ASSESSMENT OF CONFORMITY ASSESSMENT BODIES

	Name and surname	Function	Date	Signature
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1. SUBJECT AND SCOPE

This procedure defines activities related to the preparation and realization of assessment for the purposes of initial accreditation, surveillance, reassessment, extension, reduction, suspension, or withdrawal.

2. ABBREVIATIONS AND DEFINITIONS

2.1 Abbreviations

- **ATCG** - Accreditation body of Montenegro;
- **CAB** - Conformity Assessment Body;
- **EA** - European co-operation for Accreditation;
- **IAF** - International Accreditation Forum;
- **ILAC** - International Laboratory Accreditation Cooperation.

2.2 Definitions

For the purposes of the procedure, terms based on valid versions of the standards MEST EN ISO/IEC 17000—Conformity assessment—Vocabulary and general principles, MEST EN ISO/IEC 17011—Conformity assessment—Requirements for accreditation bodies accrediting conformity assessment bodies, and MEST ISO 9000—Quality management systems—Fundamentals and vocabulary, Law on Accreditation (Official Gazette of Montenegro, No. 54/09), etc, are used.

accreditation - third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

accreditation body - an authoritative body that performs accreditation.
NOTE: The authority of an accreditation body is generally derived from the government.

accreditation certificate - an official document or set of documents stating that accreditation has been granted for a defined scope

Conformity Assessment Body (CAB) - the body that performs conformity assessment activities and that can be the object of accreditation

accreditation symbol - mark for the use of which the accreditation body permits accredited CAB to indicate its accreditation status.

combined marks - marks of ILAC or IAF mutual recognition agreements in combination with the accreditation symbol for the use of which the accreditation body permits accredited conformity assessment bodies.

Document of conformity - document of conformity: test report, calibration certificate, certificate, inspection report/certificate, verification/validation report, proficiency testing report, issued by an accredited conformity assessment body for activities covered by the granted scope of accreditation

appeal - request by a conformity assessment body for reconsideration of any adverse accreditation decision related to its desired accreditation status

complaint - expression of dissatisfaction, other than appeal, by any person or organization, to an accreditation body, relating to the activities of that accreditation body or of an accredited conformity assessment body, where a response is expected.

assessment - process undertaken by an accreditation body to determine the competence of a conformity assessment body, based on standard(s) and/or other normative documents and for a defined scope of accreditation

NOTE The assessment of the competence of a CAB includes the determination of the competence for the tasks performed by the CAB as a whole, including the competence of the personnel, the validity of the conformity assessment methodology and the validity of the results of conformity assessment

scope of accreditation - specific conformity assessment activities for which accreditation is sought or has been granted. The scope of accreditation can be fixed or flexible. Flexible scope of accreditation is the scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters that fall within the competence of the conformity assessment body, as confirmed by the accreditation body.

flexible scope of accreditation - scope of accreditation expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body.

extending the scope of accreditation - adding conformity assessment activities to the scope of accreditation

Withdrawal of accreditation - canceling accreditation for the full scope

Reducing the scope of accreditation - canceling part of the scope of accreditation

suspension of accreditation - temporary revocation of accreditation, for all or part of the scope of accreditation.

assessment programme - a set of assessments consistent with a specific accreditation scheme that the accreditation body performs on a specific conformity assessment body during an accreditation cycle

interested parties - persons or organizations with a direct or indirect interest in accreditation.
Note: Direct interest refers to bodies that undergo accreditation, and indirect interest refers to bodies and other organizations that use or rely on accredited conformity assessment services.

3. REFERENCES TO OTHER DOCUMENTS

In this procedure, the definitions given in the following documents shall apply:

- Regulation on requirements for accreditation and market surveillance (Regulation (EC) 765/2008)
- MEST EN ISO 9000 - Quality management systems - Fundamentals and vocabulary
- MEST EN ISO/IEC 17011 - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies
- MEST ISO/IEC 17000 - Conformity assessment - Vocabulary and general principles.

Note: The documents are referenced without the year of the publication, meaning that the latest valid version of the document is used.

4. DESCRIPTION OF TASKS AND RESPONSIBILITIES

4.1 ACCREDITATION REQUIREMENTS/CRITERIA

Criteria for granting and maintaining accreditation are set out in:

- Law on Accreditation;
- Montenegrin standards transposing international, i.e. European harmonized standards, which contain general requirements to be met by conformity assessment bodies for certain accreditation schemes;
- mandatory documents, such as guidelines for the application of European and international

standards and guidelines in the field of accreditation and conformity assessment issued by EA, IAF and ILAC;
- Rules of Accreditation adopted by ATCG.

The list of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited CABs (ZPR.01.27-1) is publicly available on the ATCG web portal (www.akreditacija.me).

When there is a change in the requirements for accreditation, the ATCG is obliged to update the list on the ATCG web portal (www.akreditacija.me) and in that way notify the conformity assessment bodies, as well as provide information about the transitional period in which they must comply with the amended requirements of accreditation.

Active participation of ATCG in European and international accreditation organizations and harmonization of accreditation rules and procedures with international standards, policies, and principles of EA, IAF, and ILAC is the responsibility of the managers of the competent Departments and Services while monitoring the changes in the List of EA publications and international documents is the responsibility of the Advisor in the Service for International Cooperation. The heads of the Services have the responsibility to organize meetings of responsible staff at least once a month, (and if necessary more often) at which decisions will be made on possible changes to ZPR.01.27-1 and the way of implementation of changed documents into the ATCG management system, taking into account all information obtained.

If there is a need for additional interpretation of requirements from reference documents for accreditation, for which there are no instructions for application, ATCG will consult technical bodies (committees) and other interested parties.

4.2 INITIAL ACCREDITATION

4.2.1 Application

The accreditation process is initiated by receipt of an Application for accreditation submitted by a CAB in written or electronic form. The application for accreditation contains:

a) general features of the conformity assessment body, including legal entity, name, address(es), legal status and human and technical resources;
b) general information concerning the conformity assessment body, such as its activities, its relationship with a larger entity if any, addresses of all its physical locations that should be covered in the scope of accreditation;
c) clearly defined requested scope of accreditation;
d) commitment to fulfilling the requirements for accreditation and other obligations of the CAB.

Along with the Application for accreditation, CAB shall submit the appropriate required documents/information such as founding acts, a copy of the Quality Manual, if any, and other documents of the quality system (rules, procedures, records). The documents/information to be provided for each accreditation scheme are specified in the Application for accreditation form.

The application for accreditation on the appropriate form that can be found on the ATCG website is submitted directly to ATCG premises or submitted by official mail. ATCG also accepts scanned applications submitted by electronic mail to the official ATCG e-mail address, whereby they must be previously filed, verified, and signed by an authorized person in the CAB.

Depending on the accreditation scheme, accreditation applications are formalized in the following forms:

- ZPR.01.01-1 - Application for accreditation of testing laboratories,

- ZPR.01.02 - Application for accreditation of calibration laboratories,
- ZPR.01.03 - Application for accreditation of inspection bodies,
- ZPR.01.04 – Application for accreditation for certification bodies for products, processes and services,
- ZPR.01.05-1 - Application for accreditation for certification bodies for QMS,
- ZPR 01.06-1 - Application for accreditation of medical laboratories according to the standard MEST EN 15189.

Responsibility: Conformity assessment body

4.2.2 Application Review

The application for accreditation with accompanying documentation is filed in the ATCG in the prescribed manner.

Responsibility: Archivist

The completeness of each submitted application for accreditation and accompanying documentation is reviewed in 5 business days from the date of submission and, in case of incompleteness of the application, the ATCG will request the conformity assessment body to complete the application. The application for accreditation can be amended only once. If the conformity assessment body does not submit a complete application, including all the documents required by it within 10 business days from ATCG's request, ATCG will not accept the application and the conformity assessment body in that case has the right to submit a complaint.

Responsibility: Advisor/Head of the competent Department

Through the application for accreditation review process, ATCG determines its ability to carry out the assessment, in terms of its policies and procedures, its competence, and the availability of personnel suitable for the assessment and decision-making activities. Also, the review includes determining the ability of ATCG to carry out the initial assessment and make a decision in a timely manner within 6 months from the date of receiving the application.

Where, based on the review, it is determined that ATCG has the ability to carry out the accreditation process unhindered, this shall be recorded on the back of the Application for accreditation using the signatures of the Director of ATCG, the Head of the Accreditation Service and the Head of the competent Department, with indication of the date of the application review.

Where, based on the review, it is determined that ATCG cannot accept the application for accreditation (e.g. the submitted scope of accreditation is not within the scope of activities of ATCG or any other justified reason), the conformity assessment body shall be notified thereof in writing, with an adequate explanation of the reasons for non-acceptance of the application. The conformity assessment body has the right to submit a complaint if it is dissatisfied with ATCG's decision not to accept the application.

If there is evidence of fraudulent behavior, intentional providing of false information or concealing of information by the applicant, at any point in the application or initial assessment process, ATCG shall not accept the application or decide to terminate the accreditation procedure. The conformity assessment body has the right to submit an appeal if it is dissatisfied with the ATCG's decision.

Responsibility: Director of ATCG/Head of the Accreditation Service/Head of the competent Department

4.2.3 Contracting

After accepting the application for accreditation, ATCG shall submit to the applicant a standardized

Accreditation Agreement (form ZPQ.00.07) stating the rights and obligations of the contracting parties in the accreditation procedure. In case the authorized representative of the applicant does not sign the agreement within 15 business days, ATCG will make a decision not to initiate the accreditation procedure. The applicant for accreditation has the right to appeal if it is dissatisfied with the ATCG's decision.

The date of signing of the Accreditation agreement shall be considered the formal beginning date of the accreditation procedure.

Responsibility: ATCG Business Secretary/Director of ATCG

4.2.4 Preliminary visit (pre-assessment visit)

Pre-assessment is carried out at the client's request.

ATCG announces a pre-assessment visit, which is carried out by the lead assessor at the client's headquarters and/or at other client locations where activities subject to accreditation are performed. During the pre-assessment visit, ATCG determines:

- whether the conditions for conducting the initial assessment have been met,
- whether the scope of activities for the initial assessment is clearly defined
- and collects other information important for planning and organizing the initial assessment.

If the assessor identifies deficiencies in the system arrangements, work operations, or in the performance of activities subject to accreditation that would negatively affect the initial assessment from being carried out, the assessor informs the client accordingly.

After the pre-assessment has been completed, the assessor prepares a written report, which is then provided to the client.

In the report, the assessor highlights any deficiencies concerning the compliance with the accreditation requirements.

The report also includes a recommendation for the continuation of the accreditation procedure.

The report may also include information about an agreement reached with the client on temporarily suspending the procedure until the client has carried out the agreed activities.

In that case, ATCG waits for the client to confirm that the activities have been completed before the procedure can continue.

If the client fails to provide ATCG, within a reasonable period (three months), with evidence that the conditions for continuing the procedure have been met, ATCG shall issue a notice to the client and request that, within 15 days of receiving the notice, the client specify the timeframe within which the agreed activities will be completed.

If the client does not specify a deadline within the prescribed period, or if the proposed deadline is unreasonably long such that the total duration of the temporary suspension would exceed six months, ATCG shall issue a notice to the client of its intention to terminate the accreditation procedure, stating that the accreditation agreement will then cease to be valid.

If the client fails to respond within 30 days from the date the notice was sent, and does not declare that they will be ready for the initial assessment to be carried out within no more than two months, ATCG shall issue a decision to terminate the accreditation procedure and deliver it to the client. Upon issuance of the decision to terminate the accreditation procedure, the Accreditation agreement with the client is deemed terminated.

If significant deficiencies are identified during the pre-assessment and no agreement is reached with

the client at the end of the visit regarding a temporary suspension or termination of the accreditation procedure, ATCG shall inform the client of the findings and propose either temporarily suspending the procedure until the deficiencies are resolved or terminating the accreditation procedure and the Accreditation agreement.

If the client, despite this proposal, still insists on proceeding with the initial assessment, the procedure shall continue in accordance with the rules governing the initial assessment.

During the preliminary visit, strict care must be taken to avoid consulting the CAB.

Responsibility: Head of the competent Department/Lead assessor

4.3 PREPARATION FOR ASSESSMENT

4.3.1 Appointment of an assessment team

ATCG assessment team is composed of a lead assessor, an adequate number of technical assessors and/or technical experts, ensuring that the team as a whole has the necessary competence for assessing the requested scope of accreditation. In principle, the lead assessor is also the team leader of the assessment team.

Within 15 working days from the conclusion of the Accreditation Agreement (if the CAB has not chosen a preliminary visit as an option), or from the receipt of the notification of the CAB's intention to proceed with the accreditation process (if the CAB has chosen a preliminary visit as an option), ATCG shall notify the CAB of the composition of the assessment team that will carry out the assessment process.

ATCG assessment team with stated names of the members of the team, and their roles within the team, as well as with information on organization in which they are employed, shall be delivered to CAB on the form *ZPR.01.07 Team proposal*. CAB is obliged to respond on its consent with the proposed assessment team within 10 business days. In case a written objection against individual members of the team is submitted, it shall be considered and if it is determined that the objection was justified (confirmed conflict of interest, previous negative experiences with a team member, etc.), the new assessment team shall be appointed with due care taken to avoid conflict of interest. If the conformity assessment body does not agree with the amended assessment team, ATCG may decide to terminate the accreditation procedure. The conformity assessment body has the right to appeal if it is dissatisfied with ATCG's decision to terminate the accreditation procedure.

After obtaining written consent from the CAB for the proposed assessment team, ATCG finalizes a Contract for Engagement of Assessors (form ZPQ.00.08-1) with each externally engaged team member individually. This Agreement outlines the specific assessment tasks and also incorporates provisions on independence, impartiality, and information confidentiality. The agreement will be considered concluded and enter into legal force when ATCG, via the official e-mail address, receives a signed and thus scanned copy of the agreement from the assessor. Upon receipt of the scanned and signed Agreement, it is signed by an authorized person of ATCG, and the signed and scanned copy with the ATCG official seal is sent in electronic form to the assessor. In order for the Agreement to have the evidentiary force of the original document, the contracting parties undertake to make the remaining two copies of the Agreement signed in person. After all engagement agreements have been concluded, the Director of ATCG makes the Decision on the appointment of the ATCG assessment team.

Responsibility: Head of the competent Department/Head of the Accreditation service/*ATCG Business secretary/* Director of ATCG

Immediately after the conclusion of the engagement agreement(s), and with the aim of timely preparation for the implementation of the assessment, ATCG delivers the necessary documentation to the appointed team members, which includes at least the following:

a) for the accreditation scheme for testing/calibration laboratories (ISO/IEC 17025)

to the lead assessor:

- Application for accreditation (on form ZPR.01.01-1 or ZPR.01.02), with accompanying annexes 1, 2, 3, 5, 8, 9 and 10 (documents provided by CAB);
- Procedures PR.01, PR.11 and PR.12;
- corresponding legislation related to technical fields, when applicable and relevant;
- forms: Assessment plan (ZPR.01.08), Lead assessor checklist (ZPR.01.10), Record of attendance at the closing meeting (ZPR.01.20), Report on nonconformities (ZPR.01.21-1), Assessment report (ZPR.01.22)
- any additional information relevant to the assessment and provided by the CAB.

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01 - PA.06).

to the technical assessor:

- Application for accreditation (on form ZPR.01.01-1 or ZPR.01.02), with accompanying annexes 2, 3, 5, 6, 7, 8 and 10 (documents provided by CAB);
- Procedures PR.01, PR.11 and PR.12;
- relevant legislation related to technical fields, when applicable and relevant;
- Assessment plan, assessor worksheet (ZPR.01.15-1);
- any additional information relevant to the assessment and provided by the CAB.

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01 - PA.06).

to the technical expert:

- Application for accreditation (on form ZPR.01.01-1 or ZPR.01.02), without accompanying attachments;
- relevant legislation related to technical fields, when applicable and relevant;
- Assessment plan, assessor worksheet (ZPR.01.15-1):
- Any additional information relevant to the assessment and provided by the CAB.

b) for the accreditation scheme for medical laboratories (ISO 15189)

to the lead assessor:

- Application for accreditation (on form ZPR.01.06-1), with accompanying annexes 1, 2, 3, 4, 5, 6 and 10 (documents provided by CAB);
- Procedures PR.01, PR.11 and PR.12;
- relevant legislation related to technical fields, when applicable and relevant;
- forms: Assessment plan (ZPR.01.08), Lead assessor checklist (ZPR.01.14-1), Record of attendance at the closing meeting (ZPR.01.20), Report on nonconformities (ZPR.01.21-1), Assessment report (ZPR.01.26-1)
- any additional information relevant to the assessment and provided by the CAB.

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01 - PA.06).

to the technical assessor:

- Application for accreditation (on form ZPR.01.06-1), with accompanying annexes 2, 3, 4, 5, 7, 8, 9 and 10 (documents provided by CAB);
- Procedures PR.01, PR.11 and PR.12
- corresponding legislation related to technical fields, when applicable and relevant
- Assessment plan, assessor worksheet (ZPR.01.19-1);
- any additional information relevant to the assessment and provided by the CAB.

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01 - PA.06).

to the technical expert:

- Application for accreditation (on form ZPR.01.06-1), without accompanying attachments;
- corresponding legislation related to technical fields, when applicable and relevant
- Assessment plan, assessor worksheet (ZPR.01.19-1)
- Any additional information relevant to the assessment and provided by the CAB.

c) for the accreditation scheme for inspection bodies (ISO/IEC 17020):

to the lead assessor:

- Application for accreditation (on form ZPR.01.03), with accompanying annexes 1, 2, 3, 5, 6 and 7 (documents provided by CAB);
- Procedures PR.01, PR.11 and PR.12;
- coresponding legislation related to technical fields, when applicable and relevant;
- forms: Assessment plan (ZPR.01.08), Lead assessor checklist (ZPR.01.11), Record of attendance at the closing meeting (ZPR.01.20), Report on nonconformities (ZPR.01.21-1), Assessment report (ZPR.01.23)
- any additional information relevant to the assessment and provided by the CAB.

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01-PA.03 and PA.05).

to the technical assessor:

- Application for accreditation (on form ZPR.01.03), with accompanying annexes 2, 3, 5 and 7 (documents provided by CAB);
- Procedures PR.01, PR.11 and PR.12
- corresponding legislation related to technical fields, when applicable and relevant
- Assessment plan, assessor worksheet (ZPR.01.16);
- any additional information relevant to the assessment and provided by the CAB.

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01-PA.03 and PA.05).

to the technical expert:

- Application for accreditation (on form ZPR.01.03), without accompanying attachments;
- corresponding legislation related to technical fields, when applicable and relevant
- Assessment plan, assessor worksheet (ZPR.01.16)
- Any additional information relevant to the assessment and provided by the CAB.

d) for the accreditation scheme for certification bodies for product certification (ISO/IEC 17065)

to the lead assessor:

- Application for accreditation (on form ZPR.01.04), with accompanying annexes 1, 2, 3, 5, 6, 7 and 8 (documents provided by CAB);
- Procedures PR.01, PR.11 and PR.12;
- corresponding legislation related to technical fields, when applicable and relevant;
- forms: Assessment plan (ZPR.01.08), Lead assessor checklist (ZPR.01.12), Record of attendance at the closing meeting (ZPR.01.20), Report on nonconformities (ZPR.01.21-1), Assessment report (ZPR.01.24)

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01-PA.03 and PA.05).

to the technical assessor:

- Application for accreditation (on form ZPR.01.04), with accompanying annexes 2, 3, 5, 7 and 8 (documents provided by CAB);
- Procedures PR.01, PR.11 and PR.12
- corresponding legislation related to technical fields, when applicable and relevant
- Assessment plan, assessor worksheet (ZPR.01.17);
- any additional information relevant to the assessment and provided by the CAB.

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01-PA.03 and PA.05).

to the technical expert:

- Application for accreditation (on form ZPR.01.04), without accompanying attachments;
- corresponding legislation related to technical fields, when applicable and relevant
- Assessment plan,
- Forms: Worksheet (ZPR.01.18-1), Worksheet on witnessing of the auditor's work (ZPR.01.45), Worklist related to the reviewed of client file (ZPR.01.47)
- Any additional information relevant to the assessment and provided by the CAB.

e) for the accreditation scheme for certification bodies for management system certification (ISO/IEC 17021-1)

to the lead assessor:

- Application for accreditation (on form ZPR.01.05-1), with accompanying annexes 1, 2, 3, 4, 5, 6, and 8 (documents provided by CAB);
- Procedures PR.01 and PR.11;
- Instruction UP.03;
- Record ZUP.03.01, provided by the CAB
- corresponding legislation related to technical fields, when applicable and relevant;
- forms: Assessment plan (ZPR.01.08), Lead assessor checklist (ZPR.01.13-1), Record of attendance at the closing meeting (ZPR.01.20), Report on nonconformities (ZPR.01.21-1), Assessment report (ZPR.01.25)

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01-PA.03).

to the technical assessor:

- Application for accreditation (on form ZPR.01.05-1), with accompanying annexes 2, 3, 5 and 8 (documents provided by CAB);
- Procedures PR.01 and PR.11;
- corresponding legislation related to technical fields, when applicable and relevant
- Assessment plan;
- Forms: Worksheet (ZPR.01.18-1), Worksheet on witnessing of the auditor's work (ZPR.01.45), Worklist related to the reviewed of client file (ZPR.01.47)
- any additional information relevant to the assessment and provided by the CAB.

Note: ATCG will also inform about other relevant normative documents that are publicly available on ATCG website (such as: the valid List of documents containing the requirements to be fulfilled by the applicant for accreditation and the accredited conformity assessment body (on form ZPR.01.27-1) and Accreditation rules PA.01-PA.03).

to the technical expert:

- Application for accreditation (on form ZPR.01.05-1), without accompanying attachments;
- corresponding legislation related to technical fields, when applicable and relevant
- Assessment plan;
- Forms: Worksheet (ZPR.01.18-1), Worksheet on witnessing of the auditor's work (ZPR.01.45), Worklist related to the reviewed of client file (ZPR.01.47)
- Any additional information relevant to the assessment and provided by the CAB.

NOTE: The assessor is obliged, during the assessment, to verify the current versions and amendments of the reference documents, and to appropriately record the findings of the performed verification in the worksheet/checklist/assessment report.

The advisor in the competent department is responsible for keeping records about the above communication.

NOTE: Assessors and technical experts who are permanent employees of ATCG do not need to be provided with the above-mentioned internal documentation (procedures, guidelines, forms), considering it as available to them at ATCG. Record of internal communication must be also kept

Responsibility: Advisor in the competent department/ Head of the competent Department

4.4 ASSESSMENT

ATCG plans the conducting of initial assessments according to the order in which applications are received, except in cases where certain conformity assessment activities are identified as priority due to specific circumstances. In such cases, the Accreditation Service issues a decision on priority consideration.

ATCG conducts regular assessments in accordance with the Plan of surveillance visits, in line with the established Assessment Programmes.

At least 30 days before the assessment, ATCG informs the CAB about:

- the composition of the assessment team,
- the planned duration and cost of the assessment,
- the proposed dates of the on-site assessment at the CAB’s premises (assessment notification).

ATCG also informs the CAB about the content and sequence of the assessment (Assessment Plan), at least 5 working days before the date of the assessment.

For training purposes or for monitoring the performance of assessors, ATCG may delegate observers,

candidates for assessors (trainees) and their mentors within the assessment team. Observers may also be included in the team for the purpose of peer evaluations or for other justified reasons.

Determining the locations at which the assessment shall be carried out, the number of days of assessment and the selection of a representative sample of conformity assessment activities from the scope of accreditation that shall be the subject of the initial assessment and assessments during the accreditation cycle for all types (schemes) of accreditation that are within the scope of activities of ATCG is one of the key activities in the implementation of the assessment procedure. For assessments in the accreditation cycle, ATCG applies an appropriate assessment programme to ensure that the conformity assessment activities representative of the scope of accreditation are assessed at all relevant locations. Depending on the activities performed at different locations, ATCG shall select suitable assessment techniques including, but not limited to: on-site assessment, remote assessment, witnessing, document review, file (case) review, measurement audits, review of performance in proficiency testing and other interlaboratory comparisons, validation audits, unannounced visits, interviewing.

In case when ATCG assessment team includes assessors/technical experts from other accreditation bodies, as well as in the case when ATCG performs assessment within the framework of cross-frontier accreditation, the number of days of assessment also depends on the scope of preparatory work that needs to be realized (translation and reading of documents in a foreign language, production and translation of records created in the assessment process, etc.). Also, in case of transition to a new version of the reference document for accreditation, ATCG may decide to increase the number of days of assessment.

In case when a CAB does not wish to submit complete management system documentation as required by Application for accreditation, ATCG can increase the number of days of assessment, in order to review the missing documentation at CAB's location.

4.4.1 Assessment types and techniques

ATCG uses various techniques for the purposes of CAB assessment. These techniques depend on the type of assessment, applicable requirements and associated risks and are chosen to ensure that the CAB is assessed most efficiently.

Types of assessment:

i) Initial assessment - a formal assessment of a new applicant for accreditation (or an accredited CAB for a new reference standard) to ensure that the assessment of conformity with all accreditation requirements has been effectively carried out

ii) Regular assessment (surveillance) - carried out 1-3 times during the accreditation cycle depending on the assessment programme (i.e. risk) to ensure that the accreditation criteria are maintained

iii) Reassessment - conducted in the last (fourth) year of each accreditation cycle to ensure that the CAB continues to meet all accreditation requirements

iv) Witnessing - is conducted to assess the CAB's ability to perform the actual conformity assessment activity. It is realized either at the CAB’s location or during the witnessing of the personnel who carry out the conformity assessment activity at one or more locations of their clients. The witnessing can be included in the on-site assessment (e.g. testing) or take place as a separate activity (such as the witnessing of inspection activities or of a management system audit).

v) Extension of the scope of accreditation - is carried out in order to extend the granted scope of accreditation of the CAB. In addition to extending to new conformity assessment procedures,

this may also involve changing the location where conformity assessment activities are carried out or changing key resources (e.g. equipment).

vi) Additional assessment - it can be carried out if it was not possible to fulfill all aspects of the assessment during the planned assessment. Alternatively, additional assessment may be necessary to confirm the effective implementation of corrective actions or to ensure the elimination of weaknesses in the system. Other reasons for additional assessment include, but are not limited to, reinstatement following a period of voluntary, involuntary, or financial suspension, investigation of appeals, or change of legal entity.

vii) Extraordinary assessment - an assessment that is carried out without giving the client any notice or with a time-limited notice

viii) Assessment for the needs of transition - is carried out to verify the fulfillment of new/amended requirements when there is a change in the reference standard or other key accreditation criteria
Note: If the change results in a new rather than a revised standard, then this is referenced as 'Migration' and not as 'Transition'.

Assessment techniques:

The assessment is carried out according to a predetermined and agreed plan and based on the perceived risks using selected assessment techniques (e.g. on-site assessment, witnessing the carrying out of the conformity assessment procedure, vertical audit, file review, interview with personnel, remote assessment, etc.).

During the development of the Assessment programmme and Assessment plan, it is taken into account that CAB assessment may include one or a combination of the following assessment techniques:

a) Review of the required documentation submitted by the CAB
b) On-site assessment – Assessment of CAB's activities at specific locations,
c) On-site assessment – Assessment of the CAB management system and its implementation
d) On-site assessment – Review of generated records/files related to the conformity assessment process, performed activities, reports and other supporting documentation
e) On-site assessment – Witnessing the CAB's personnel performing conformity assessment activities
f) On-site assessment – Interview with personnel (evaluation of technical competence of personnel through interviews)
g) Remote assessment – Assessment of CAB's locations using appropriate IT tools
h) Remote assessment – Review of the required documentation, excluding the evaluation of CAB locations

NOTE: Assessment of the required-submitted documentation

When it is conducted:
This type of assessment is used in cases when a physical visit is not considered necessary, for example:

- for minor extensions/changes within the granted accredited scope,
- for changes within the accredited CAB,
- to verify the performance of the accredited CAB (e.g., following a complaint),
- for simpler activities that do not require a complex assessment.

How it is conducted:

1. ATCG appoints an assessor and requests relevant documentation from the CAB.
2. The assessor reviews the CAB’s documentation and prepares a documentation review report.

3. If nonconformities are identified, ATCG:
   - submits to the CAB a nonconformity report,
   - requests from the CAB a cause and impact analysis of the nonconformities, a proposal for corrective actions, and a plan and deadlines for implementing those actions.
4. The CAB has one week to propose corrective actions and two weeks to provide evidence of the actions taken.
5. After reviewing the submitted evidence, the assessor issues a recommendation for accreditation (positive or negative).

In situation when:

- the documentation is incomplete,
- the evidence is insufficient,
- the CAB disagrees with the findings,
- or the resolution of nonconformities is inadequate,

the assessor may recommend a follow-up assessment or closure of the process without granting/extending accreditation.

NOTE: The assessments conducted by using techniques specified under g) and h) should be a subject of review at least during regular internal audits.

Responsibility: Head of the competent department / Lead assessor / Technical assessor

4.4.2 Determining the time required for the assessment and selecting a representative sample of the scope of accreditation for assessment

The number of activities carried out by the CAB should be taken as the main factor in determining the time for assessment on the basis of the assessor day. In addition to the scope of CAB's activities, the number of personnel performing the conformity assessment activities, the organizational structure of the organization, the locations where the activities are carried out, the size and complexity (significance) of the scope of accreditation shall also be evaluated.

Also, in order to determine the competence and performance of the CAB, it is necessary to witness a sample of its conformity assessment activities prioritizing critical testing/inspection/certification activities and activities carried out on-site.

The adequate time needed for the assessment (number of assessor-days) is determined by the person reviewing the application for accreditation, taking into account all types of information and data provided by the CAB, when forming the assessment team.

ATCG must consider the risks associated with the activities of the CAB when planning the assessment, developing accreditation programs, or in case of the extension of the scope of accreditation, as outlined in clauses 7.4.6, 7.9.3, and 7.10.1 of the ISO/IEC 17011 standard.

The risk-based approach supports the goal of assessment by ensuring that appropriate and representative samples are taken. Such assessments focus on issues that are important in the current situation (arising from the internal and external context relevant to the CAB) and that may affect the CAB's ongoing compliance with accreditation requirements. Specifically, this includes competence, consistent performance, and impartiality, which impact conformity assessment activities. ATCG should consider the risks associated with the CAB providing potential unreliable conformity assessment activities, as well as the consequences of such activities on the CAB's clients, stakeholders, and the public.

The use of a risk-based approach can impact the duration or frequency of assessments, the selection of assessment techniques, and the composition of the assessment team. The goal of risk-based assessment is to optimize the value of the assessment and provide justification for the duration or

frequency of the assessment, the selection of appropriate assessment techniques, and the composition of assessment team.

When preparing for the assessment, the ATCG will consider the risks associated with the activities, locations, and personnel of CAB covered by the scope of accreditation, as well as the risks related to the operation and structure of the CAB. ATCG is not limited only to the risks outlined in section 4.7.2 of this document, since other risks may also be considered.

The assessment program should also reflect all other risks specific to the subject assessment. The list of risks (table below) should be taken into consideration when planning the assessment, including preparation time, assessment time, and the composition of the team.

The risk factors (based on EA-2/19 INF:2022, *List of Risks for Accreditation Processes and Operation of National Accreditation Bodies*) that should be considered and may affect the number of assessment days, the assessment technique, and the interval between consecutive assessments at the CAB locations are outlined in the following table:

Risk area:	**Potential risk:**
Activities	- Complexity of the scope of accreditation (conformity assessment activities). - Conformity assessment schemes that involve evaluation – assessment of factory production control and testing of product samples taken from production, as well as post-delivery product inspection. - Existence of conformity assessment activities that may post a significant risk to safety and health (e.g. testing/monitoring product characteristics to ensure food safety). - Relationship between standard and non-standard conformity assessment procedures (e.g., methods/procedures developed in laboratories, inspection bodies, or certification bodies). - Conformity assessment activities that are subject to authorization/ designation. - Frequency of conformity assessment activities. - Organization of the CAB: number of locations, geographic areas, foreign locations, management of multiple management systems for different organizational units/standards. - Existence and complexity of external (legal) requirements and regulations (national and EU) for the specific sector (e.g., diversity of regulatory texts and requirements). - General level of competence and compliance in the areas where the CAB operates (e.g., critical findings, complaints, market surveillance operating in the same sector). - Amount and frequency of services provided to clients, such as the number of certificates, test reports, etc. - Market share of the CAB. - Outsourcing activities and the share of outsourcing within the conformity assessment process. - Performance of other activities that may interfere with or conflict with conformity assessment tasks (e.g., consultancy services, manufacturing of products being tested, etc.). - Frequency and nature of changes within the CAB during the accreditation cycle; key changes such as ownership, key personnel, locations, equipment, etc.

	- Remote work/virtual locations (e.g., when individuals spend a significant amount of time working independently from a centralized location). - Flexible scope of accreditation for the CAB. - Previous performance in external monitoring activities (external quality control) (e.g., proficiency testing or inter-laboratory comparisons). - Previous performance related to the effective and timely resolution of non-conformities. - Number and nature of findings identified in previous assessments or previous accreditation cycles. - Previous performance in relation to significant non-conformities. - Previous performance in conducting effective root cause analysis and determining the extent of identified non-conformities. - History of sanctions (full or partial), e.g., suspensions (reasons for suspension within the accreditation cycle), reduction of scope, etc. - History of extraordinary assessments during the accreditation cycle. - Existence of complaints regarding the performance of the CAB for specific conformity assessment activities, particularly those submitted to ATCG. - Resolution of complaints, sectoral feedback, and available information regarding the CAB's performance (media, etc.).
Pesonell	- Competence and experience of the CAB personell; - Staff turnover; - Resource capacity and ability to provide conformity assessment services in a timely and competent manner; - Ratio of newly hired to experienced staff for specific functions (particularly regarding conformity assessment activities).
Locations	- Number of locations and the activities on locations - Level of control and supervision over CAB locations - Critical activities carried out at the locations (e.g., process development and approval, contract review, decision-making, competence approval, and staff performance monitoring) - Type of location – permanent, temporary, or mobile - Geographic distribution of locations

The assessment program is updated following information received about changes in the CAB, after an extension of the scope of accreditation, a reduction of the scope of accreditation, or after any change to the scope of accreditation.

Factors that increase the assessment time (assessor-days)

1) activity carried out at more than one location with limited transportation and communication resources;
2) requires the use of translation services;
3) activities carried out with high precautionary measures
4) assessment in accordance with the rules of cross-border accreditation;
5) activities regulated by legislation;
6) a large number of CAB personnel and/or a broad scope to be assessed.

Factors that reduce the assessment time (assessor-days)

1) transfer of accreditation;
2) scope to be assessed and the number of CAB personnel are limited;
3) maturity of the applicant's management system;

4) simplicity of conformity assessment activities and performance of the same activities by large number of personnel;
5) the fact that the CAB is already accredited according to the requirements of another accreditation standard.

The assessment time (assessor-days) includes review of the CAB's documented information, assessment planning, performing of necessary correspondence activities, and assessment activities, including witnessing and review of CAB's files and reporting carried out by the assessors."

The calculated time (assessor-days) does not include the time assessors spend traveling to and from the CAB's location. One assessor day corresponds to an 8-hour working day.

The times listed in the tables below are defined for normal circumstances. These times may be subject to change due to the above-mentioned specific factors.

Responsibility: Head of the competent department

4.4.2.1 Determining the time (man-days) required for the assessment of laboratories, selecting a representative sample of the scope of accreditation for assessment

The scope of activities is considered the key factor in determining the assessment time needed for the accreditation assessment of a laboratory. It shall be evaluated whether the organization has subsidiaries, the number of laboratory personnel, the organizational structure, the locations where the activities are performed, and also the volume and complexity of the activities performed (whether there are any critical fields of testing). In order to determine the competence of the laboratory, it is necessary to witness a sample of testing activities or to carry out the assessment by prioritizing the critical laboratory activities. Furthermore, the assessor samples the scope of accreditation, by taking into account the test/calibration methods and the similarity of the materials (matrix) being tested and the devices being calibrated. Information on sampling is recorded in the Assessment report and the Work list of the technical assessor/expert containing the objective evidence gathered during the on-site assessment. Planning of the assessment is carried out by the lead assessor using the Assessment programme developed for a particular laboratory, taking into account any issues of scope extension to be carried out together with surveillance assessment, as well as reports from previous assessments, implementation of PT activities, reports on interlaboratory comparisons.

As a rule, the number of days of assessment of testing/calibration laboratories shall be determined based on the number of fields/sub-fields of testing or calibration, as well as the number of testing methods/techniques or calibration items within a certain field/sub-field.

The number of days of assessment at the laboratory's location during the initial assessment shall be, as a rule, 1 for the lead assessor (assessment of system requirements of reference documents) and 1 for technical assessor/technical expert for each field/sub-field of testing or calibration from the requested scope of accreditation. The number of days at the laboratory's location can be increased depending on the number of testing methods/techniques or calibration items within a certain field/sub-field. This number is determined depending on the number of witnessing that need to be conducted in order to assess the representative sample of the requested scope of accreditation, as well as other assessment techniques to be used.

If the testing/calibrations from the requested scope of accreditation are conducted at several locations, the assessment shall be performed at all locations where some of the following activities are performed: testing/calibration, sampling. Depending on the scope and type of listed activities, the number of days at each location shall be determined. At locations where other activities are performed, such as: storage (warehouse space), storage of samples, preparation of samples/calibration items, etc. the assessment does not have to be carried out if it is determined that these activities do

not present a risk to testing/calibration procedure. In any case, insight into these activities shall be realized through a review of records of activities at these locations.

During the initial assessment, the performance of representative testing/calibration methods for each field (sub-field) of testing/calibration and each testing technique/calibration method, i.e. calibration item, shall be witnessed and assessed.
Note: the term testing laboratory in this procedure also applies to medical laboratory.

For example, if a testing laboratory has applied for accreditation in areas of food and items of general use, with testing methods using techniques such as AAS, ELISA and spectrophotometry, then the assessment will cover methods from both areas and all techniques without the need to repeat the techniques on different test items from these two areas. This approach prevents the duplication of assessment activities by two or more technical assessors/experts covering different areas of testing.

For example, if a medical laboratory has applied for accreditation for the scope containing methods for testing of biological material of human origin using various testing techniques then the assessment will cover the selection of representative testing methods from each individual testing technique. If multiple parameters are determined simultaneously within a testing method (for example, using a biochemical analyzer that measures several different parameters from the same sample), the assessment will cover that method to verify the accuracy and reliability of such a multi-parametric technique (e.g., lipid profile, which includes measuring cholesterol, triglycerides, and other lipids in blood, etc.).

If sampling is part of the requested scope of accreditation, then it must be assessed.

For example, if a calibration laboratory has applied for accreditation in fields of mass, force and pressure, and as calibration items weights and non-automatic weighing instruments in the area of mass, manometers in the area of pressure, and force measuring devices in the area of force, the assessment will cover the following calibration methods: calibration of weights, calibration of weighing instruments, calibration of manometers, and calibration of force measuring devices. If, for example, the laboratory has listed two or more different calibration methods for the same calibration item within the requested scope, it is sufficient to assess only some methods (or even one) that are critical and/or characteristic for that specific field of calibration.

The selected testing methods/techniques or calibration methods for asessment must collectively constitute a representative sample of the required scope of accreditation. If more persons in the laboratory are authorized to perform the same testing or calibration activity, the assessment process in accreditation cicle will provide that each time other operator is assessed, unless explicitly required for some specific reasons (e.g. to assess the effectiveness of corrective actions).

During the initial assessment of laboratories for microbiological testing, it is essential to assess both quantitative methods (e.g., determining the number of coagulase-positive staphylococci) and qualitative methods (e.g. detection of Salmonella species), by witnessing the performance of the entire testing method. Similarly, during the initial assessment of laboratories for sensory testing, it is necessary to assess the performance of the entire testing method by witnessing.

TABLE 1 (initial accreditation)

Laboratory	
Preparation for assessment and summarization of assessment results (management system document review and reporting, reporting on the findings of the assessment) (assessor-days)	On-site activities: assessment of management system and test/calibration methods (assessor- days)

1 ± 0,5 **Explanation:** As a rule, each team member spends 1 day on the specified activities (0.5 days for preparatory activities and document review, and 0.5 days for necessary reporting); this number of days may be increased considering some of the factors listed in section 4.2 — e.g., large accreditation scope, flexible accreditation scope, etc. — or decreased considering some of the factors listed in section 4.2, with the maximum increase or decrease being 0.5 days.	1 for the lead assessor + 1 for the technical assessor/technical expert for each field/sub-field of testing or calibration ***Note:*** *The number of assessors/experts is determined through analysis for each area separately, in such a way that all testing/calibration areas are covered.* This number of days may be increased depending on the number of testing/calibration methods/techniques within a given field/sub-field, as described in the text above, and is determined based on the number of witness audits that need to be conducted to assess a representative sample of the accreditation scope.

The number of assessment days at the CAB's location may be increased in the cases listed in Table 1A below.

TABLE 1A

For assessment activities covering:	Additional assessor-days (per assessor/technical expert)
Flexible scope of accreditation	Min 0.5
Accreditation for authorization/designation purposes	Min 0.5

For other accreditation assessments, the following applies:

TABLE 1B

Surveillance	Assessor-days (per assessor/technical expert)
Preparation and summarization of assessment results – analysis of the Assessment Program and preparation of the assessment plan, reporting on assessment findings (assessor-days)	In accordance with Table 1
On-site activities (assessment in accordance with the Assessment Program) (assessor-days)	1 for the lead assessor + the number of days for other team members depends on the Assessment Program, which is developed and updated in the manner defined by this Procedure.

TABLE 1C

Surveillance + Extension of scope	Assessor-days (per assessor/technical expert)
Preparation and summarization of assessment results – document review and reporting on the document review, analysis of the Assessment Program and preparation of the assessment plan, reporting on assessment findings (assessor-days)	In accordance with Table 1
On-site activities: assessment of the implementation of the management system and the testing/calibration methods for which the extension is requested, as well as assessment following the Assessment Program – surveillance activities (assessor-days)	1 for the lead assessor + 1 for the technical assessor/technical expert for each field/sub-field of testing or calibration for which the extension is requested + the number of days for team members, depending on the Assessment Program, which is developed and

	updated in the manner defined by this Procedure. The number of days may be increased depending on the extension request (e.g., if a larger number of witness audits need to be conducted) or decreased if the CAB is already accredited in the field/sub-field of testing or calibration and/or for the testing/calibration techniques, as well as depending on Method 1 or Method 2 of scope assessment as described in the text below.

TABLE 1D

Extension of scope	Assessor-days (per assessor/technical expert)
Preparation and summarization of assessment results – document review and reporting on the document review, preparation of the assessment plan, reporting on assessment findings (assessor-days)	In accordance with Table 1
On-site activities: assessment of the implementation of the management system and the testing/calibration methods, including witnessing (assessor-days)	In accordance with Table 1 Additionally, the calculated number of days may be reduced if the CAB is already accredited in the field/sub-field of testing or calibration and/or for the testing/calibration techniques, as well as depending on whether Method 1 or Method 2 of scope assessment, as described in the text below, is used.

The time allocated for assessments within the accreditation cycle is determined through a risk analysis, and it is summarized in the Assessment Program.

Elements to be considered for the assessment of the scope accreditation of laboratories:

The criteria for selecting a representative sample are as follows:

- different equipment/analytical systems (e.g., spectrophotometer, atomic absorption spectrophotometer, gas chromatograph, biochemical analyzer, hematological analyzer, immunoassay analyzer, flow cytometer)
- the area of technical competence defined by a single measurement technique
- the type of material on which testing is performed (matrix) – water, food, air, concrete, etc.
- specificity of the method

In the case of calibration laboratories, during initial accreditation assessment, all stated calibration procedures/methods must be evaluated, which includes:

- demonstration of the calibration / individual phases of the method/procedure
- conducting evaluation (for whole or part of the method/procedure, which does not have a proof of compliance gained through interlaboratory comparisons)
- review of records (technical records and management system records).

Through regular surveillance assessments during an accreditation cycle, calibration methods/ procedures must be evaluated at least once. Calibration procedures performed on-site must be assessed at the client location no later than during the first surveillance after the initial accreditation.

For the assessment of accreditation scope, both in initial assessment and in surveillance assessments throughout the accreditation cycle, the following factors must be considered:

a) testing/calibration/medical examinations methods may be divided into homogeneous groups, considering the following criteria: field/subfield of testing/calibration, testing technique, fixed and/or flexible scope, product/material being tested, calibration object, frequency of testing/calibration.

b) selected testing/calibration/medical examination methods may be evaluated in two ways: Type 1: witnessing of performing the entire testing/calibration/medical examination method. Type 2: documentation review of generated records, from sampling to the testing report or calibration certificate.

c) for each group of testing/calibration/medical examination methods, the selected number of methods to be assessed, testing items/calibration objects as well as sampling methods must be sufficient to confirm the laboratory's competence (personnel, equipment, testing location/ calibration conditions, etc.).

d) findings from previous evaluations (e.g. non-conformities, PT activity results, staff fluctuation, suspensions, location changes (relocation) of the laboratory etc.);

e) internal calibrations performed by the laboratory;

f) fixed and/or flexible scope of accreditation.

There must be a written justification for the elements considered (during the initial assessment, it is formed during the preparation phase for assessment or in the phase of preparing the Assessment Plan, and thereafter in the Assessment Program).

Upon request, the ATCG will provide to the laboratory information on how the representative sample of the scope of accreditation for assessment was selected.

For the purpose of the preparing initial assessment and the preparation of the Assessment Program, it is necessary to combine both types of assessing the scope of accreditation in such a way that tests/calibrations can be assessed more than one time within the accreditation cycle using different techniques (see above – b) Type 1 and/or Type 2).

When creating an Assessment Program, the following risk factors should also be taken into account:

- in case of the implementation of mandatory activities related to testing as a support to product certification (e.g. for the needs of designated/authorized bodies), or medical testing for diagnosing the health condition of patients, or calibration in the process of verification of legal measuring instruments - Type 1 or a combination of Type 1 and Type 2 techniques shall be used during the execution of each assessment at the laboratory location;
- in case of the activities performed by the laboratory that involve testing for the purpose of food monitoring and control/ - Type 1 technique shall be used during the execution of each assessment at the laboratory location;
- in case of laboratories conducting sampling as a standalone activity (e.g. sampling of waste gas emission) – assessment of sampling using Type1 technique is mandatory during initial assessment (or assessment to extend the scope of accreditation for this activity) while for other assessments combination of Type 1 and Type 2 techniques shall be used;
- if the laboratory provides opinions and interpretations - assessment in correlation with the corresponding testing/calibration method shall be carried out by using Type 1 technique at the initial assessment, while in other assessments, Type 2 technique may also be used;
- if the laboratory uses non-standardized methods (in risk analysis it should be also assessed the ratio between standard and non-standardized methods), the procedure related to planning and validation of related methods shall be assessed by Type 2 technique at each assessment at the laboratory location, when relevant;
- availability of appropriate proficiency testing (PT) activities and other relevant activities

ensuring the validity of testing/calibration results - technical areas where there are no or a limited number of available PTs and other relevant activities, and which represent a higher risk, Type 1 technique or combination of Type 1 and Type 2 techniques shall be used during the execution of each assessment at the laboratory location;

- In case of flexible scope of accreditation, at the laboratory location, Type 1 and Type 2 techniques shall be used for the assessment of the scope of accreditation, depending on changes to the list of accredited activities between two assessments.

Based on the assessment of potential risks, ATCG has established a conditional classification of laboratories into the three basic groups – see Section 4.7.2 a), Table 1 - Determining the risk group for testing/calibration laboratories

Responsibility: Head of the competent department / Lead assessor / Technical assessor

4.4.2.2 Determining the time (man-days) required for the assessment of inspection bodies, selecting a representative sample of the scope of accreditation for assessment

The scope of activities for which the CAB applies is considered a key factor in determining the evaluation time for assessing conformity assessment bodies that will be subject to accreditation based on the „assessor-day“parameter. Assessment, among other things, depends on whether the organization operates from multiple locations, the number of personnel, organizational structure, locations where activities are conducted, as well as the scope and complexity of the accreditation scope.

When selecting a representative sample of the scope of accreditation, it is crucial to ensure that the sample adequately represents all aspects of the subject and type of inspection. This is vital for the accuracy and reliability of the results.

Steps for selecting a representative sample:

Defining inspection items

a) Clear identification of all components, materials, or products subject to inspection.

b) Clear identification of different types of inspection (which may require different approaches in sample selection).

When inspection item within the scope is divided into several sub-items (e.g. division in terms of working media, products, etc.), the sample selected for the initial assessment will be the one requiring the strictest inspection (e.g. inspection of pressure vessels for refrigeration devices in the area of pressure vessel inspection), or the one that is most representative in the group.

When the CAB performs inspection of different items using related or identical procedures, equipment, personnel, etc. (e.g., cylinders for breathing apparatus or cylinders for fire extinguishers), it is considered sufficient to observe only one of the items from the set with related inspection characteristics during the initial assessment.

The lead assessor, in collaboration with the Head or Department, decide on the preparation and updating of the accreditation program and the representative sample for evaluation in each assessment.

Within one accreditation cycle (three consecutive surveillance assessments and re-assessment), sampling of the assessment scope is conducted in a way that ensures all items or related groups of oversight subjects are assessed at least once.

Using the approach outlined in this procedure, the time required for efficient assessment of CABs of various sizes and/or with multiple branches can be calculated using the assessor-day parameter.

In general, the number of assessor-days for assessing inspection body is based on the number of inspection areas or the product/product groups being inspected.

Furthermore, to assess the competence of the inspection body, it will be essential to conduct on-site witness audits for selected representative sample of inspection activities, which means performing assessment at the location where inspection is performed and with priority given to critical inspection activities.

During surveillance assessments conducted within the accreditation cycle, all accredited inspection activities must be assessed. The work and performance of all inspectors conducting inspection activities within the accreditation scope should be assessed during the accreditation cycle.

When sampling is part of the inspection activities, the requirements of the MEST EN ISO/IEC 17025 standard, clause 7.3, must be applied.

If the activities of the inspection body are carried out at multiple locations (sites where key inspection activities are performed, such as issuing reports, managing equipment, making decisions, etc.), all such locations must be assessed during the initial accreditation. Depending on the scope and type of the mentioned activities, the number of days at each individual location is determined.

The number of days of assessment at the location of the inspection body during the initial assessment shall be, as a rule, 1 for the lead assessor (assessment of system requirements of reference documents) and 1 for a technical assessor/technical expert for each inspection field according to the scope of accreditation.

The number of days at the location of the inspection body can be increased, all depending on the diversity of products/groups of products (subgroups of products as it is defined in PR.11) or the type of inspection within the inspection field (products as it is defined in PR.11).

During the initial assessment, witnessing of a representative inspection from each field of inspection (products/group of products as it is defined in PR.11) from the requested scope of accreditation shall be conducted. The representativeness shall be decided by the appointed technical assessor/technical expert in consultation with the Head of the Inspection body's department and the lead assessor. For the assessment of each inspection field from the scope of accreditation (products/group of products as it is defined in PR.11), the number of assessment-witnessing days shall, as a rule, be 1, but this number can be increased by taking into account the number of products for witnessing within the inspection field. Also, the time required for the realization of the witnessing can be increased if it is a complex inspection activity (e.g., several types of inspections according to the contract, a large number of inspection activities, etc.).

If accreditation is a prerequisite for authorization/designation, accreditation can be granted based on an assessment of the CAB's operation under simulated conditions. The accredited and then authorized/designated IB is required to timely notify ATCG of its first real inspection activity for the purpose of its witnessing (assessment) by ATCG. If such activity is not provided at all by the first accreditation surveillance assessment, ATCG will suspend the granted accreditation for this activity.

The number of assessment days shall be increased by at least 0.5 days if it is necessary to perform an assessment or witnessing in the process of using an external testing service (by the inspection body) that supports the inspection. In addition to all activities that include the initial assessment, during the on-site assessment at the location of the inspection body, the assessment team shall also carry out file review for previously conducted inspection activities by reviewing a minimum of 1 file within each field respectively group of products (as applicable) from the requested scope of accreditation.

Numbers indicated in Table 2 are taken into account when determining the total initial assessment time in terms of assessor-days.

TABLE 2

Inspection body	
Preparation for assessment and summarization of assessment results (management system document review and reporting, reporting on the findings of the assessment) (assessor-days)	On-site activities: assessment of the management system and inspection activities (assessor- days)
1 ± 0,5 Explanation: As a rule, each team member spends 1 day on the specified activities (0.5 days for preparatory activities and document review, and 0.5 days for necessary reporting); this number of days may be increased by taking into account some of the factors listed in section 4.2 and the text above — e.g., a large number of different product groups, a large number of different inspection types, etc. — or decreased by considering some of the factors listed in section 4.2, with the maximum increase or decrease being 0.5 days.	1 for the lead assessor + 1 for the technical assessor/technical expert for each field of inspection (product group/product) according to the scope of accreditation Note: The number of assessors/experts is determined through analysis for each area separately, in such a way as to cover all fields of inspection. This number of days may be increased depending on the factors mentioned in the text above and is determined based on the number of witness audits that need to be conducted to assess a representative sample of the accreditation scope, which may also include assessment for designation/notification (minimum 1 assessor-day). Legal requirements, regulatory requirements, standards, or requirements of the competent authority may affect the required extent of witnessing and, consequently, the number of assessment days.

Witnessing of inspection activities shall be carried out in each inspection field, with high-risk inspection activities being prioritized. The time for on-site assessment will be calculated depending on the activity that will be assessed (for example, on-site assessment would include hydraulic lift, electric lift, crane, mobile crane and escalator for the initial accreditation assessment of an inspection body that applied for accreditation with the scope that includes hydraulic lift, electric lift, crane, mobile crane, platform for lifting vehicles, escalators).

The times listed in Table 2, expressed in assessor-days, are provided for initial accreditations.

Assessments within the accreditation cycle are by the rule conducted annually by using appropriate assessment techniques, unless otherwise determined during the development of the Assessment Program. When developing the Assessment Program, it shall be ensured that the time between consecutive assessments on inspection body location does not exceed two years. The Assessment Program shall cover the entire scope of accreditation and all locations of the inspection body during one accreditation cycle. In general, assessments within the accreditation cycle are carried out through on-site assessments at the premises of the inspection body, and by the rule include all accreditation requirements defined in the reference documents for accreditation and other normative documents, as well as a specified number of witness audits of inspection activities. During assessments within the accreditation cycle, personnel whose work in performing inspections is being assessed—the ones whose performance is witnessed by the ATCG assessment team (ATCG)—are selected in such a way that the work and performance of all key personnel responsible and authorized for performing inspection activities within the assigned scope of accreditation is reviewed and assessed. This includes personnel whose work may have an impact on the quality of results from accredited inspections.

If more inspectors of the inspection body are authorized to carry out the same inspection activities, the witnessing will be organized so that the same individuals are not repeatedly assessed (unless otherwise planned for specific reasons, such as assessing the effectiveness of corrective actions). The selection of inspectors whose work is to be witnessed by the evaluation team (ATCG) is made by the ATCG, considering risk factors (e.g., newly hired inspectors, complexity of inspection tasks,

effectiveness of internal monitoring - supervision of inspector performance, etc.).

Based on the assessment of potential risks, ATCG has established a conditional classification of inspection bodies into the three basic groups – see Section 4.7.2 b), Table 2 - Determining the risk group for inspection bodies.

TABLE 2A

Surveillance	Assessor-days (per assessor/technical expert)
Preparation and summarization of assessment results – analysis of the Assessment Program and preparation of the assessment plan, reporting on assessment findings (assessor-days)	In accordance with Table 2
On-site activities (assessment in accordance with the Assessment Program) (assessor-days)	1 for the lead assessor + the number of days for other team members depends on the Assessment Program, which is developed and updated in the manner defined by this Procedure

When the extension of the scope of accreditation is assessed together with surveillance/reassessment, the time for assessment of the extension shall be calculated, depending on the size and characteristics of the requested extension of the scope of accreditation, and added to the time calculated for surveillance/reassessment.
If the inspection bodies, which have applied for accreditation in accordance with ISO/IEC 17020, have more than one branch office, the number of assessor-days for assessment in the branches is calculated as follows:

- Assessments in the branches are determined taking into account the scope and volume of the inspection activities held in the branches, the number of personnel and the level of complexity (significance) of the inspection activities
- All branch offices of the inspection body should be evaluated during the accreditation process.

When deciding on the number of on-site witnessing, the ATCG needs to consider the following aspects:

- fields and types of inspection
- the inspection body's procedures for the selection, authorization, training, and monitoring of inspectors, with regard to the qualifications and experience required for different fields and types of inspections;
- internal audit procedures of the inspection body;
- locations where inspectors operate;
- all legal requirements;
- the extent to which the inspector's professional opinion is required
- number of inspectors;
- frequency of inspections;
- requirements for inspector's competence, e.g. certification of persons or formal qualification.

The on-site assessment is usually carried out at each regular assessment. When determining the number of witnesses, the same criteria used for the initial assessment will be taken into account concerning the type of inspection and the inspectors whose performance needs to be witnessed. At least one aspect of the inspection body's technical scope must be witnessed each year. When deciding which inspectors will be witnessed, the following will be taken into account:

- new employees or new authorizations;
- qualifications and experience;
- place;

- all legal requirements;
- the extent to which the inspector's professional opinion is required

Responsibility: Head of the competent department / Lead assessor / Technical assessor

4.4.2.3 Determining the time (man-days) required for the assessment of product certification bodies, selecting a representative sample of the scope of accreditation for assessment

By using the procedures and approaches specified in this procedure, the time required for effective assessment for the purposes of accreditation of product certification bodies of different sizes and/or with multiple branches shall be calculated by means of the assessor-day parameter.

The scope of activities is considered the key factor in determining the assessment time needed for the accreditation assessment of a product certification body. It shall be evaluated what specific products or groups of products are being certified, the number of product groups, whether the certification body has more than one subsidiary, the number of personnel involved in certification activities, and the organizational structure.

The initial assessment shall be realized in a way that the selected assessment techniques assess the fulfillment of all requirements for accreditation (requirements of reference standards for accreditation and other normative documents) and the scope of accreditation. As a rule, the number of assessment days shall be determined based on the number of certification schemes/procedures, i.e., the number and/or nature of products/groups of products within them and/or activities within the certification scheme. The number of assessment days at the location of the certification body during the initial assessment shall be, as a rule, 1 for the lead assessor (assessment of system requirements of reference documents) and 1 for technical assessor/technical expert for each certification scheme. The number of days at the location of the certification body can be increased, all depending on the diversity of products/groups of products covered by the certification scheme, as well as activities within the certification scheme.

If the certification activities from the requested scope of accreditation are carried out at several locations, the assessment shall be performed at all locations where some of the following activities are performed: policy formulation; development of certification schemes, contracting, conducting assessments, reviews and certification decisions. During the initial assessment, witnessing shall be conducted in a representative number of activities from each certification scheme according to the requested scope of accreditation. The representativeness shall be decided by the appointed technical assessor/technical expert in consultation with the competent Head of Accreditation Service and the lead assessor. If the certification scheme includes the evaluation (review/assessment) of the factory production control, or product testing where the certification body does not have accredited laboratory within its structure and it subcontracts a testing laboratory whose competence has been confirmed by means other than accreditation, these activities shall be a subjects of evaluation during the initial accreditation assessment. In the last case, the ATCG will evaluate how the certification body has verified the competence of the non-accredited laboratory, according to the ISO/IEC 17025:2017 standard, and concerning: 1) Chapter 6 – Resource Requirements, and 2) Chapter 7 – Process Requirements (excluding Section 7.9 – Complaints).

If the certification body subcontracts specific tasks related to the inspection, it must ensure that the subcontractor meets the requirements of the ISO/IEC 17020 standard. In the case of subcontracting the audit of the management system, it must ensure that the requirements of the ISO/IEC 17021-1 standard are met.

If the certification body does not have an accredited inspection body within its structure, or subcontracts a non-accredited inspection body, this must be evaluated during the initial accreditation

assessment. Specifically, the ATCG will conduct an evaluation of how the certification body has verified the competences of the non-accredited inspection body in relation to the ISO/IEC 17020 standard: 1) Chapter 6 – Resource Requirements, and Chapter 7 – Process requirements, except for 7.5 and 7.6, Complaints. Similarly, if the certification body does not have an accredited certification body for management systems within its structure or subcontracts a non-accredited certification body for management systems, this must be evaluated during the initial accreditation assessment. Specifically, the ATCG will conduct an evaluation of how the certification body has verified the competence of the non-accredited certification body in relation to the ISO/IEC 17021-1 standard, with respect to: Chapter 7 - Resource Requirements and Chapter 9 - Process requirements.

The selection of certification body clients for witnessing certification activities is determined by the ATCG based on the submitted Plan of certification activities by the certification body.

Numbers and criteria indicated in Table 3 are taken into account when determining the total assessment time in terms of assessor-days.

TABLE 3

Product certification body		
Preparation for assessment and summarization of assessment results (management system document review and reporting, reporting on the findings of the assessment) (assessor-days)	On-site activities: assessment of the management system and certification scheme (assessor- days)	On-site activities: Witness audits
1 ± 0.5 Explanation: As a rule, each team member spends 1 day on the specified activities (0.5 days for preparatory activities and document review, and 0.5 days for necessary reporting); this number of days may be increased by taking into account some of the factors listed in section 4.2 and the text above — e.g., a large number of different certification schemes, a large number of different product groups/products within the certification scheme, a large volume of evaluation activities within the certification scheme, etc. — or decreased by considering some of the factors listed in section 4.2, with the maximum increase or decrease being 0.5 days.	1 for the lead assessor + 1 for the technical assessor/technical expert for each certification scheme according to the scope of accreditation *Note: The number of assessors/experts is determined through analysis for each certification scheme, also taking into account the type of product/product groups within the scheme if relevant.* This number of days may be increased depending on the factors mentioned in the text above, i.e., depending on the diversity of products/product groups covered by the certification scheme, as well as the activities within the certification schemes, which may also include assessment for the purposes of designation/notification (minimum 1 assessor-day). Legal requirements, regulatory requirements, standards, or the requirements of the competent authority may affect the required extent of witnessing, and consequently, the number of assessment days. For each product group, the calculations will be made taking into account the risk status and the potential duration of	For each product group, the calculations will be made taking into account the risk status and the potential duration of certification activities subject to witnessing (see the table below for the minimum number of witness audits)

	certification activities subject to witness.	

TABLE 3 A

Surveillance	Assessor-days (per assessor/technical expert)
Preparation and summarization of assessment results – analysis of the Assessment Program and preparation of the assessment plan, reporting on assessment findings (assessor-days)	In accordance with Table 3
On-site activities: assessment of the management system and certification scheme (assessor-days)	1 for the lead assessor + the number of days for other team members depends on the Assessment Program, which is developed and updated in the manner defined by this Procedure
On-site activities: Witness audits	Depends on the Assessment Program, as well as the Certification Activities Plan of the CAB

TABLE 3 B

Extension of the scope of accreditation / new certification scheme / new group of products	
Preparation and summarization of assessment results – document review and reporting on the document review, preparation of the assessment plan, reporting on assessment findings (assessor-days)	In accordance with Table 3
On-site activities (assessor-days)	1 for the lead assessor + the number of days for other team members depends on the Assessment Program, which is developed and updated in the manner defined by this Procedure
New certification scheme/ group of products	1 assessor-day per scheme/product group (for which the extension is requested) If the extension relates to a similar product group within the same certification scheme, the time may be reduced to 0.5 days per assessor.
Witness audit	At least one witness audit per scheme/product group If the extension relates to a similar product group within the same certification scheme, the witness audit may be replaced by a review of the files of completed certification activities.

If the extension of the scope of accreditation is applied together with surveillance/reassessment, this time should be calculated in addition to the time (assessor-days) allocated for the surveillance/reassessment, depending on the breadth and characteristics of the scope of extension, and added to the time calculated for the surveillance/reassessment.

The minimum number of witness audits during is determined as follows:

The number of products inside of group of products	Minimum number of witness audits
up to 5	1
up to 10	2
up to 15	3

up to 25	4
up to 40	5
≥ 40	8

The connection between product groups determines a representative sample for conducting accreditation assessments and is based on similar or identical product characteristics or on similar or identical methods of product evaluation, i.e., the certification scheme.

The time calculated for the assessment at the location will be determined based on the activity being certified. The certification body will be required to provide certification plans, and the assessment time will be determined according to these plans.

Specifically:

a) Certification Bodies Providing Certification of PDO, PGI, and TSG

The minimum number of witness audits related to accreditation of certification bodies certifying protected agricultural and food products (PDO, PGI, and TSG) is determined following the provisions set out in EA-3/02 - EA Policy for the Accreditation of Certification Bodies Providing Certification of PDO, PGI, and TSG.

Concerning the above-mentioned, during initial assessment and/or assessment for extension of the accreditation scope, a witness audit is required for at least one category from each product group within the requested accreditation scope, that is, the highest-risk categories within the product group are selected. These categories include:

- **Product group: Animal products (raw and processed)**: **Categories:** 1. Meat (and offal), 2. Processed meat products (cooked, salted, dried, etc.), 3. Cheeses, 4. Other animal products (eggs, honey, dairy products, etc., excluding butter);
- **Product group: Plant products (raw and processed)**: **Categories:** 1. Oils and fats (butter, margarine, oils, etc.); 2. Fruits, vegetables, and cereals and their processed products, 3. Beer, 4. Beverages derived from plant extracts, 5. Bread, pastries, cakes, desserts, and other bakery products; 6. Other agricultural and food products (spices, tea, etc.).
- **Product group: Category: Fisheries (raw and processed products)**: Fish, shellfish, crustaceans, and their products.

During the accreditation cycle, all certified product categories that are under accreditation shall be assessed by witness audit or file review.

b) Certification bodies for product certification in the field of organic production

The criteria for witness audits of certification bodies for product certification in the field of organic production are provided in Instruction UP.02, Instruction for the assessment and accreditation of certification bodies for product certification in the field of organic production.

Note: The criteria for the certification of product certification bodies that deal with organic production certification are expanded in such a way that for tasks of assessing the equivalence of standards with EU regulations within the review of certification body's documentation procedure, the number of assessment days is increased by 1 for each product category, as and that the number of assessment days during the assessment cycle can be increased depending on changes in standards that are equivalent to EU regulations.

c) Certification for the purposes of designation (notification)

If a new applicant applies for accreditation for the purpose of notification, the document review, on-site assessment, and witness audit will be carried out for multiple product groups within the relevant certification schemes. ATCG applies all criteria for the selection of witnessing in accordance with

Annex C of the document EA-2/17, *Accreditation for Notification Purposes*.

If, during the validity of the accreditation, the certification body submits a request to extend the granted scope of accreditation with additional items (e.g., categories) within an already granted product group for which a witness audit was conducted in the current accreditation period, it is not necessary to conduct a witness audit for that additional item within the same accreditation period. In this case, the fulfilment of accreditation requirements and the competence of the certification body may be assessed using other assessment techniques, without a witness audit, provided that no risks or serious deficiencies were identified during the assessment, and the granted scope can be extended with the additional item within the existing product group.

If, during the validity of the accreditation, the certification body submits a request to extend the granted scope of accreditation with an additional item within an already granted product group, and that product group has not been subject to a witness audit in the current accreditation period, the following will be carried out:

- Witness audit for the specific item from the relevant certification scheme that is the subject of the extension (if possible), or
- Witness audit for another item within the relevant certification schemes under the granted accreditation for the given product group.

If accreditation is a prerequisite for designation/authorization, accreditation may also be granted with witnessing of the certification body's activities under simulated conditions. The designated/authorized accredited certification body is obliged to inform ATCG about its first conformity assessment activity in order to enable ATCG to witness its operation under real conditions. If witnessing is not made possible before the first regular surveillance assessment, ATCG will suspend the granted accreditation. The number of assessment days is, as a rule, the same as if it were a real witness audit. Additionally, in these cases, legal requirements, regulatory requirements, standards, or the requirements of the competent authority may affect the required extent of witnessing.

NOTE: Accreditation of certification bodies conducting certification of protected agricultural and food products (PDO, PGI and TSG) – For the granting of accreditation, ATCG shall conduct at least one office assessment of the CAB and at least one on-site witnessing for each product category. In exceptional cases, on-site witnessing may be postponed as a condition for accreditation if the CAB's business activities are directly linked to authorization by the national competent authority. However, accredited certificates for these scopes may be issued only after the relevant witnessing activities have been successfully completed and ATCG has issued a positive decision. If the outcome of the postponed on-site witnessing is negative, ATCG shall consider reducing the scope of accreditation. If product conformity assessment includes testing (sensory or other) performed solely by the certification body or subcontracted to another body, ATCG shall plan the assessment of that activity (through on-site witnessing and/or office assessment of the CAB) for the purpose of granting accreditation. The ATCG assessment team must include competent experts for the assessment of testing activities

In addition to all activities included in the initial assessment, the assessment team is obliged, during the on-site assessment at the certification body, to review completed certification cases by examining the files (client cases of the certification body), with a minimum of 1 file (case) for each certification scheme within the requested scope of accreditation, and at least 1/5 of the square root of the number of completed certifications. In doing so, attention is paid to reviewing certifications from the highest-risk product groups, where applicable.

In the case of accreditation of certification bodies that, in addition to certification in Montenegro, also conduct activities abroad, ATCG will apply the criteria set out in document IAF MD 12.

Assessments within the accreditation cycle are, as a rule, carried out once a year using appropriate assessment techniques, unless otherwise determined by the Assessment Program. When preparing the Assessment Program, care is taken to ensure that the time between consecutive on-site assessments at the certification body does not exceed two years (except in the case of the first accreditation cycle). The Assessment Program covers witnessing across the entire scope of accreditation, that is, all certification schemes and locations of the certification body during one accreditation cycle.

Each assessment within the accreditation cycle is conducted through an on-site assessment at the certification body, which, as a rule, includes the assessment of all accreditation requirements defined by international documents and other normative documents, and through a certain number of witnessing of relevant certification activities, including witnessing of activities the certification body carries out at its client's location.

During the assessment, the performance and competence of personnel responsible for performing conformity assessment of the product shall be evaluated, including those personnel involved in the evaluation of factory production control, evaluating conformity assessment results and reviewing and making certification decisions.

The personnel whose competence is to be assessed is selected in such a way that, within the accreditation cycle, the work and performance of all personnel involved in the certification activities within the scope of accreditation is assessed. If more individuals within the certification body are authorized to carry out the same certification activities, the assessments will be conducted in such a manner that the same individuals are not repeatedly assessed, unless otherwise planned for specific reasons (e.g., to evaluate the effectiveness of corrective actions).

If the certification activities within the scope of accreditation are carried out at more than one location, all locations where one or more of the following activities are conducted will be evaluated during the initial assessment: formulation of policies, development of processes and/or procedures, contract review, planning of conformity assessments, conducting conformity assessments, reviewing and approving c results, and making decisions based on those results.

In the accreditation cycle, all locations of the certification body where one or more of the aforementioned critical activities are conducted must be evaluated at least once again.

The schedule for assessments at different locations of the certification body during the accreditation cycle is determined by the Assessment Program and depends on the results of previous assessments and the decisions made regarding accreditation. Based on the assessment of potential risks, ATCG has established a conditional classification of product certification bodies into the three basic groups – see Section 4.7.2 c), Table 3 - Determining the risk group for product certification bodies.

Responsibility: Head of the competent department / Lead assessor / Technical assessor

4.4.2.4 Determination of the time required for assessment of a management system certification body

The total number of assessment days depends on the number of assessment days at the headquarters/locations of the certification body and the number of assessment days necessary for witnessing the work of the certification body.

The selection of clients of the certification body for which the required witnessing will be carried out is determined by ATCG based on the submitted tables (Data on personnel involved in the certification process; and Overview of certified clients under the scope of accreditation and activity plan for the next 12 months) by the certification body. The certification body submits data in the form of request

ZPR.01.05-1 Request for accreditation of certification bodies for management systems on the basis of which the Assessment programme is created.

Factors and criteria that influence the determination of the number of witnessings in the initial assessment:

- Witnessing of (critical) codes divided by Clusters from the required scope of accreditation;
- Witnessing of the implementation procedure of Phase 1 and Phase 2 for one initial certification;
- Witnessing of the implementation of an audit with one client from abroad, if any.
- Factors and criteria that affect the determination of the number of witnessings and the choice of clients during the cycle (4 or 8 years):
- Witnessing of (critical) codes divided by Clusters from the requested scope of accreditation,
- Witnessing of the implementation procedure of Phase 1 and Phase 2 for one initial certification,
- Witnessing of the audit of one client from abroad who was issued a certificate under accreditation, if any,
- One witnessing in conducting audit at a client with multiple locations,
- One witnessing in conducting audit at a client that has over 350 employees,
- One witnessing for clients with an integrated management system,
- For management systems within which less than 10 certificates have been issued, one witnessing is realized per cycle,
- Witnessing for the purpose of transition to a new edition of the reference standard for certification,
- Feedback from interested parties (e.g. complaints about the work of an accredited certification body; complaints about the work of certified organizations),
- Results of internal audits of the certification body,
- On the basis of findings during on-site assessments or witnessings,
- Requirements of scheme owner

CB QMS and EMS:

For the purposes of determining a representative sample and number of witnessings, ATCG grouped all IAF codes into clusters, especially for certification bodies for certification in the area of QMS, or in the area of EMS as given in the document IAF MD 17:2019, clauses 5 and 6.

During the initial assessment and assessment for the purpose of expanding the scope of accreditation, the required number of certificates is determined according to the following rules:

• if the cluster has only one critical code, a witnessing will be performed for that critical code in order to grant accreditation for all codes belonging to the cluster – for example, for QMS, to determine locations, number of assessment days and required witnessings in CAB assessment
cluster Food, with one certification in IAF code 03, accreditation will be granted for other codes of this cluster, i.e. for IAF codes 01 and 30; similarly, for EMS, cluster Paper, with one certification in code 09, ATCG can grant accreditation for other codes of that cluster, namely 07 and 08;

• if the cluster has more than one critical code, the following verifications will be performed:

- for all critical codes for EMS that are marked with "i" ("critical code" column); for example, for EMS, Manufacturing of Goods cluster, with one witnessing in IAF codes 04 or 05, accreditation will be granted for all non-critical codes of that cluster (06 and 23), but witnessings are required for other critical codes (04 or 05);
- for one of the critical codes marked with "or" ("critical code" column), for example, for QMS in the "Mechanical" cluster with one witnessing in IAF codes 20 or 22, ATCG can grant accreditation for other codes of that cluster (17, 18, 19, 20 or 22);
- in all critical codes that are identified with "i", i.e. critical codes in square brackets [...] or in a critical code identified by "or" (in the "Critical Code" column); for example, for OHSMS cluster "Chemistry" with one certification in IAF code 7 or 10 or 12 or 13 or 16, ATCG can grant accreditation in all non-critical codes, i.e. 14 and 15, plus 17 of that cluster. The remaining critical codes in square brackets, 7 or 10 or 12 or 13 or 16, must be witnessed to be assigned. Another variant, for the same cluster mentioned above, is to grant accreditation in IAF code 17 and in all

other IAF codes with one certification in IAF code 17, i.e. 7, 10, 12, 13, 14, 15 and 16, of that cluster;

• if the certification body does not have a client for witnessing in the IAF code identified as critical, the ATCG may proceed as follows:

- if a witnessing has been made for one non-critical code - for example, for QMS, for the Food cluster, with one witnessing in IAF code 01, accreditation will also be granted for other non-critical codes of this cluster, i.e. for IAF codes 01 and 30.

At the initial assessment for each type of management system, ATCG will verify the phase 1 and phase 2 audits, with at least one client. If the certification body has no new clients, then witnessing of one certification audit or two surveillance audits of existing clients, covering key processes, can be carried out.

CB OHS&S

Locations, number of assessment days and required witnessings are determined according to the same criteria as for certification bodies for quality management system certification - QMS, with the difference that for the purposes of determining a representative sample and the number of witnessings, the IAF codes are grouped into clusters as given in point 7 of the document IAF MD 17:2019.

CB FSMS

The assessment at the location for FSMS (Food Safety Management System) will include, among other things, the evaluation to confirm that of:

a) The certification body (CB) has competent staff to perform contract reviews and to select the propper category and subcategory of the food chain (see Annex S in ISO/TS 22003:2015).

b) The CB has established technical criteria for describing the competency requirements for personell in each defined subcategory.

c) The CB has competent staff in at least one subcategory of the food chain.

d) The CB has established a process that ensures accredited certification will only be offered in subcategories where the CB has competent staff.

e) The CB maintains an updated list of subcategories where it has competent staff. This list should be available to the ATCG upon request.

According to ISO/TS 22003:2015 Annex A, clusters in the food chain are:

1. Farming (categories A+B),
2. Food and feed processing (categories C+D),
3. Catering (category E),
4. Retail, transport and storage (categories F+G),
5. Auxiliary services (categories H+I+J) and
6. Biochemical (category K).

During the initial assessment, it is necessary to realize at least one witnessing in each of the mentioned clusters.

In order to expand the scope of accreditation within one cluster, witnessing is not necessary. For expansion related to a new cluster, witnessing is required. In each specific situation, the ATCG will decide whether it is necessary to realize more witnessings.

ATCG will realize at least one witnessing within cluster 2. Food and animal feed processing (if it is part of the scope of accreditation) in the calendar year and at least one witnessing in each of the other areas during the accreditation period.

One witnessing can cover several categories if the activities fit together.

During the initial assessment of the certification body when the required scope of accreditation covers one or several areas, it is necessary a witnessing during the initial certification audit, which includes phase 1 of the audit. At least one witnessing that includes phase 1 verification must be realized in the accreditation cycle.
During the accreditation cycle, it is necessary to carry out witnessings in those areas (which are part of the scope of accreditation of the certification body) with high risk and food safety risks.
ATCG will, if possible, plan the verifications by verifying the work of a team of auditors who have not previously been subject to verification for a given category in the food chain.
Also, if possible, ATCG will, when selecting a sample for witnessing and planning the witnessing, take care to avoid repeating witnessing with the same clients of the certification body. During the planning of the witnessing, ATCG will take into account the results of previously realized witnessing.

ATCG may take into account certification body accreditations for other certification schemes and standards related to food safety (such as management system certification schemes and product certification schemes) for categories within the same cluster, when deciding which witnessing need to be implemented. In such cases, ATCG can use witnessing that was realized within the framework of another certification scheme instead of certain (but not the main part) necessary witnessing based on the criteria specified in this point. These activities should be based on the certification activities of the client of the certification body and the structure of the auditor.

CB ISMS

During the initial assessment, it is necessary to realize at least one witnessing respecting the principle of priority according to the sectoral complexity of the ISMS, as stated:

1. Telecommunications
2. Finance/Banking/Insurance/Administration
3. Energy
4. Healthcare
5. Industry/Agriculture/Fishing/Construction/Recycling
6. Services/Transportation/Trade/Research and Development/Education

The initial assessment statement must cover Phase 1 and Phase 2 audits.

Assessment in the accreditation cycle includes on-site assessment(s) and at least one more witnessing in a certification or recertification audit. For certifications in the accreditation cycle, audits are chosen at organizations with a more complex ISMS and, where appropriate, respecting the previously mentioned principle of priority. Depending on the demonstrated performance of the certification body, the number of certifications may increase.

ATCG certifies the work of a representative number of auditors of the certification body, taking care to certify the work of various auditors and those who are most frequently engaged in verification work during the validity period of the accreditation.

During the initial assessment, the number of assessment days at the location of the certification body is, as a rule, 1 for the lead assessor (assessment of system requirements of reference documents) and 1 for the technical assessor/technical expert (review and assessment of documentation from ST clients' cases) if the scope of the requested accreditation is one type management system. Each additional type of management system increases the number of days for assessment at the location of the certification body, as a rule, by ½ day. Also, the number of days for assessment at the location of the certification body depends on the activities performed at the specified locations.

The number of days necessary to carry out the assessment for the purpose of expanding the scope of accreditation depends on the number of types of management systems for which the expansion of the scope of accreditation is requested. If the expansion of the scope of accreditation refers to an increase

in the number of clusters for one type of management system, the number of days at the location depends on the number of clusters for which the increase is requested, as well as on the degree of risk that these clusters represent.
The number of assessment days at the location of the certification body is determined depending on the number of cases of MSCB clients that the technical assessors need to review in accordance with the file review plan (one technical assessor for 1 assessment day can review a maximum of 3-4 cases depending on the complexity of the case i.e. of the number of codes and management systems covering a specific subject.

During the assessment, performance and competence must be assessed:
- persons who perform certification audits,
- persons who perform tasks of reviewing the verification report and making a decision on certification, as well as
- persons who review the application, select the members of the verification team and determine the verification time.

The staff whose work is evaluated is selected so that in the accreditation cycle, the work of all the staff participating in the specified activities from the certification procedures from the scope of accreditation is evaluated. If in the certification body, several different persons are authorized to perform the same activity in the certification process, the assessment will be performed in such a way that the executors whose work is certified are not repeated (unless otherwise planned for certain reasons, e.g. assessment of the effectiveness of implemented corrective measures).

When certifying the work of auditors, auditors are selected from the group of auditors who perform 80% of the total number of audits according to the management system, and those with the highest number of auditor days in the last 12 months, taking care to certify different auditors in the accreditation cycle, where possible.

Responsibility: Head of the competent department / Lead assessor / Technical assessor

4.4.3 Document Review

The assessment team shall review all relevant documented information submitted by the CAB in order to evaluate the conformity of its system with the applicable standard(s) and other accreditation criteria. The applicant for accreditation shall be provided with a Document Review Report containing information on identified nonconformities and/or deficiencies, and the conformity assessment body is required to submit a response to this report.

The CAB shall eliminate the nonconformities and/or deficiencies identified during the document review within a period not exceeding 20 working days for initial assessments and assessments for the purpose of extending the scope of accreditation, and within a period not exceeding 10 working days for reassessment (in cases where the reassessment does not include scope extension). If the assessment team considers that the evidence provided for the resolution of nonconformities is not adequate, the same findings shall be repeated in the next phase of the assessment. ATCG may, taking into account the nature of the unresolved nonconformities, decide to terminate the accreditation process, against which the conformity assessment body has the right to appeal.

Responsibility: Assessment team / Head of the relevant Department / Head of the Accreditation Service / Director of ATCG

4.4.3 On-site assessment

An assessment plan shall be prepared for each assessment and the date of the on-site assessment shall be agreed with the conformity assessment body, on the form ZPR.01.08 Assessment plan. During the initial assessment all sites where one or more of the following activities covered by the scope of accreditation are carried out shall be assessed: policy formulation, development of processes and/or procedures, contract review, planning of conformity assessment, carrying out conformity assessment activities, review and approval of conformity assessment results and decision-making on these results.

When witnessing of planned and agreed conformity assessment activities cannot be performed during on-site assessment, it is planned separately - before or after the on-site assessment. The selection of representative samples of conformity assessment activities, which shall be subject to witnessing, is done in accordance with the witnessing criteria which include determining the locations at which the assessment will be carried out, the number of days of assessment and selection of a representative sample of conformity assessment activities from the requested scope of accreditation.

On-site assessment consists of the opening meeting, the assessment and the closing meeting.

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

If during the opening meeting client initiates a withdrawal of some method(s) contained in the sought or granted scope of accreditation, the changes can be confirmed with the consent of all parties involved and documented (with signatures on the printed copy of the request for accreditation/scope of accreditation), which is later on subject to verification by the Accreditation Committee. Any other change related to the scope of accreditation cannot be accepted during the opening meeting. Other changes to the scope of accreditation are result of the assessment process and decision making proces, and are desribed in clause 4.9 of this document.

During the assessment, the conformity assessment body must provide ATCG assessment team with access to all relevant documents, access to all premises related to the conformity assessment activities for which accreditation is sought, as well as interviews with the staff involved in the assessment activities. The members of the assessment team shall, during the assessment, duly communicate with the team leader, exchanging the assessment findings. These findings shall be recorded in the appropriate form of checklist (from ZPR.01.11 to ZPR.01.14-1) intended for use by lead assessors and form of Work list (from ZPR.01.15-1 to ZPR.01.19-1) intended for use by technical assessors/experts. During the assessment of Certification Bodies and Inspection Bodies, members of the assessment team are required to use the Checklist for the assessment of impartiality in accordance with MEST EN ISO/IEC 17065:2020 and the Checklist for the assessment of impartiality in accordance with MEST EN ISO/IEC 17020, which are provided to them together with the documentation necessary for carrying out the assessment.

In the event of an unforeseen situation that results in a reduction of the assessment time allocated in the Assessment Plan, caused by reasons attributable to ATCG, and the activities outlined in the Plan are not fully completed, the uncompleted assessment hours will be carried out at another time at ATCG's expense, subject to prior agreement with the CAB. In the case of unforeseen circumstances that lead to a reduction of the assessment time allocated in the Assessment Plan, caused by reasons attributable to the CAB, and the activities outlined in the Plan are not fully completed, the uncompleted assessment hours will be carried out at another time at the CAB's expense, subject to prior agreement with ATCG. Since the Assessment Program represents a series of assessments consistent with the specific accreditation scheme that ATCG carries out for a particular conformity

assessment body during the accreditation cycle, all these changes will be reflected in it.

If nonconformities are identified during the assessment in relation to the requirements for accreditation, they shall be recorded in the form ZPR.01.21-1 Report on nonconformities. The categorization of nonconformities shall be as follows:

Type A - A deviation from the accreditation criteria which has led or may lead:

- to incorrect or unreliable conformity assessment results, or
- to improper use of the ATCG accreditation symbol or in any other way to unjustified reference to ATCG accreditation, or
- to a specific threat to human health or safety or to the environment, or
- to a deviation that calls into question the fundamental effectiveness of the quality management system, or
- to the repeated occurrence of a Type B nonconformity related to the same standard requirement.

Type B - A deviation from the accreditation criteria which, by its nature and significance, does not indicate a systemic problem and is not expected to lead to the situations described under the definition of a Type A nonconformity. change 1 from 14.05.2026.

Nonconformities of Type A and B require the implementation of corrective actions within the initial assessment, within a period not exceeding 3 months.

During regular, reassessment, and extraordinary assessments, in the case of identified Type A nonconformities, the deadline for corrective actions may not exceed two (2) months.

Type B nonconformities require the implementation of corrective actions during regular, reassessment, and extraordinary assessments within a period not exceeding 3 months.

Depending on the nature and significance of the nonconformity, Shorter deadlines for the implementation of appropriate corrective actions may also be set, except in the case of the initial assessment.

The deadlines to be met are documented in each nonconformity report.

Comments - Comments refer to potential weaknesses in the system that can lead to nonconformity, but if treated in a timely manner can lead to opportunities for improvement.

At the closing meeting, the assessment team shall inform the conformity assessment body on the findings identified during the assessment, including identified nonconformities and/or comments/concerns, if any, the procedure for resolving identified nonconformities, comments/concerns, and the assessment team's recommendation regarding the accreditation decision.

At the closing meeting, the evaluated scope of accreditation is determined and signed by the representatives of the CAB and the assessment team.

Note 1: The evaluated scope of accreditation does not have to be the final scope of accreditation (the final scope of accreditation is determined after resolution of non-conformities (where applicable) and being verified by the Accreditation Committee).

Note 2: If the assessment team, during the evaluation process, determines the need for additional assessment because the nature of the nonconformity is such that the effectiveness of corrective actions or the assurance of addressing vulnerabilities in the system cannot be confirmed through the submission of written evidence (documentation), it is the responsibility of the lead to inform the

representatives of the CAB during the closing meeting, to justify the need and to request a written approval from CAB (statement and signature at the copy of a scope of accreditation).

Participants shall confirm their presence at the closing meeting by signing the record ZPR.01.20 Minutes on attendance at the closing meeting.

The conformity assessment body shall be given the opportunity to ask questions or seek clarification regarding the findings of the assessment team. Identified nonconformities shall be detailed in the Report on nonconformities. If there is no understanding, i.e. no agreement is reached regarding the identified nonconformities and/or comments, the team leader shall record that the minutes that he shall produce on the spot and give to the representatives of the CAB to sign. Representatives of the conformity assessment body shall comment on the findings of the assessment and in case of disagreement with the assessment team's findings, the conformity assessment body may send to ATCG the explanation for the disagreement. Nonconformity reports, including their categorization, as outputs of the assessment, are subject to review by the competent Accreditation Department in order to ensure their completeness, consistency, and compliance with applicable requirements and criteria.

Responsibility: Assessment team

4.4.4 Assessment report

The original Assessment report (ZPR.01.22 to ZPR.01.26-1), which also includes information from the assessor's worksheets (ZPR.01.15-1 to ZPR.01.19-1), shall be available to the CAB in the ATCG premises (archive) no more than 20 working days after the assessment, and its collection is confirmed by the CAB's representative signature within the ATCG delivery register.

In the case of certification bodies, in addition, the Assessment report also contain data from working sheets of assessors ZPR.01.45, ZPR.01.46 and ZPR.01.47. For certification bodies certifying information systems management systems, the assessment report contains data from working sheets of assessors ZPR.01.49. The assessment report contains the findings on competence, the assessed scope of accreditation, and the identified nonconformities (if any).

The Report may also include observations for potential improvements, which must not recommend specific solutions. ATCG is responsible for the content of the assessment report. Therefore, all submitted assessment documentation is reviewed by the competent Head of Department / Head of the Accreditation Service to confirm whether the assessment team's findings are relevant and sufficient for the given recommendation regarding accreditation.

If the Head of the Accreditation Service acted as the lead assessor in a particular assessment, the submitted assessment documentation is reviewed by the Head of the relevant Department.

The review of the assessment documentation is carried out within 5 working days from the date of submission of the complete documentation to ATCG, and is verified in the form "Checklist for Report Review."

During the review of the submitted documentation, the lead assessor may be requested to supplement/amend the Assessment Report or clarify certain statements in the Report, which the lead assessor is obliged to provide within a period not exceeding 5 working days.

If the report on the outcome of the assessment differs from the outcome presented at the end of the assessment, ATCG must provide a written explanation of this to the assessed conformity assessment body.

Responsibility: Lead assessor / Head of the competent department

4.4.5 Resolving nonconformities and comments/concerns

When nonconformities are identified during an assessment, CAB shall, within a defined time (not longer than 10 business days) submit the proposed corrective actions for resolving identified nonconformities, as well as the root cause analysis and the extent of the nonconformities (form ZPR.01.21-1). If the lead assessor and members of the assessment team find that the proposed actions are not adequate, CAB shall be given an additional time of 10 business days to define new proposed actions. The deadline for resolving nonconformities may not exceed three months. This deadline may be extended by one more month at the request of the conformity assessment body.

The conformity assessment body shall, within the defined deadline, notify ATCG in writing of resolving the identified nonconformities and submit evidence of effective implementation of corrective actions, i.e. evidence of elimination of nonconformities.
Confirmation of adequate resolution of non-conformities can be carried out through the review of submitted written evidence (documentation) and/or through the follow-up assessment, of which the CAB is informed during the evaluation of the proposed corrective actions.

When assessing the proposed corrective actions, the assessment team will recommend to ATCG whether a follow-up assessment at the CAB's location should be conducted. ATCG may decide whether a follow-up assessment is necessary for one or more nonconformities. These activities are approved by the Head of the competent Department, or by the Head of the Accreditation Service in cases where the Head of the competent Department conducted the assessment in question, upon the proposal of the assessment team.

The confirmation of the elimination of nonconformities may be verified through the review and evaluation of submitted written evidence and/or through a follow-up assessment, about which the conformity assessment body is informed during the evaluation of the proposed corrective actions.

If the submitted evidence is deemed inadequate, the conformity assessment body is given a period of 5 working days to provide additional information—supplemented evidence and/or to enable the conduct of a follow-up assessment. Upon a written request from the conformity assessment body, this deadline may be extended by an additional 5 days from the expiry of the previously deadline.
After verification of the implementation of corrective actions for the elimination of identified nonconformities, including, where necessary, verification of the implementation of corrective actions through a follow-up assessment.

After the completion of corrective actions, the Head of the competent Department or the Head of the Service verifies the completeness and adequacy of all documentation relevant to the assessment in question, including the Report and its annex, if applicable (Annex 2), before these documented information are made available to the client.

The Assessment Report contains a recommendation regarding accreditation and a proposed scope of accreditation, or a proposal for modification of the scope of accreditation in the case of surveillance assessments.

The conformity assessment body is required, within no more than 2 working days, to confirm the correctness of the proposed scope of accreditation or to indicate any possible errors. ATCG will accept additional alignment of the proposed scope / proposed changes to the scope only if it is confirmed that an omission occurred during verification by the assessment team in relation to the actual assessment results, which must be confirmed by the assessment team itself.

If comments were identified during the assessment, the assessment team confirms whether they have been satisfactorily addressed during the subsequent assessment of the conformity assessment body. If it is established at that time that the identified comments have not been resolved, a nonconformity may be raised in relation to that requirement.

If, during the period of resolving nonconformities, changes occur that may affect the final recommendation of the assessment team (e.g., change of key personnel, change of location where conformity assessment activities are performed), an additional assessment may be conducted.

4.4.6.1 Additional Assessment

When it is conducted:

An additional assessment shall be conducted:

- when, during the period for the closure of nonconformities and prior to the decision-making stage, changes occur that may affect the final recommendation of the assessment team (e.g. change of key personnel, change of the location where conformity assessment activities are performed).

The conformity assessment body shall enable the additional assessment to be carried out without delay.

If nonconformities are identified during this assessment, the deadline for their closure, depending on the corrective actions whose adequacy is assessed during the assessment itself, shall not exceed five working days from the date of the assessment.

Responsibility: Assessment team / Head of competent Department / Advisor in competent Department

4.5 ACCREDITATION DECISION-MAKING

4.5.1 Recommendation of the assessment team

After the completion of the assessment activities and verification that identified nonconformities have been resolved, or that the proposed actions and deadlines for resolving identified concerns are adequate, the assessment team shall determine recommendation regarding accreditation.
An integral part of the assessment team's recommendation is the established scope of accreditation, for which the competent Head of Department has performed mandatory verification of the current versions of the applicable standards and confirmed this by signing the annex to the certificate.

Responsibility: Assessment team

4.5.2 Accreditation decision-making process

The decision on accreditation (granting, maintaining, extending, reducing, suspending and withdrawing accreditation) is made by the director of ATCG on the basis of the proposal of the Accreditation Committee.

When maintaining accreditation is not related to re-assessment and there is no change in scope of accreditation, or when the CAB has requested a reduction, suspension, or withdrawal, ATCG may carry out a process that does not require an independent decision. The decision is made by the ATCG director based on the proposal of the Head of the Accreditation Service.

The Accreditation Committee consists of permanent ATCG personnel different from those who carried out the assessment in relation to which decision is being made and externally contracted experts who provide the necessary technical expertise in the conformity assessment fields subject to

accreditation decision.

The Chair of the Committee is a person permanently employed in the Accreditation body who did not participate in the accreditation procedure of the conformity assessment body that is the subject of accreditation.

Members of the Committee are externally engaged persons who provide professional and technical expertise in connection with the relevant accreditation scheme and conformity assessment procedures, and who did not participate in the accreditation procedure of the conformity assessment body that is the subject of accreditation.

In the event that it is necessary to provide additional expertise for certain areas of conformity assessment, the Committee will engage expert(s) from the Register of members of the Accreditation Committee (ZPR.01.48), according to the decision of the director of ATCG made at the proposal of the President of the Committee.

On the basis of the complete documentation, the Chair of the Accreditation Committee shall, in accordance with the Rulebook on formation and tasks of the Accreditation Committee, convene a session of the committee. The information submitted to the Accreditation Committee for review and assessment shall include the following:

a) unique identification of the conformity assessment body;
b) date(s) and type(s) of assessment(s) (e.g. initial, reassessment);
c) name(s) of the assessor(s) and, if applicable, technical expert(s) involved in the assessment;
d) unique identification of all locations assessed;
e) scope of accreditation that was assessed;
f) the assessment report(s);
g) a statement on the adequacy of the organization and procedures adopted by the conformity assessment body to give confidence in its competence, as determined through its fulfilment of the requirements for accreditation;
h) sufficient information to demonstrate the satisfactory response to all nonconformities;
i) where relevant, any further information that may assist in determining the competence of the conformity assessment body as determined through conformity with requirements;

If the Committee determines that the available information is insufficient to make an appropriate decision proposal, additional information shall be requested from the assessment team or the conformity assessment body, which may also include conducting a supplementary assessment. The conformity assessment body shall provide the additional information and/or enable the supplementary assessment to be carried out within a period not exceeding five days.

Based on the assessment of all received and any other relevant information, the Accreditation Committee shall make the proposal of the decision on accreditation, and the decision shall be notified to the CAB in writing without undue delay, including clarification where relevant.

After re-assessment, the decision on accreditation renewal is made by the Accreditation Committee based on the received documentation and evaluation of the information regarding the coverage of the entire scope of accreditation. This decision takes into account assessment reports from all evaluations conducted during the accreditation cycle, including the recent reassessment report.

In the assessment process, there may be cases where the recommendation and opinion of the assessment team differ from the opinion of the Accreditation Committee, which is different from the one that performed the assessment. In that case, an additional review shall be performed with the appointed assessors. One of the possible solutions is to conduct an additional assessment (at the expense of the accreditation body), including witnessing in order to gather new evidence for the disputed case.

The conformity assessment body has the right to appeal against a decision on accreditation that is unfavorable to it. The procedure regarding appeals is documented in the procedure for Resolving complaints and appeals (PR.08), which is available on the ATCG internet portal.

Responsibility: Accreditation Committee / Head of the Accreditation Service / Director

4.5.3 Accreditation certificate and reference to accreditation

If, by means of the accreditation procedure, it is determined that the conformity assessment body meets the requirements for accreditation, ATCG shall make a Decision on Accreditation and issue to the conformity assessment body the Accreditation Certificate (ZPR.01.28 – ZPR.01.33). The effective date of accreditation is the date of or a date after the Decision on Accreditation.

ATCG, in the accreditation certificate, provides information on accreditation to accredited CABs in a transparent manner (website akreditacija.me), identifying the following:

a) the identity and, where relevant, the logo of the accreditation body;
b) the name of the accredited conformity assessment body and the name of the legal entity, if different;
c) scope of accreditation;
d) the locations of the accredited conformity assessment body and, as applicable, the conformity assessment activities performed at each location and covered by the scope of accreditation;
e) the unique accreditation identification of the accredited conformity assessment body;
f) the effective date of accreditation and, if applicable, its expiry or renewal date;
g) a statement of conformity and a reference to the international standard(s) and/or other normative document(s), including issue or revision used for assessment of the conformity assessment body.

NOTE The information can be provided in an accreditation certificate and other suitable means (e.g. electronic media).

The Accreditation Certificate is the Addendum is accompanied with the Appendix to the Accreditation Certificate containing summary and detailed scope of accreditation (from ZPR.01.34-1 to ZPR.01.38-1).

The scope of accreditation identifies at least the following:

a) For certification bodies:

- the type of certification (e.g. management systems, products, processes, services or persons);
- certification scheme(s);
- the standards, normative documents and/or regulatory requirements to which management systems, products, processes and services, or persons are certified, as applicable;
- industry sectors, where relevant;
- product, processes, service and persons categories where relevant.

b) For inspection bodies:

- the type of inspection body (as defined in ISO/IEC 17020);
- inspection schemes, where relevant;
- the field and range of inspection for which accreditation has been granted;
- the regulations, inspection methods, standards and/or specifications

c) For calibration laboratories:

- the calibration and measurement capability (CMC) expressed in terms of:
- measurand or reference material;

- calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;
- measurement range and additional parameters where applicable, e.g. frequency of applied voltage;
- measurement uncertainty.

d) For testing laboratories (including medical laboratories):
- materials or products tested;
- component, parameter or characteristic tested;
- tests or types of tests performed and, where appropriate, the techniques, methods and/or equipment used.

When ATCG uses a flexible scope of accreditation, a documented procedure PR.12 Flexible scope of accreditation is applied for the use and management of flexible scopes.

ATCG, in addition to the Accreditation Certificate, issues the accreditation symbol which the conformity assessment body shall use in accordance with the Rules for the use of the Accreditation Symbol and claims of accreditation. Accreditation Certificate is valid for four years.

Responsibility: ATCG Director

4.6 REGISTER OF ACCREDITED CONFORMITY ASSESSMENT BODIES

The Register of accredited conformity assessment bodies contains the following:
1. the accreditation number;
2. the name and address of the accredited conformity assessment body, including locations where it performs accredited activities;
3. general information on the accredited conformity assessment body;
4. information on the status of accreditation, as well as on changes of the status, if any;
5. date of the initial and last accreditation, as well as the expiry date of the accreditation;
6. contact details;
7. valid scope of accreditation.

The register is publicly available on the ATCG internet portal.

Responsibility: Head of the Accreditation Service

4.7 ACCREDITATION CYCLE AND PROGRAMME OF ASSESSMENT

The accreditation cycle begins at or after the date of the decision for granting the initial accreditation decision or after the decision related to re-assessment and lasts 4 (four) years. Before the end of the accreditation cycle, reassessment must be planned and conducted, taking into account the information gathered from previous assessments carried out during the accreditation cycle, which will be recorded in the Assessment Program under the section related to reassessment to ensure full coverage of the accreditation scope. The decision on accreditation renewal is made in accordance with Article 4.5.2. of this document. ATCG conducts activities to ensure that the accredited conformity assessment body continuously meets the accreditation requirements for the tasks for which accreditation has been granted.

ATCG applies ZPR.01.09-1 Assessment Program for assessing the conformity assessment body activities during the accreditation cycle to ensure that the conformity assessment activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle, based on experience gained. ZPR.01.09-1 Assessment program ensures that the requirements of the international standards and other normative documents containing requirements for conformity assessment bodies and the scope of accreditation are assessed, taking into consideration assessed risks.

METHOD OF DETERMINING THE ELEMENTS OF THE ASSESSMENT PROGRAM, ACCORDING TO ACCREDITATION SCHEMES

During the initial assessment, in addition to the CAB location where conformity assessment is performed, all other CAB locations where one or more of the following activities are performed must be also assessed: policy formulation, development process/procedures, contract review, planning of conformity assessment, reviewing and approving the results of conformity assessment and deciding on results.

For assessment purposes in the accreditation cycle, ATCG applies an appropriate Assessment Program to ensure that conformity assessment activities, or at least those that are representative of the scope of accreditation, are assessed at relevant locations. Depending on the activities performed at individual locations, ATCG will select suitable assessment techniques that include, but are not limited to:

- on-site assessment,
- assessment from a distance,
- witnessing the implementation of conformity assessment activities,
- reviewing the document,
- reviewing the file,
- measurement checks,
- review of CAB performance in proficiency testing and other inter-laboratory comparisons,
- validation checks,
- unannounced visits,
- interviewing the staff.

In general, the number of CAB assessment days for a certain type of accreditation depends on the type of assessment, the size of the CAB, the number of CAB locations, as well as the scope of accreditation, i.e. the number/complexity of conformity assessment activities for which accreditation is sought/held.

The assessment program can be modified after expanding the scope of accreditation, reducing the scope of accreditation, or after each change in the scope of accreditation. In these cases, the principle of selecting a representative sample of the scope of accreditation remains the same.

Risk factors that can influence the chosen assessment technique and the time between successive assessments at the CAB location can be:

- complexity of conformity assessment activities (eg. conformity assessment schemes consisting of checking - assessment of factory production control and examination of product samples taken from production, product control after delivery);
- the existence of potentially risky conformity assessment activities (eg examination/control of product characteristics in order to achieve food safety);
- the ratio of standard and non-standard conformity assessment procedures (eg methods/procedures developed in the laboratory/control or certification body);
- conformity assessment activities that are the subject of authorization/appointment;
- the frequency of performance of conformity assessment tasks;
- the existence of objections and appeals to the work of CAB for certain tasks of conformity assessment, especially those sent to ATCG;

- the number and nature of the findings determined in the previous assessment, or in the previous cycle of accreditation;
- number of locations and activities performed there;
- the frequency of changes in the TOU and their nature in the accreditation cycle (eg, changes in personnel, equipment, etc.);
- reasons for suspension in the accreditation cycle.

In the case when the ATCG assessment team includes assessors/technical experts from other national accreditation bodies, as well as in the case when the ATCG performs assessment within the framework of cross-border accreditation, the number of assessment days also depends on the volume of preparatory actions that must be carried out (translation and reading of documents on in a foreign language, preparation and translation of records created in the evaluation process, etc.). Also, in case of transition to a new edition of the reference document for accreditation, ATCG may decide to increase the number of assessment days.

In cases where the CAB does not want to submit all the required documentation of the Management System, as required by the Application for Accreditation, ATCG may increase the number of assessment days, in order to review the missing documentation at the TOU location.

ADDITIONAL RISK FACTORS IN ASSESSMENT PLANNING FOR CERTIFICATION BODIES FOR MANAGEMENT SYSTEMS

For management system certification bodies, additional risk factors to be taken into consideration are:

- number of issued certificates for individual management systems;
- the number of auditors available to the certification body;
- number of accepted/submitted certification transfers;
- the number of audits that were not carried out within the time provided by the procedures certification body;
- the complexity of the organization of the client of the certification body, and the existence of combined and multi-location audits.

In order for ATCG to adequately implement the planning of supervisory assessment visits to certification bodies for management system certification, it is necessary, in accordance with IAF MD 15, to collect data on the success of the management system certification system, which will be carried out on an annual basis (within January of each calendar year).

ADDITIONAL RISK FACTORS IN ASSESSMENT PLANNING FOR PRODUCT CERTIFICATION BODIES

For certification bodies for product certification, additional risk factors to be taken into consideration are:

- the complexity of the certification body (e.g. number of locations, number of persons who perform audits, outsourcing, decentralized decision-making process, etc.);
- certification of products of clients who, as a legal entity, are part of a larger legal entity entities;
- the complexity of the client's organization, combined audits and multi-location checks.

The designated/authorized certification body is obliged to notify ATCG of its first on-site conformity

assessment activity in order to enable ATCG to witness its operations under real conditions. If witnessing is not made possible before the first regular surveillance assessment, ATCG will reduce or withdraw the granted accreditation.

ADDITIONAL RISK FACTORS IN ASSESSMENT PLANNING FOR TESTING / CALIBRATION / MEDICAL LABORATORIES

When assessing the scope of accreditation for laboratories in the initial assessment, as well as in the assessments during the accreditation cycle, the following should be taken into consideration:

a) testing/calibration methods are divided into homogeneous groups taking into account the following criteria: area/subfield of testing/calibration, testing technique, fixed and/or flexible scope, product/material being tested, object of calibration, frequency of testing/calibration;
b) the selected test/calibration methods can be evaluated in two ways:
c) method 1: confirmation of the implementation of the entire test/calibration method;
d) way 2: documentary evaluation of available records, starting from sampling and ending with test reports, i.e. calibration certificates/certificates;
e) for each group of test/calibration methods, the selected number of assessment methods/calibration items must be sufficient to confirm the competence of the laboratory (personnel, equipment, test location/calibration conditions, etc.);
f) findings from previous evaluations (eg non-conformities, results of PT activities, frequent changes of personnel, suspensions, changes of location (relocation) of the laboratory, etc.);
g) internal calibration carried out by the testing laboratory;
h) fixed and/or flexible scope of accreditation.

The elements taken into account must be provided within the Assessment Program. At the request of the laboratory, ATCG will provide information on how a representative sample of the scope of accreditation for assessment was selected. During the assessment, i.e. the development of the Assessment Program, it is necessary to combine both methods of assessing the scope of accreditation, in such a way that tests/calibrations can be assessed several times in the accreditation cycle using different methods (method 1 and/or method 2).

Additional risk factors to be taken into consideration are:

- implementation of mandatory activities related to tests for the purpose of product certification (e.g. for the needs of appointed/authorized bodies) or calibration in the process of measuring standards certification/ mandatory certification (method 1) or a combination of certification (method 1) and documentary evaluation (method 2) during the implementation of each assessment at the laboratory location;
- activities of laboratories that carry out food control/attestation is mandatory (method 1) during the implementation of each assessment at the laboratory location;
- laboratories that perform sampling as part of the scope of accreditation (e.g. emissions of waste gases - assessment of sampling by method 1 is mandatory during the initial assessment or assessment for the purpose of extending the scope of accreditation; in other types of assessment, method 2 can be used) or perform sampling as an independent activity (assessment of sampling by method 1);
- the laboratory gives opinions and interpretations/ evaluation by method 1 with the implementation of the associated testing/calibration method is mandatory during the initial evaluation or evaluation for the purpose of expanding the scope of accreditation; in other types of assessment, method 2 can be used);
- the testing laboratory/calibration is carried out in the field (e.g. in the user's premises)
- the ratio of standard and non-standard test methods/calibration/use of non-standard methods is always a

greater risk and it is mandatory to assess the planning and method validation procedure during each assessment at the laboratory location;

- the availability of appropriate PT activities and other activities for ensuring the validity of test/calibration results/technical areas where there are no or a small number of available PT and other activities represent a greater risk and an attestation (method 1) or a combination of attestation (method 1) and documentary evaluation is mandatory (method 2) during the realization of each assessment at the laboratory location;
- flexible scope of accreditation / evaluation of the scope of accreditation depends on changes in the list of accredited activities between two assessments at the laboratory location.

ADDITIONAL RISK FACTORS IN ASSESSMENT PLANNING FOR INSPECTION BODIES

The assessment program includes the assessment of the entire scope of accreditation and all locations of the inspection body during the duration of one accreditation cycle.

Each assessment in the accreditation cycle is realized through assessment at the location of the inspection body, which, as a rule, includes the assessment of all requirements for accreditation that are defined by reference standards for accreditation and other normative documents, and through a certain number of witnessing of inspection activities.

The initial assessment is carried out in such a way that the selected assessment techniques are used to assess the fulfillment of all requirements for accreditation (requirements of reference standards for accreditation and other normative documents) and the scope of accreditation.

If the inspection from the requested scope of accreditation is carried out at several locations, the assessment is performed at the locations where some of the following activities are performed: policy definition; development of control processes and/or procedures, controller selection process and, if appropriate, review of contracts, planning of conformity assessment, review and approval of conformity assessment results and decision on conformity assessment results. Depending on the scope and type of activities mentioned above, the number of days at each individual location is determined.

During the initial assessment, the witnessing of representative inspections from each area of inspection from the requested scope of accreditation is realized. Representativeness is decided by the appointed technical assessor/technical expert in consultation with the competent Head of the Department for accreditation of Inspection bodies.

For the assessment of each area of inspection from the scope of accreditation, the number of days of assessment on site is as a rule 1, but the number can be increased taking into account the number of products or groups of products for inspection. Also, the time necessary for the realization of the assessment can be increased when it performs complex inspection activities (eg. several types of inspection according to the contract with client, long-term inspection process, etc.).

During the initial assessment, it is necessary to assess the work of the inspection body during the implementation of the planned and contracted inspection work, except in cases where accreditation is a prerequisite for authorization/appointment. Then, during the initial assessment, evaluation of the performance of the inspection may be realized through a simulation, and the number of evaluation days is, as a rule, the same as for a real assessment. If accreditation is a prerequisite for designation/authorization, it may be granted based on witnessing the operation of the conformity assessment body under simulated conditions. The designated/authorized inspection body is required to inform ATCG about its first conformity assessment activity to enable ATCG to witness its

operation under real conditions. If witnessing is not possible by the first regular surveillance assessment, ATCG will reduce or withdraw the granted scope of accreditation.

Also, in these cases, legal requirements, requirements of regulations, standards or requirements of the competent administrative authority may affect the required scope of the certification.

The number of assessment days is increased by at least 0.5 days, for example, when the inspection body is using external examination services (tests) that support inspection.

Additional risk factors to be considered:

During the evaluations in the accreditation cycle, the work of all key personnel who are responsible and authorized to perform inspection tasks within the scope of accreditation is checked and evaluated, i.e. personnel whose work affects the quality of the results of accredited inspections. If several different persons (inspectors) are authorized to perform the same inspection activities in the inspection body, the assessment will be performed in such a way that the persons whose work is witnessed are not repeated (unless otherwise planned for certain reasons, e.g. evaluation of the effectiveness of implemented corrective measures).

The selection of inspectors whose work will be witnessed by the ATCG evaluation team should be made by the ATCG and following risk factors must be taken into account (e.g. new employees, risks and complexity of inspection activities and tasks, effectiveness of internal monitoring (supervision of work) of inspectors, etc.)

Responsibility: Head of Department/ assessor

4.7.1 Regular assessments in the accreditation cycle

Regular assessments are carried out in accordance with ZPR.01.09-1 Assessment program, using applicable assessment techniques, taking into account that the period between two assessments at the client's location cannot exceed two years.

The interval between assessments in the accreditation cycle, as well as the applicable assessment techniques, depend on the results of the assessments carried out, the nature of the identified nonconformities, the effectiveness of the established management system, the results of internal audits, management reviews, the results of participation in inter-laboratory comparisons and PT activities, the results of resolving complaints, the frequency changes in the accredited CAB that may affect the accreditation status, etc.

CAB is obliged to submit the necessary documentation for the realization of Regular assessment no later than 1.5 months before the planned implementation date. As a rule, the assessment team remains the same during the accreditation cycle, but is engaged in a composition corresponding to the planned assessment activities in accordance with the assessment program.

During the preparation phase of each assessment (surveillance, extension, or reaccreditation), ATCG provides the accredited CAB with a Questionnaire on Changes (reference: ZPR.01.51), with a response deadline of no more than 10 days.

The questionnaire covers information on:

- Changes in ownership, legal, management, and operational structure;
- Changes in relationships with clients, parent, or affiliated organizations;
- Changes in resources, locations, equipment, personnel, scope of accreditation;
- Any other changes that may affect the criteria under which accreditation was granted.

During the assessment itself, the assessment team has to:

• Verify the information provided in the ZPR.01.51 questionnaire.
• Ask additional questions if there are any ambiguities.
• For accredited inspection bodies, the potential impact of changes on the Type A independence requirements must be specifically analysed, in accordance with Annex A.1, items b) and c) of the standard MEST EN ISO/IEC 17020, as well as Annex A – *Requirements for the independence of inspection bodies*, An1 of ILAC P15. Compliance with the independence requirements A.1(b) and A.1(c) for Type A is binary (yes/no), meaning that partial fulfilment of the Type A independence requirements is not possible. It also means that conducting a risk analysis with the aim of determining control measures to reduce risks to impartiality in situations where the Type A independence requirements are not met is not possible. Therefore, the only acceptable option is to eliminate the situation that is not in conformity with these Type A independence requirements. The independence requirement A.1(d) (MEST EN ISO/IEC 17020) for Type A *can* be addressed through control measures resulting from a risk analysis.

The documentation that is submitted to assessors/technical experts for the purposes of preparing and conducting regular CAB assessment includes:

- the report from the previous assessment (on the respective form ZPR.01.22-ZPR01.26) with accompanying records, and when applicable, the concluded Report(s) on nonconformities (on the form ZPR.01.21-1
- quality management system documents submitted by the CAB, if relevant;
- records on the participation in ILCs/PTs;
- internal audit report and management review submitted by the CAB;
- records on the resolution of appeals and complaints;
- information and documentation submitted by the CAB about the changes since the previous assessment than can affect accredited activities.
- information on changes in accreditation criteria and supporting documentation, when applicable
- changes in the legislation, when applicable
- Assessment plan
- Checklist / Worksheet form
- Valid forms that are applied during and after the assessment (e.g. Record of attendance at the final meeting, Report on nonconformities, Assessment report, Work list on the witnessing of the auditor's work (for certification bodies for products / for certification bodies for MS), Work list in connection with the reviewed client case/file (for certification bodies for MS), etc.)
- For certification bodies, record of annual provision of information of the certification body (ZPU.03.01)

Note: In the event that there is a change in the team member in relation to the previous assessment, the newly appointed member(s) will be provided with additional related documentation in accordance with clause 4.3.1 of this document.

Note: Assessors and technical experts who are permanent employees of ATCG do not need to be provided with the above-mentioned internal documentation (procedures, guidelines, forms), considering it as available to them at ATCG. Record of internal communication must be also kept.

Advisor in the competent department is responsible for keeping records about above communication

During one accreditation cycle, all conformity assessment procedures from the scope of accreditation must be assessed using appropriate assessment techniques.

4.7.2 Criteria for developing the Assessment program

Testing/calibration laboratories (including medical laboratories):

Assessment of the laboratory and the scope of accreditation in the accreditation cycle is planned through the Assessment program (ZPR.01.09-1) taking into account the risk associated with testing/calibration work according to the scope of accreditation.

In the first cycle of accreditation, all laboratory locations where one or more critical activities are performed, except for the initial assessment, are assessed at least once more. The assessment schedule at different locations of the laboratory during the validity of the accreditation is determined by the Assessment program for the accreditation cycle and depends on the results of previous assessments and related decisions on accreditation.

Also, the Assessment Program plans to select personnel whose work will be verified by the ATCG assessment team during the accreditation cycle, whereby risk factors must be taken into account (e.g. new employees, risks and complexity of inspection activities, effectiveness of internal monitoring - supervision of the work of inspectors etc.)

Based on the assessment of possible risks (Table 1), ATCG established a conditional division of laboratories into three groups: low-risk laboratories, medium-risk laboratories and high-risk laboratories.

Table 1: Risk group determination for testing / calibration laboratories

	Risk factors	Criteria			Score
		1	2	3	
1.	Complexity of the scope of accreditation	1-2 areas of testing without high-risk areas* / 1-2 areas of calibration	3-5 areas of testing, which may include (no more than 2) high-risk areas* / 3-5 areas of calibration	More than 5 areas of testing, which may include high-risk areas* / More than 5 areas of calibration	
2.	The ratio of standard to non-standard methods in the applied/granted scope of accreditation	All methods are standard.	More than 2/3 of the methods are standard.	More than 2/3 of the methods are non-standard.	
3.	Number of locations	1	2	More than 2	
4.	The scope and frequency of services provided to clients (e.g., the number of issued reports).	5-100 (in a specific area of testing/calibration, excluding routine testing/calibration)	100-500 (in a specific area of testing/calibration, excluding routine testing/calibration)	More than 500 (in a specific area of testing/calibration, excluding routine testing/calibration)	
5.	Movement and migration on the staff	There is no staff migration	There is no migration of key personnel responsible for staff management, result analysis, and report verification.	There is migration of key personnel responsible for staff management, result analysis, and report verification.	

6.	The ratio of newly hired to experienced personnel for specific functions (especially related to testing, result interpretation, and reporting).		More than 2/3 of the personnel with experience	Less than 2/3 of the personnel with experience	
7.	Nonconformities in the accreditation cycle that could pose a risk to the competence in performing testing/calibration tasks		No	Yes	
8.	Previous "history" of sanctions (full or partial), e.g., suspension/reduction of scope, etc.	No		Yes	
9.	Previous performance in external activities monitoring the validity of results (e.g., PT or ILC comparisons).	The results are satisfactory	For non-conformities resulting from unsatisfactory participation results in PT and ILC, appropriate corrective actions have been implemented	For non-conformities resulting from unsatisfactory participation results in PT and ILC, appropriate corrective actions have not been implemented	
10.	Reporting on opinions and interpretations	No		Yes	
11.	Combination of fixed and flexible scope of accreditation	No		Yes	
12.	Conducting sampling as a standalone activity	No		Yes	
13.	... *other applicable risk (please state)*				
	Average Score:				

*Note: High-risk areas of testing include food safety, medical testing, product safety testing, etc.

Based on the assessment of possible risks, ATCG established a conditional division of the Laboratory into the following three groups:

Low-risk laboratories: average score < 1.5
Medium-risk laboratories: average score 1.5 – 2.5
High-risk laboratories: average score > 2.5

The frequency and comprehensiveness of assessments in the accreditation cycle are affected by various risk factors, and the following rules for planning assessments in the cycle must be observed:

- As a rule, in the first cycle of accreditation, ATCG will carry out annual assessments at the location of the laboratory.
- ATCG may consider postponing on-site surveillance assessments in the first accreditation cycle in certain cases:
  • At the request of the laboratory: the lab may submit a justified request for postponement, for example, due to temporary operational inability, organizational changes, or extraordinary circumstances (e.g., natural disasters);
  • At the initiative of ATCG: if ATCG assesses that a certain assessment can be postponed due to reasons beyond its control, while maintaining confidence in the competence of the laboratory.

  If the request comes from the laboratory, ATCG may request additional information or documentation to assess the risk related to the postponement. During the postponement period, ATCG will consider alternative surveillance methods, such as remote assessment or document review (e.g., internal audit reports, management review minutes, generated reports with supporting records, reports on implemented corrective actions, results of handling complaints and appeals, results of completed PT/ILC activities, etc.). The maximum duration of the postponement generally does not exceed 6 months without serious consequences for the accreditation status.
- Starting from the second accreditation cycle, it is possible to omit the annual on-site assessment of an accredited laboratory and extend the period between two consecutive assessments in accordance with the Assessment Program if the laboratory is classified as low-risk laboratory. However, it shall be ensured that the period between two consecutive on site assessments does not exceed 2 years (24 months). The extension of the period between on-site assessments is also possible in cases where the laboratory has been conducting testing/calibration for many years in the same field(s) without significant changes (in relation to the reference documents for testing/calibration), while maintaining a stable operating system. This rule applies to laboratories in the low-risk and medium-risk category.
- If the annual on-site assessment of the laboratory is omitted, then the assessment shall be conducted through a documentation review, which will cover at least the review of internal audit reports, management review reports, generated testing/calibration reports with acompaning technical records, results from proficiency testing (PT)/inter-laboratory comparisons (ILC) and other activities related to ensuring the validity of testing/calibration results, reports on implemented preventive/corrective actions, and results from the resolution of complaints if occurred during the previous period, etc. It must be ensured that the period between two consecutive on-site assessments does not exceed 2 years (24 months).
- For laboratories in the high-risk category, the annual on-site assessments are required regardless of the accreditation cycle.
- A reduction in the period between assessments at the laboratory location is possible when there is objective evidence (indicators) of potential problems in the laboratory's work (e.g. justified objections to the laboratory's work, high turnover of staff, departure of key personnel, frequent change of reference documents related to the testing procedure/ benchmarking, financial instability, etc.).

Responsibility: Head of the competent department / Lead assessor

Inspection bodies:

Assessment of inspection bodies and the scope of accreditation in the accreditation cycle is planned through the Assessment programme (ZPR.01.09-1) taking into account the risk associated with inspection activities according to the scope of accreditation.

In the first cycle of accreditation, all locations of the inspection body where one or more critical

activities are performed, except for the initial assessment, are assessed at least once more. The assessment schedule at different locations of the inspection body during the validity of the accreditation is determined by the Assessment programme for the accreditation cycle and depends on the results of previous assessments and related decisions on accreditation.

Also, the Assessment programme plans to select a inspector whose work will be verified by the ATCG assessment team during the accreditation cycle, where risk factors must be taken into account (e.g. new employees, risks and complexity of inspection activities, the effectiveness of internal monitoring - supervision of the inspector's work and etc.)

Based on the assessment of possible risks (Table 2), ATCG established a conditional division of inspection bodies into three groups: low-risk inspection bodies, medium-risk inspection bodies, high-risk inspection bodies.

Table 2: Determination of the risk group for the inspection body

	Risk factors	Criteria			Score
		1	2	3	
1.	The complexity of the scope of accreditation	1-2 areas of inspection, without high-risk areas*	3-5 areas of inspection, which may include high-risk areas* (no more than 2)	More than 5 areas of inspection, which include high-risk areas*	
2.	Number of Locations	1	2	>2	
3.	The number of staff engaged in inspection	<10	10-20	>20	
4.	Changes in key personnel	1	2	>2	
5.	The ratio of newly hired to experienced personnel for specific functions (especially related to inspection, result interpretation, and reporting).		> 2/3 of experienced staff	< 2/3 of experienced staff	
6.	Non-conformities in the accreditation cycle that could pose a risk to the competence in performing inspection tasks that are under accreditation.		No	Yes	
7.	Previous "history" of sanctions (full or partial), e.g., suspension/reduction of scope, etc.	No		Yes	
8.	The areas of inspection that are subject to designation/authorization		No	Yes	
9.	… *other applicable risk (please state)*				
	Average Score:				

** High-risk areas of inspection include, for example, food, medical testing, product safety testing, etc.*

Based on the assessment of possible risks, ATCG established a conditional division of the Inspection bodies into the following three groups:

Low risk Inspection bodies: average score < 1.5 Medium risk
Inspection bodies: average score 1.5 – 2.5 High risk
Inspection bodies: average score > 2.5

The frequency and comprehensiveness of assessments in the accreditation cycle are affected by various risk factors, and the following rules for planning assessments in the cycle must be observed:

- As a rule, in the first cycle of accreditation, ATCG will carry out annual assessments at the location of the inspection body.
- ATCG may consider postponing on-site surveillance assessments in the first accreditation cycle in certain cases:
  • At the request of the CAB: the CAB may submit a justified request for postponement, for example, due to temporary operational inability, organizational changes, or extraordinary circumstances (e.g., natural disasters);
  • At the initiative of ATCG: if ATCG assesses that a certain assessment can be postponed due to reasons beyond its control, while maintaining confidence in the competence of the CAB.

  If the request comes from the CAB, ATCG may request additional information or documentation to assess the risk related to the postponement. During the postponement period, ATCG will consider alternative surveillance methods, such as remote assessment or document review (e.g., internal audit reports, management review minutes, generated reports with supporting records, reports on implemented corrective actions, results of handling complaints and appeals etc.). The maximum duration of the postponement generally does not exceed 6 months without serious consequences for the accreditation status.
- From the second cycle of accreditation, if it is a inspection body from a low-risk group, it is possible to increase the period between two on-site assessments, while it must be taken into account that the period between two consecutive on-site assessments cannot exceed 2 years (24 months).
- The extension of the period between consecutive on-site assessments of the inspection body is possible in cases where the inspection body has been performing inspections in the same technical area for many years, and where there have been no significant changes (e.g. personell, imspection methods), while maintaining a stable operating management system. This rule applies to inspection bodies in the low-risk and medium-risk categories, with the condition that the period between two consecutive on-site assessments cannot exceed 2 years (24 months).
- If the annual on-site assessment of the inspection body is omitted, then the assessment shall be conducted through a documentation review, which will cover at least the review of review of internal audit reports, management review reports, generated inspection reports with accompanying technical records, reports on implemented preventive/corrective actions, and results from the resolution of complaints and appeals if occurred during the previous period, etc. It must be ensured that the period between two consecutive on-site assessments does not exceed 2 years (24 months).
- For inspection bodies from the high-risk group, the implementation of annual assessments at the location is understood regardless of the accreditation cycle.
- Reducing the period between assessments at the site of the inspection body is possible when there is objective evidence (indicators) of possible problems in the work of the inspection body (e.g. justified objections/complaints from clients, high turnover of staff, departure of key staff, frequent change of reference documents related to the control procedure, financial instability, etc.).

- Type A inspection body must provide ATCG a risk analysis related to its impartiality, as well as evidence of maintaining compliance with the requirements of A.1b and A.1c of ISO/IEC 17020.

Responsibility: Head of the competent department / Lead assessor

Certification bodies for product certification:

Assessment of certification bodies for product certification (CBP) and their scope of accreditation in the accreditation cycle is planned through the Assessment programme (ZPR.01.09-1) taking into account the risk associated with certification work according to the scope of accreditation.

In the first cycle of accreditation, all CBP sites where one or more critical activities are performed, except for the initial assessment, are assessed at least once more. The assessment schedule at different STP locations during the validity of the accreditation is determined by the Assessment Program for the accreditation cycle and depends on the results of previous assessments and related accreditation decisions.

Also, the Assessment programme plans to select the auditor of the certification body whose work will be verified by the ATCG assessment team during the accreditation cycle, where risk factors must be taken into account (e.g. newly hired, risks and complexity of certification activities, effectiveness of internal monitoring - monitoring of work auditor, etc.)

Based on the assessment of possible risks (Table 3), ATCG has established a conditional division of CBP into three groups: low-risk certification bodies, medium-risk certification bodies and high-risk certification bodies.

Table 3: Determination of the risk group for the certification body for product certification

	Risk factors	Criteria			Score
		1	2	3	
1.	The complexity of the scope of accreditation.	1-2 certification schemes	3-5 certification schemes	>5 certification schemes	
2.	The ratio of internal and externally engaged personnel	All internal	External less than 50%	External more than 50%	
3.	The ratio of newly hired to experienced personnel for specific functions (especially related to certification and decision-making on certification)		More than 2/3 of the experienced staff	Less than 2/3 of the experienced staff	
4.	Certification schemes that include testing	Own resources	Combined (internal and external resources)	External resources	

5.	Nonconformities in the accreditation cycle that could pose a risk to the competence to carry out certification under accreditation		No	Yes	
6.	Previous "history" of sanctions (full or partial), e.g., suspension/reduction of scope, etc.	No		Yes	
7.	The certification scheme(s) is (are) subject to designation/authorization		No	Yes	
8.	Number of locations	1	2	> 2	
9.	... *other applicable risk (please state)*				
	Average Score:				

Based on the assessment of possible risks, ATCG established a conditional division of CBP into the following three groups:

First group - Low risk certification bodies - Average Score < 1.5
Second group - Certification bodies of medium risk - Average score 1.5 - 2.5
Third group - High-risk certification bodies - Average score > 2.5

The frequency and comprehensiveness of assessments in the accreditation cycle are affected by various risk factors, and the following rules for planning assessments in the cycle must be observed:

- As a rule, in the first cycle of accreditation, ATCG will carry out annual assessments at the CBP location.
- ATCG may consider postponing on-site surveillance assessments in the first accreditation cycle in certain cases:
  • At the request of the CPB: the CPB may submit a justified request for postponement, for example, due to temporary operational inability, organizational changes, or extraordinary circumstances (e.g., natural disasters);
  • At the initiative of ATCG: if ATCG assesses that a certain assessment can be postponed due to reasons beyond its control, while maintaining confidence in the competence of the CPB.

  If the request comes from the CPB, ATCG may request additional information or documentation to assess the risk related to the postponement. During the postponement period, ATCG will consider alternative surveillance methods, such as remote assessment or document review (e.g., internal audit reports, management review minutes, generated certificates with supporting records, reports on implemented corrective actions, results of handling complaints and appeals etc.).

  In these cases, ATCG will document the analysis carried out (minutes of the meeting of the competent personnel), including the decision on postponement and alternative surveillance methods during the postponement period, update the Assessment Program, and inform the CAB accordingly.

  The maximum duration of the postponement generally does not exceed 6 months without serious consequences for the accreditation status.

- From the second cycle of accreditation, if it is an CBP from a low-risk group, it is possible to increase the period between two on-site assessments, where care must be taken that the period between two consecutive on-site assessments cannot exceed 2 years (24 months).
- The extension of the period between consecutive on-site assessments of a product certification body is also possible in cases where the certification body applies a certification scheme that has not significantly changed over a long period of time, and where there have been no significant changes (e.g. personnel), while maintaining a stable operating management system. This rule applies to product certification bodies in the low-risk and medium-risk categories, with the condition that the period between two consecutive on-site assessments cannot exceed 2 years (24 months).
- If the annual on-site assessment of the product certification body is omitted, then the assessment shall be conducted through a documentation review, which will cover at least the review of review of internal audit reports, management review reports, generated certification reports with accompanying technical records, reports on implemented preventive/corrective actions, and results from the resolution of complaints and appeals if occurred during the previous period, etc. It must be ensured that the period between two consecutive on-site assessments does not exceed 2 years (24 months).
- For CBP s from the high-risk group, the implementation of annual assessments at the location is understood regardless of the accreditation cycle.
- Reduction of the period between assessments at the CBP site is possible when there is objective evidence (indicators) of possible problems in the operation of the CBP (e.g. justified objections/complaints from clients, departure of key personnel, frequent change of reference documents related to the certification procedure, financial instability etc.).
- In the event that the owner of the certification scheme has requirements regarding the on-site assessment of the CBP, ATCG will comply with these requirements regardless of which risk group the CBP belongs to.

Responsibility: Head of the competent department / Lead assessor

Certification bodies for management system certification:

Assessment of certification bodies for management system certification (STSM) and their scope of accreditation in the accreditation cycle is planned through the Assessment programme (ZPR.01.09-1) taking into account the risk associated with certification work according to the scope of accreditation.

In the first cycle of accreditation, all STSM sites where one or more critical activities are performed, except for the initial assessment, are assessed at least once more. The assessment schedule at different STSM locations during the validity of the accreditation is determined by the Assessment Program for the accreditation cycle and depends on the results of previous assessments and related accreditation decisions.

Also, the Assessment programme plans to select the auditor of the certification body whose work will be verified by the ATCG assessment team during the accreditation cycle, where risk factors must be taken into account (e.g. newly hired, risks and complexity of certification activities, effectiveness of internal monitoring - monitoring of work auditor, etc.)

Based on the assessment of possible risks (Table 4), ATCG has established a conditional division of MSCB into three groups: low-risk certification bodies, medium-risk certification bodies and high-risk certification bodies.

Table 4: Determination of the risk group for the certification body for management system certification

	Risk factors	Criteria			Score
		1	2	3	
1.	The complexity of the scope of accreditation	1-2 certification schemes	3-5 certification schemes	>5 certification schemes	
2.	The ratio of internal and externally hired personnel	All internal	External less than 50%	External more than 50%	
3.	Certification schemes involve assessing a person's competence based on a practical exam		No	Yes	
4.	Nonconformities in the accreditation cycle that could pose a risk to the competence to carry out certification under accreditation		No	Yes	
5.	Previous "history" of sanctions (full or partial), e.g., suspension/reduction of scope, etc.	No		Yes	
6.	Number of locations	1	2	> 2	
	... *other applicable risk (please state)*				
	Average Score:				

Based on the assessment of possible risks, ATCG established a conditional division of STP into the following three groups:

First group - Low risk certification bodies - Average Score < 1.5
Second group - Certification bodies of medium risk - Average score 1.5 - 2.5
Third group - High-risk certification bodies - Average score > 2.5

The frequency and comprehensiveness of assessments in the accreditation cycle are affected by various risk factors, and the following rules for planning assessments in the cycle must be observed:

As a rule, in the first cycle of accreditation, ATCG will carry out annual assessments at the STSM location.

An increase in the period between assessments at the STSM location during the first accreditation cycle is possible only in case of extraordinary circumstances that are beyond the control of ATCG and/or STSM. If the annual assessment at the STSM location is not possible due to the above reasons, the subject assessment will be performed remotely or, as a last resort, through a review of documentation (e.g. internal audit report, management review report, generated certificates and accompanying records, results preventive/corrective actions taken, results of resolution of objections and appeals, reports on auditor monitoring, etc.). Care must be taken that the period between two consecutive site assessments cannot exceed 2 years (24 months).

From the second cycle of accreditation, if it is a STSM from a low-risk group, it is possible to increase the period between two on-site assessments, where care must be taken that the period between two consecutive on-site assessments cannot exceed 2 years (24 months).

From the second accreditation cycle, if it is a STSM from the medium risk group, it is possible to increase the period between two on-site assessments, whereby instead of the annual on-site assessment, the assessment of the inspection body is carried out through a review of documentation (e.g. internal audit report, review report by management, generated certificates and supporting records, results of preventive/corrective actions taken, results of resolution of objections and appeals, auditor monitoring reports, etc.). Care must be taken that the period between two consecutive on-site assessments cannot exceed 2 years (24 months).

For STSM from the high-risk group, the realization of annual assessments at the location is understood regardless of the accreditation cycle.

Reduction of the period between assessments at the STSM site is possible when there is objective evidence (indicators) of possible problems in the work of the STSM (e.g. justified objections/complaints from clients, departure of key personnel, frequent change of reference documents related to the certification procedure, financial instability etc.).

In the event that the owner of the certification scheme has requirements regarding the on-site assessment of STSM, ATCG will comply with these requirements regardless of which risk group the STSM belongs to.

Responsibility: Head of the competent department / Lead assessor

4.7.3 Extraordinary assessment

Extraordinary assessment is carried out as necessary, namely:
- when there are objections to the work of the accredited conformity assessment body;
- when changes occur in the accredited conformity assessment body that may affect the conditions under which the accreditation was granted (changes in legal status, organization, management structure, conformity assessment procedures, material-technical and human resources, etc.);
- if, after suspension, it is necessary to check whether the accredited conformity assessment body meets the accreditation requirements again
- based on information about the situation in the accredited conformity assessment body, which may affect the status of the granted accreditation
- based on other issues that may affect the conformity assessment body's ability to meet accreditation requirements

The decision to conduct an extraordinary assessment is made by the director of the ATCG.

Responsibility: Head of the competent Department / Director of ATCG

4.8 ACCREDITATION RENEWAL

4.8.1 Reassessment

Reassessment activities start at least 4 months before the expiry date of the accreditation, by the conformity assessment body submitting the application for accreditation renewal with the accompanying documentation specified in the application form.

All phases of the reassessment are realized as in the initial assessment, except for the realization of

the preliminary visit. For reassessment, if possible, new assessment team shall be appointed, different from team(s) that performed assessments in the previous accreditation cycle.

The documentation that is submitted to the assessors/technical experts in order to prepare the reassessment is the same as for the initial assessment (see clause 4.3.1.). In addition to that, Assessment report (forms from ZPR.01.22 to ZPR.01.26-1) related to previous assessments, accompanying records and information about closing of nonconformities (form ZPR.01.21-1) if applicable are also submitted.

Advisor in the competent department is responsible for keeping records about above communication.

Responsibility: Head of the competent Department / Head of the Accreditation Service

4.8.2 Extension of validity of accreditation

If the accredited conformity assessment body had submitted an application for accreditation renewal to ATCG within the prescribed period, and the decision on the accreditation renewal has not been made before the expiry date of the accreditation, and only if the delay is caused by ATCG, the director may decide to extend the validity of accreditation until the renewal of accreditation, but the extension of validity may not be for more than 3 months from the expiry date of the accreditation.

Responsibility: Head of the Accreditation Service / Director of ATCG

4.9 CHANGES IN THE SCOPE OF ACCREDITATION

4.9.1 Extending the scope of accreditation

An accredited conformity assessment body may apply for extension of the scope of accreditation at any time during the validity of the accreditation, including an extension of the scope of accreditation in the accreditation renewal process, but in such case instead of submitting application for extension of accreditation the conformity assessment body shall identify within the requested scope of accreditation the conformity assessment activities for which extension is sought. Assessment for the purpose of extending the scope of accreditation can be carried out as an independent procedure or combined with a regular assessment during the accreditation cycle.

Based on the risk associated with the activities or locations to be covered by the scope extension, the appropriate technique(s) to be applied are defined. A review of ATCG resources is conducted, followed by assessment preparation, review of documented information, assessment, and decision-making, as prescribed in this document.

The application for extension of the scope of accreditation in the existing accreditation field shall be submitted at least 2 months before the planned date of regular assessment, or 4 months before in the new field of accreditation. In case of untimely application for extension, ATCG may not accept the application as part of the regular assessment and shall, at the request of the applicant, conduct an independent procedure for the extension of the scope of accreditation, after the completion of the regular assessment procedure. An application for extension of the scope of accreditation shall not be accepted if the accredited body has not fulfilled its obligations to the ATCG. The extension of the scope of accreditation does not affect the validity of the Accreditation Certificate.

The documentation that is submitted to assessors/technical experts for the purposes of preparing and conducting CAB assessment for the purpose of extending the scope of accreditation includes:

- Application for accreditation (on the respective form ZPR.01.01-1 to ZPR.01.06-1) with accompanying annexes (The application is submitted to all team members, while the (respective) annexes of the Application are submitted to the lead/technical assessor in accordance with their expertise)
- Assessment report from the previous assessment with relevant records;
- Information about nonconformities from the previous assessment, if any
- relevant legislation related to technical fields, when applicable and relevant;
- Assessment plan is submitted to all team members
- All relevant internal documentation (forms) in accordance with clause 4.3.1 of this document.

Note: In the case when a new team member is engaged in relation to the previous assessments of the CAB during the accreditation cycle, the newly appointed member(s) will be provided with additional relevant documentation in accordance with clause 4.3.1 of this document.

Note: Assessors and technical experts who are permanent employees of ATCG do not need to be provided with the above-mentioned internal documentation (procedures, guidelines, forms), considering it is available to them at ATCG. Record of internal communication must be also kept.

Advisor in the competent department is responsible for keeping records about above communication.

The granted extension of accreditation is taken into account when reviewing and updating the Assessment Programme (ZPR.01.09-1).

Responsibility: Head of the competent Department / Head of the Accreditation Service / Director of ATCG

4.9.2 Reducing the scope of accreditation

The scope of accreditation of an accredited conformity assessment body may be reduced at the request of the conformity assessment body or on the basis of an appropriate accreditation decision made after an assessment has been carried out.

The conformity assessment body has the right to appeal if it is dissatisfied with the ATCG's decision to reduce the scope of accreditation.

Responsibility: Head of the competent Department / Head of the Accreditation Service / Director of ATCG

4.9.3 Other changes in the scope of accreditation

a) At any point during the accreditation cycle, the conformity assessment body may request a modification of the current scope of accreditation, e.g., due to changes in the reference document for conformity assessment (standard, technical regulation, etc.), changes in the year of publication of the reference document, and similar reasons.

   The conformity assessment body (CAB) is obligated to submit ATCG the request for changes to the Scope of accreditation along with the justification for changes, which includes an impact analysis to the CAB management system. Upon receiving such request and accompanying documentation, the advisor in relevant department with the constent of the head of that department forwards the request and supporting documentation to the lead assessor and the technical assessor/expert for review. Additional documentation may be requested for provision by CAB, if needed. Depending on the context and extent of the required activities, contracts with the assessors may be concluded if necessary and the CAB will be accordingly charged for the associated costs.

   ATCG, after analyzing the submitted request, decides on the method of verification for the requested change and necessary activities to be carried out (e.g. on-site assessment, review of the documentation, etc.) which will be communicated to the CAB in writing.

There might be also situations where ATCG based on review of Request for changes and accompanying documentation provided by CAB decides not to conduct any further evaluation in order to make specified changes to the scope of accreditation. (e.g. new edition of a standard - with the new year of publication, does not bring any changes in relation to conformity assessment method).

Requests for changes to the scope of accreditation received during the period between regular accreditation assessments are reviewed by relevant ATCG personnel and assessors/technical experts, decided upon by the Accreditation Committee and formally verified by the ATCG Director.

Note**:** A change in the subject/item of conformity assessment, the type of conformity assessment, or the location of the conformity assessment body is also considered a scope extension and is implemented in accordance with article 4.9.1 of this document. This is also taken into account when reviewing the Assessment Program.

Responsibility: *Advisor and Head of the relevant department / Accreditation Commission / Director of ATCG*

b) During the period between regular assessments, ATCG is also obliged to monitor changes in reference documents cited in the issued scopes of accreditation. This responsibility falls under the Advisor in the Service for Development and International Cooperation. On the other hand, the monitoring of changes in legal and regulatory framework is the responsibility of the ATCG Business Secretary.

Responsibility: *Advisor in the Service for Development and International Cooperation / ATCG Bussiness Secretary*

4.10 SUSPENSION OF ACCREDITATION

4.10.1 Suspension on request - Voluntary suspension

At any time during the validity of the accreditation, accredited conformity assessment body may request from the ATCG to suspend accreditation, either for part or entire scope of accreditation, due to its temporary inability to perform accredited conformity assessment activities with observance of accreditation criteria. The requested suspension may be granted for a maximum period of 6 months. Accredited conformity assessment body should request lifting of the suspension in writing at least one month before the expiry of the suspension.

Suspension of accreditation may be lifted on the basis of the results of an assessment, or on the basis of submitted adequate evidence that the circumstances that led to the suspension have ceased.

If conditions for lifting suspension are not met, ATCG shall reduce the scope of accreditation to the extent to which accreditation had been suspended, or withdraw the accreditation if the entire scope of accreditation had been suspended.

Conformity assessment body has the right to appeal if it is dissatisfied with the ATCG's decision to reduce the scope of accreditation or withdraw the accreditation.

Duration of the suspension shall not affect the accreditation validity period.

Responsibility: Head of the Accreditation Service / Director of ATCG

4.10.2 Suspension by ATCG - Forced suspension

ATCG may suspend accreditation based on the results of activities in the accreditation cycle, due to noncompliance with accreditation criteria or noncompliance with contractual and other obligations by the accredited conformity assessment body, the results of the assessment or on the proposal of the Accreditation Committee. This suspension may last for a maximum period of 6 months, and may cover part or the entire scope of accreditation. Exceptionally, if accreditation is a precondition for authorization / designation and there is a change in the regulations governing the subject field of conformity assessment, ATCG may decide to suspend accreditation for additional six months, until the conformity assessment body adapts to the amended regulations. Accredited conformity assessment body should request lifting of the suspension in writing at least one month before the expiry of the suspension.

If conditions for lifting suspension are not met, ATCG shall reduce the scope of accreditation to the extent to which accreditation had been suspended, or withdraw the accreditation if the entire scope of accreditation had been suspended.

Conformity Assessment Body has the right to appeal if it is dissatisfied with the ATCG's decision on forced suspension.

Duration of the suspension shall not affect the accreditation validity period.

Responsibility: Accreditation Committee / Director of ATCG

4.11 TERMINATION OF ACCREDITATION

4.11.1 Quitting accreditation

An accredited conformity assessment body may quit the accreditation for any reason and request from ATCG in writing to cancel accreditation at any time.

4.11.2 Withdrawal of accreditation

ATCG may withdraw the granted accreditation based on the results of activities in the accreditation cycle, due to noncompliance with accreditation criteria or noncompliance with contractual and other obligations of the accredited conformity assessment body, at the proposal of the Accreditation Commission. In particular, ATCG shall initiate the process for withdrawing accreditation if when performing activities during the accreditation cycle finds evidence of fraudulent behavior, intentional providing of false information or concealing of information, or evidence of abuse of accreditation or violation of accreditation rules by an accredited conformity assessment body. After withdrawal of accreditation, the conformity assessment body shall return to ATCG the Accreditation Certificate and the Appendix to the Accreditation Certificate with the Scope of Accreditation, and shall demonstrate, by means of a written declaration, that it shall undertake all actions preventing the use of the accreditation symbol and textual claims of accreditation after the withdrawal of accreditation.

The conformity assessment body has the right to appeal if it is dissatisfied with the ATCG's decision to withdraw accreditation.

The conformity assessment body, whose accreditation has been withdrawn, may submit a new application for accreditation after 6 months from the date of withdrawal of accreditation, or after 12 months from the date of withdrawal of accreditation due to abuse of accreditation or violation of accreditation rules.

Responsibility: Accreditation Committee / Director of ATCG

4.12. COMPLAINTS AND APPEALS

Complaints and appeals are resolved in accordance with the procedure PR.08 Resolving complaints and appeals.

4.13 RECORDS ON CABS

ATCG has a documented procedure PR.02 Management of documents and records prescribing that the records shall be retained at least for the duration of the current cycle plus the previous full accreditation cycle.

Responsibility: Advisor in the competent Department / Head of the competent Department

5. FORMS

Ord. no.	Title	Reference	Edition/ Date of update	Storage method (paper/electronic form)	Retention period
1.	Application for accreditation of a testing laboratory	ZPR.01.01-1	00/03.12.2024.	Registry – Paper form	At least 8 years
2.	Application for accreditation of a calibration laboratory	ZPR.01.02	00/14.09.2020.	Registry – Paper form	At least 8 years
3.	Application for accreditation of an inspection body	ZPR.01.03-1	00/03.12.2024.	Registry – Paper form	At least 8 years
4.	Application for accreditation of a certification bodies for products, processes and services	ZPR.01.04-1	00/03.12.2024.	Registry – Paper form	At least 8 years
5.	Application for accreditation of a certification body for QMS	ZPR.01.05-1	00/02.04.2024.	Registry – Paper form	At least 8 years
6.	Application for accreditation of a medical laboratory according to MEST EN ISO 15189:2016	ZPR.01.06-1	00/26.02.2024.	Registry – Paper form	At least 8 years
7.	Team proposal	ZPR.01.07	00/14.09.2020.	Registry – Paper form	At least 8 years
8.	Assessment plan	ZPR.01.08	00/14.09.2020.	Registry – Paper form	At least 8 years
9.	Assessment programme	ZPR.01.09-1	00/03.02.2023.	Registry – Paper form	At least 8 years
10.	Checklist for assessment of testing laboratories / calibration laboratories	ZPR.01.10	00/14.09.2020.	Registry – Paper form	At least 8 years
11.	Checklist for assessment of inspection bodies	ZPR.01.11	00/14.09.2020.	Registry – Paper form	At least 8 years
12.	Checklist for assessment of certification bodies for products, processes and services	ZPR.01.12-1	00/20.12.2024.	Registry – Paper form	At least 8 years
13.	Checklist for assessment of certification bodies for QMS	ZPR.01.13-1	00/02.04.2024.	Registry – Paper form	At least 8 years
14.	Checklist for the assessment of medical laboratories according to MEST EN ISO 15189	ZPR.01.14-1	00/26.02.2024.	Registry – Paper form	At least 8 years
15.	Worksheet for assessment of testing laboratories / calibration laboratories	ZPR.01.15-1	00/15.03.2021.	Registry – Paper form	At least 8 years
16.	Worksheet for assessment of inspection bodies	ZPR.01.16	00/14.09.2020.	Registry – Paper form	At least 8 years
17.	Worksheet for assessment of certification bodies for products, processes and services	ZPR.01.17-1	00/20.12.2024.	Registry – Paper form	At least 8 years

18.	Worksheet for assessment of certification bodies for QMS	ZPR.01.18-1	00/02.04.2024.	Registry – Paper form	At least 8 years
19.	Worksheet for the assessment of medical laboratories according to MEST EN ISO 15189	ZPR.01.19-1	00/26.02.2024.	Registry – Paper form	At least 8 years
20.	Minutes on attendance at the closing meeting	ZPR.01.20	00/14.09.2020.	Registry – Paper form	At least 8 years
21.	Report on nonconformities	ZPR.01.21-1	00/09.01.2023.	Registry – Paper form	At least 8 years
22.	Assessment report for testing / calibration laboratories	ZPR.01.22	00/14.09.2020.	Registry – Paper form	At least 8 years
23.	Assessment report for inspection bodies	ZPR.01.23	00/14.09.2020.	Registry – Paper form	At least 8 years
24.	Assessment report for certification bodies for products, processes and services	ZPR.01.24	00/14.09.2020.	Registry – Paper form	At least 8 years
25.	Assessment report for certification bodies for QMS	ZPR.01.25	00/14.09.2020.	Registry – Paper form	At least 8 years
26.	Assessment report for medical laboratories according to MEST EN ISO 15189	ZPR.01.26-1	00/26.02.2024.	Registry – Paper form	At least 8 years
27.	List of documents containing thr requirements to be met by the applicant for accreditation and accredited CABs	ZPR.01.27-1	00/03.02.2023.	Registry – Paper form	At least 8 years
28	Accreditation certificate for testing laboratories	ZPR.01.28	00/14.09.2020.	Registry – Paper form	At least 8 years
29	Accreditation certificate for calibration laboratories	ZPR.01.29	00/14.09.2020.	Registry – Paper form	At least 8 years
30.	Accreditation certificate for inspection bodies	ZPR.01.30	00/14.09.2020.	Registry – Paper form	At least 8 years
31.	Accreditation certificate for certification bodies for products, processes and services	ZPR.01.31	00/14.09.2020.	Registry – Paper form	At least 8 years
32.	Accreditation certificate for certification bodies for QMS	ZPR.01.32	00/14.09.2020.	Registry – Paper form	At least 8 years
33.	Accreditation certificate for medical laboratories according to MEST EN ISO 15189	ZPR.01.33	00/14.09.2020.	Registry – Paper form	At least 8 years
34.	Appendix to the accreditation certificate for testing laboratories	ZPR.01.34-2	00/03.12.2024.	Registry – Paper form	At least 8 years
35.	Appendix to the accreditation certificate for calibration laboratories	ZPR.01.35-1	00/03.02.2023.	Registry – Paper form	At least 8 years
36.	Appendix to the accreditation certificate for inspection bodies	ZPR.01.36-1	00/03.02.2023.	Registry – Paper form	At least 8 years
37.	Appendix to the accreditation certificate for certification bodies for products, processes and services	ZPR.01.37-2	00/03.12.2024.	Registry – Paper form	At least 8 years
38.	Appendix to the accreditation certificate for certification bodies for QMS	ZPR.01.38-1	00/03.02.2023.	Registry – Paper form	At least 8 years
39.	Appendix to the accreditation certificate for medical laboratories according to the standard MEST EN ISO 15189	ZPR.01.39-3	00/03.12.2024.	Registry – Paper form	At least 8 years
40.	Self-assessment report for testing / calibration laboratories	ZPR.01.40	00/14.09.2020.	Registry – Paper form	At least 8 years
41.	Self-assessment report for inspection bodies	ZPR.01.41	00/14.09.2020.	Registry – Paper form	At least 8 years

42.	Self-assessment report for certification bodies for products, processes and services	ZPR.01.42	00/14.09.2020.	Registry – Paper form	At least 8 years
43.	Self-assessment report for certification bodies for QMS	ZPR.01.43	00/14.09.2020.	Registry – Paper form	At least 8 years
44.	Self - assessment report for medical laboratories according to MEST EN ISO 15189	ZPR.01.44-1	00/26.02.2024.	Registry – Paper form	At least 8 years
45.	Witnessing report (MEST ISO/IEC 17021-1)	ZPR.01.45	00/03.02.2023.	Registry – Paper form	At least 8 years
46.	Witnessing report (MEST ISO/IEC 17065)	ZPR.01.46	00/03.02.2023.	Registry – Paper form	At least 8 years
47.	Worksheet related to the reviewed item/client file	ZPR.01.47	00/03.02.2023.	Registry – Paper form	At least 8 years
48.	Register of members of the Accreditation Commission	ZPR.01.48	00/03.02.2023.	Registry – Paper form	At least 8 years
49.	Checklist for assessment of CB form ISMS (additional requirements according to ISO/IEC 27006)	ZPR.01.49	00/03.02.2023.	Registry – Paper form	At least 8 years
50.	Annual training plan	ZPR.01.50	00/03.02.2023.	Registry – Paper form	At least 8 years
51.	Questionnaire on Changes	ZPR.01.51	00/15.04.2025.	Registry – Paper form	At least 8 years