inform the ATS about the facts that may jeopardise the reputation of the ATS;
- avoid revealing the data from documentation in public or publish their opinions, comments and stands related to accreditation without prior approval of the ATS;
- submit to the ATS proposals and suggestions to help develop the national accreditation system.

In addition to the aforementioned, an Assessment Team Leader (Lead Assessor) shall:

- participate in the selection of the assessment team members at the request of an Accreditation File Manager,
- draft assessment plans,
- act as a mentor to the candidates for assessors when demonstrating their competence throughout the assessor selection process,



- prevent possible conflicts,
- represent assessment team to the management of a CAB being assessed.

3.15.3 Assessors, Technical Experts and Decision-making Experts' Fees

Assessors, technical experts and decision-making experts are entitled to receive fees the amount of which is defined in the appropriate employment contract for assessors and technical experts. The fees shall be paid after the fulfilment of contractual obligations - the delivery of all contracted results by assessors, technical experts or decision-making experts.

3.15.4 Documents to Be Sent to Assessors, Technical Experts and Decision-making Experts

The ATS shall put all the documents needed for the performance of assessment activities at the disposal of assessors and technical experts and all the documents needed for decision-making to decision-making experts.

When performing assessment activities assessors and technical experts shall precisely adhere to the provisions of the ATS documents stipulating the assessment procedure and decision-making experts shall adhere to provisions of the documents governing decision-making procedure.

The ATS shall, in accordance with the Rules of Accreditation, inform assessors, technical experts and decision-making experts about the changes in the accreditation system pertaining to assessment process and/or decision-making and submit them updated versions in accordance with the procedure entitled *Document Control (ATS-PR01)*.

3.16 Conflict of Interest, Integrity, Impartiality and Confidentiality

3.16.1 Conflict of Interest

Assessors, technical experts or decision-making experts contracted to perform assessment activities or decision-making must not be on professional, financial, consultancy, nepotism or any other footing leading to a conflict of interest between assessors, technical experts or decision-making experts and a CAB being assessed or accreditation of which is being decided.

3.16.2 Integrity and Impartiality

Assessors, technical experts and decision-making experts contracted to perform assessment activities or decision-making shall display the highest level of objectivity in all circumstances during performing activities they are engaged for, and shall inform the ATS about all the facts, influences or pressures that may jeopardise independence and impartiality of their work on behalf of ATS.

3.16.3 Confidentiality

Assessors, technical experts and decision-making experts shall treat all the information obtained during assessments or accreditation decision-making as confidential in accordance with *Confidentiality Regulation (ATS-UP10-006)*. Assessment information or decision-making information may be provided to third parties only with the approval from persons and/or CAB they relate to. This does not pertain to the information submitted to the ATS if these are needed for the accreditation procedure.



3.16.4 Consultancy Services

Assessors and technical experts contracted to perform assessment activities cannot act as consultants of a conformity assessment body being assessed before they are replaced on the assessment team or before the expiry of their responsibilities and tasks as team leaders/members of assessment team of a conformity assessment body being assessed.

Decision-making experts must not accept to decide on the accreditation of CABs if they have provided the same TCAB with consulting services related to accreditation.

4 DISTRIBUTION

This document shall be used by all the ATS employees, candidates for assessors and technical experts and assessors and technical experts **and decision-making experts** that were entered in the Register. This document is available to the ATS employees and can be found on the “Juatsrv” server in the folder entitled “QMS_ATS” and its subfolder entitled “Procedures”. This document shall be made available to candidates for assessors and technical experts and assessors and technical experts through the internet portal www.ats.rs

5 ANNEXES

Annex 1: Schematic diagram of assessor and technical expert selection process

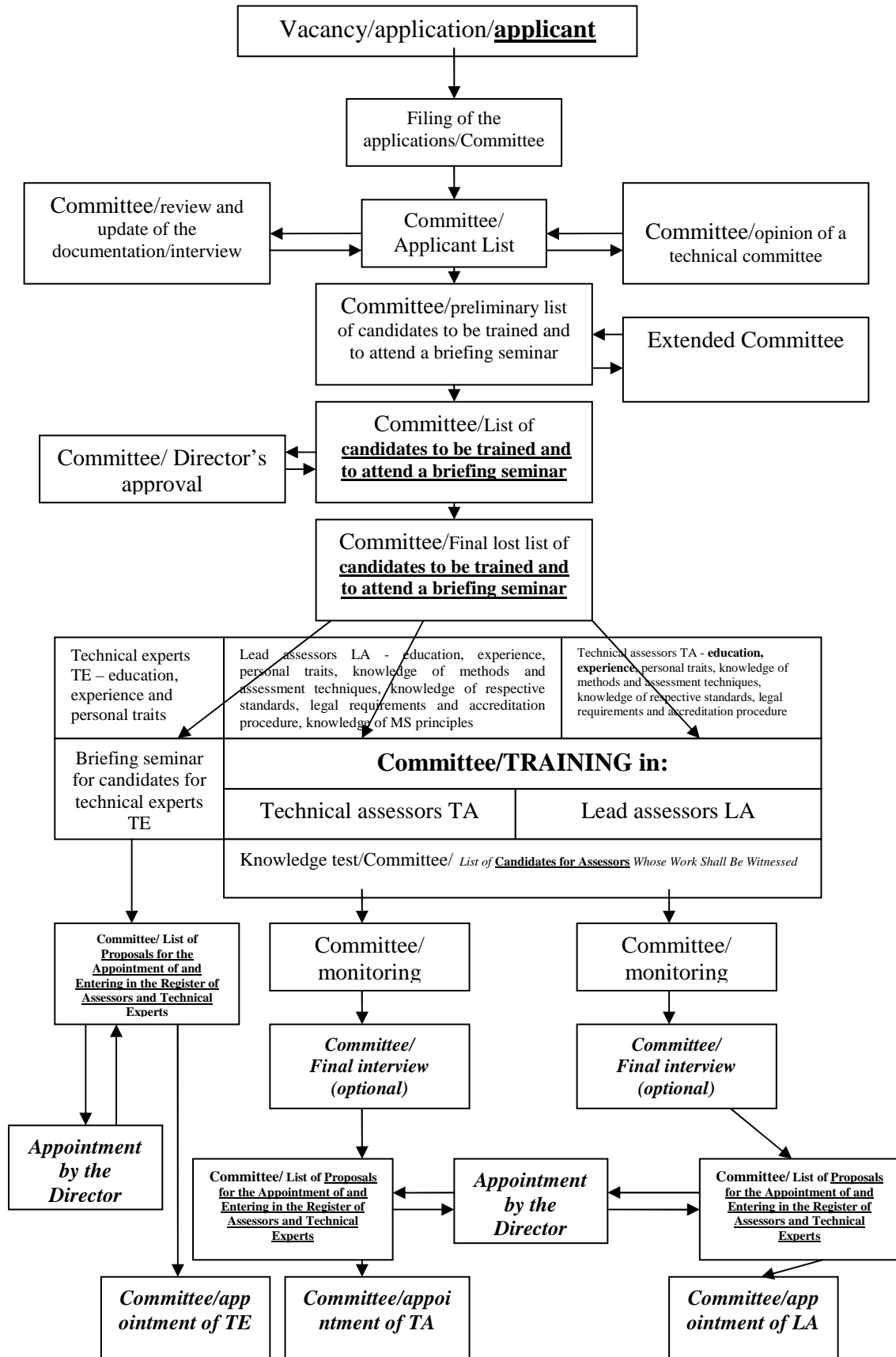
Annex 2: ID model form

6 FORMS

ATS- PR02-O01	Application for Assessors and Technical Experts
ATS- PR02-O02	Applicant List
ATS- PR02-O03	Preliminary List/List/Final List of Candidates to Be Trained and to Attend Briefing Seminars
ATS- PR02-O04	List of Candidates for Assessors
ATS- PR02-O05	Observations about the Work of Assessors and Technical Experts/Assessment Team Leader /Candidates for Assessors
ATS- PR02-O06	List of Proposals for the Appointment of and Entering in the Register of Assessors and Technical Experts
ATS- PR02-O07	Register of Assessors and Technical Experts
ATS- PR02-O08	List of Assessments Attended by Assessors/Technical Experts
ATS- PR02-O09	ATS Observations about the Work of Assessment Team

**7 ATS-PR02 DOCUMENT AMENDMENT HISTORY**

Issue/ revision	Issue/ revision date
1/0	11.02.2009
2/0	18.08.2010
2/1	18.03.2011
3/0	25.12.2011
3/1	8.10.2013
3/2	10.09.2015
4/0	31.05.2017





Annex 2



РЕПУБЛИКА СРБИЈА

ЛЕГИТИМАЦИЈА



АТЦ
АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ



Име и презиме

Ид. број

КАТЕГОРИЈА

ВОДЕЋИ ОЦЕЊИВАЧ

Категорија

Ималац ове легитимације овлашћен је да у име АТЦ - а обавља послове оцењивања у поступку акредитације и надзора над радом тела за оцењивање усаглашености.

Ималац легитимације је дужан да за време обављања наведених послова носи легитимацију и да је покаже ако се то од њега захтева.

Забрањено је давати легитимацију другим лицима, послужити се туђом легитимацијом као својом или је злоупотребити на неки други начин.

Датум



Оверава



АТЦ
АКРЕДИТАЦИОНО ТЕЛО СРБИЈЕ

Ова легитимација је власништво АТЦ - а. Ако је пронађете молимо вас да је вратите у АТЦ, Бул. Михаила Пупина 2, 11070 Београд.



Annex

3

Knowledge Requirements for Accreditation Body Personnel for Information Security Management Systems

IAF MD 16:2014, Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies

ISO/IEC 17011 clause 6.2.1 requires Accreditation body to identify competences required for each accreditation activity. The following table shows knowledge and skills which the Accreditation body of Serbia should have for specific activities while accrediting certification bodies for FSMS. **X** shall denote that ATS personnel should have general level of knowledge and skills. **X+** shall denote the need for ATS staff to possess an advanced level of knowledge and skills acquired in practice or other way.

Accreditation Functions Competences <i>Note 1</i>	Documentation Review	On-Site Assessment	Witness Assessment	Accreditation Decisions (Note3)	File management
Knowledge and ability to apply principles of assessment, practice and techniques (methodology)		X+	X+	X	X
Knowledge and ability to apply requirements as per ISO/IEC 17021 and ISO/TS 22003	X	X+	X+	X	X
Knowledge of certification process carried out by CAB	X	X+	X	X	X
Knowledge and ability to apply requirements as per ISO 22000 OR other FSMS certification standards	X	X+	X+	X	
Knowledge and ability to apply the following, as regards food safety management system: - HACCP principles, - food safety management, including PRPs, - legal framework.	X	X+	X+	X	



<p>Knowledge and ability to apply (in the section of food chain being assessed);</p> <ul style="list-style-type: none"> - current HACCP principles, - relevant PRPs - identification of food safety hazards, - control measures, - products, processes and practices, - related legal requirements (note 2). 			X+		
Knowledge of business sector of CAB clients			X		
Knowledge of cultural and social customs relating to categories and geographical areas to be assessed.		X	X		

Note 1: When the team performs the assessment, the necessary competence is required for the team as a whole, and not for each team member individually. However, when an assessment is performed by an individual, then he/she must have all the competences listed.

Note 2: The legal requirements listed in the table imply understanding of the regulations that the organisation that is the subject of witnessing is expected to be conformed to, whether they are valid for the food industry sector or the country/state/province in which the organisation operates.

Note 3: When a group (committee) reviews assessment reports and makes decisions on accreditation, necessary knowledge should be possessed by the group as a whole and not every individual member of the group.



IAF MD 13:2014, Knowledge Requirements for Accreditation Body Personnel for Information Security Management Systems (ISO/IEC 27001)

4. Knowledge requirements

4.1 In ISO / IEC 17011, clause 6.2.1 (a), requires accreditation bodies to describe (proscribe) required competences for each activity involved in the process of accreditation. Normative Annex A (IAF MD 13) specifies the areas of knowledge that the Accreditation Body shall define that are binding for specific functions in the accreditation of the bodies providing auditing and certification of ISMS. The knowledge requirements detailed in this annex are complementary to the basic skills and knowledge required for each function within the Accreditation Body.

4.2 In general, each assessor involved in ISMS assessment shall have a level of knowledge described in A1 to A5 in Annex A of IAF MD 13: 2014. The team as a whole can have the knowledge described in A6 and A7.

4.3 When a group reviews assessment reports and makes accreditation decisions, the knowledge required is to be held within the group as a whole and not by each individual member of the group.

4.4. Personnel involved in scheme management (management of the organisational unit and file management) shall have knowledge of ISO/IEC 17021-1. If the personnel do not have the other knowledge described in Annex A, the Accreditation Body shall ensure the access to the necessary knowledge.

4.5 Processes and work (operations) of the CAB's client in relation to ISMS include:

- typical business activities related to technical areas (see ISO/IEC 17021-1, clause 7.1.2);
- information and communication technology specific to the technical field;
- information security technologies and practices specific to technical areas, in particular identification of information security related threats and vulnerabilities and related mitigations and controls;
- relevant legal requirements.

Legal requirements identified here are those regulations that the organisation that is the subject of the witness would be expected to comply with either for the information security field or country/state/province within which they operate.

The following table lists the knowledge and skills that the Accreditation Body should possess for specific activities in accreditation of certification bodies for ISMS. X means that the staff of the Accreditation Body should have a general level of knowledge and skills for the given item. X + indicates the need for the staff of the Accreditation Body to have a higher level of knowledge and skills for the given item.



Accreditation functions Subject - topic	Documentary review (as part of assessment)	On-site assessment	Witnessing	Review of Report on assessment and decision-making	Scheme management – leading a unit and managing files
A1. Terminology and principles as regards ISMS including ISO/IEC 27000	X	X	X	X	X
A2. Audit Techniques – methodologies of included in ISO/IEC 27007 and ISO/IEC TR 27008		X	X		
A3. ISO/IEC 17021-1 and ISO/IEC 27006	X+	X+	X	X	X
A4. ISO/IEC 27001	X	X+	X+	X	
A5. General legal and regulatory requirements as regards ISMS	X	X	X+	X	
A6. Generic with ISMS related technologies, including - information security technologies and practice - information and communication technologies - risk assessment and risk management	X	X	X	X	
A7. CAB's client process and operation associated with ISMS			X		



IAF MD 8:2015 Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485);

Required types of knowledge and skills for personell involved in IAF ISO 13485 activities

Accreditation functions	Application Review	Documenta ry review	Assessment team	Witnessing team	Review of Report on assessment and decision-making	Managing files
Knowledge and skills						
Principles and application of quality system		X	X	X	X	
Understanding of valid GHTF SG4 Í SG3 documents. (maintained by IMDRF)		X	X+	X+	X	X
Understanding of ISO 13485			X	X	X*	
Understanding of general regulatory requirements (regulations) that are relevant to manufacturers of medical devices			X	X	X*	
Overview of medical devices, their intended use, safety and risks.			X	X		
Legal framework, including regulatory requirements, their implementation, and role of the auditing organization			X	X		
Information on CAB's client products, processes and organization to determine competences needed by the audit team and for the certification decision			X			



Information on CABs processes and organization to determine competences needed by the assessment team and for the accreditation decision						X
Understanding CAB's client's products, processes and organization				X		
Ability to confirm that the CAB's processes are appropriate to support IAF ISO 13485 scheme		X	X	X		
Ability to confirm that the CAB is competent to conduct a certification of the manufacturers, taking into account the processes and products involved			X	X	X	
Ability to determine the needed appropriate duration of assessment						X
Identification of medical devices, including complexities, technologies, use and risk classifications			X	X		
Deployment of assessor competences and requirements.						X



Knowledge on identifying and evaluating factors that impact an appropriate certification program for a medical device manufacturer seeking certification in a regulatory environment.			X	X		
Understanding of work performed at an accredited CAB		X	X		X	X
Understanding of IAF mandatory documents for ISO 13485 scheme	X	X	X	X	X	X
Understanding of ISO/IEC 17021-1		X	X	X	X	X

* NOTE 1: The level of understanding for this activity is expected to be lower than for the assessment team

Acronyms:

GHTF – the Global Harmonization Task Force (representatives of regulatory organs for medical devices)

IMDRF – The International Medical Device Regulators Forum



IAF MD14: 2014, Application of ISO/IEC 17011 in Greenhouse Gas Validation and Verification Bodies (ISO 14065:2013)

Required Additional Knowledge and Skills for Accreditation Personnel Involved with the Application of ISO 14065 Activities

The following table specifies the additional type of knowledge and skills that an Accreditation Body shall define for specific functions.

X: the Accreditation body shall define the criteria and depth of knowledge, for each of the functions which may be carried out by an individual or a group.

Accreditation functions	Conducting the Application Review, Planning Assessments and Administration of Accreditation Program	Documentation Review	Office Assessment Team	Witness Assessment Team	Reviewing Assessment Reports and Making Accreditation Decisions
Competence					
Understanding of the principles and process of validation and/or verification		X	X	X	X
Understanding of additional GHG program and/or regulatory requirements for the accreditation body and validation and/or verification bodies where applicable	X	X	X	X	X
Ability to review and understand the CAB's scope of accreditation to determine competence needed for the assessment	X	X			
Understanding of the CAB's scope of work and ability to confirm that the qualification of its personnel is		X	X	X	



appropriate for that scope of work					
Ability to determine the appropriate duration of assessment	X				
Ability to understand and assess the validation and/or verification team's process for conducting a risk-based assessment of all GHG sources, sinks and reservoirs and sampling an appropriate number of systems, sources, and calculation methodologies to look for errors or omissions within the reported GHG assertion within that sector.			X	X	X
Ability to identify the correctness of an organization's geographical boundaries, organizational boundaries, and reported units (i.e. equity share, operational control, or financial control)			X	X	X
Understanding of ISO 14064-1 or relevant GHG program requirements					



Understanding of ISO 14064-2 or relevant GHG program requirements	X	X	X	X	X
Understanding of ISO 14064-3 or relevant GHG program requirements	X	X	X	X	X
Understanding of ISO 14065 and ISO 14066 or relevant GHG program requirements	X	X	X	X	X
Understanding of IAF MD6	X	X	X	X	X
Understanding of IAF MD14	X				