AKREDITEERIMISHINDAMISE PROTSEDUUR

PROCEDURE FOR ACCREDITATION ASSESSMENT

EAK J2 – 2017

Translation from Estonian

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Authorship and principles
This guidance document is a new issue of the guide EAK J2 and it was drafted by the EAK working group including Eire Endrekson, Paavo Ruzitš, Kaire Tõugu, Maia Valm, Viktor Krutob and Kristiina Saarniit. The guide J2 replaces the EAK guides J7, J8, J13 and J17. The guide establishes the procedures applied during accreditation assessments of conformity assessment bodies conducted by the EAK.

Following of the requirements and procedures of this guide is mandatory for the EAK personnel and assessors and experts taking part in assessment.

Official language
If required, the guide may be translated into other languages. The Estonian version is and must remain like the original and shall be binding in case of different opinions concerning interpretation.

Confirmation
The guide was confirmed by the Member of EAK Management Board Kristiina Saarniit /digital signature/ on 15 December 2017.
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¹ Referred documents and templates are available on EAK website
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1. DESCRIPTION OF ACCREDITATION PROCESS

1.1 Terms

In addition to the conformity assessment and accreditation terms provided in EVS-EN ISO/IEC 17011, EVS-EN ISO/IEC 17000 and EVS-EN ISO 9000 standard the following definitions are used in this guide:

1.1.1 Body – conformity assessment body, including testing laboratory, calibration laboratory, certification laboratory, inspection body and attestation body.

1.1.2 Assessment time – time spent for assessment of accreditation, including time required for preparation, on-site assessment and performing follow-up activities.

1.1.3 Accreditation scheme – rules and processes set out in standards (EA-1/06, level 3) or other normative documents relating to accreditation of conformity assessment bodies to which the same requirements apply.

1.1.4 Accreditation criteria – international requirements for accreditation set out in standards, guides and legal acts which have been established for performance of conformity assessment and the conformity of which is confirmed by an accreditation body.

1.1.5 Accreditation requirements – applicable accreditation criteria, conditions of accreditation agreement and requirements of the EAK guides.

1.1.6 Scope of accreditation – specific conformity assessment services for which the accreditation is sought or has been granted.

1.1.7 Correction – correcting nonconformities.

1.1.8 Resolving nonconformities – implementation of correction and corrective action.

1.2 Accreditation process

1.2.1 The description of accreditation process is presented on the flow chart in Annex 1.

1.2.2 Assessment techniques used to perform accreditation are presented in Annex 2.

1.2.3 The period of accreditation cycle is 5 years, starting from the date of accreditation decision and including annual surveillance assessments and reassessment prior to the expiry date of accreditation.

2. INITIAL ASSESSMENT

2.1 Submission and review of application

2.1.1 Each body seeking accreditation shall complete and submit to the EAK an appropriate application template with the questionnaire that is published on the EAK website. This would give basic information on the activities, procedures, personnel and (key) locations (re: Annex 3) and exact data on the scope of accreditation they are seeking.

2.1.2 The scope of accreditation they are seeking shall be described in great detail both in Estonian and English, taking into account the following:

2.1.2.1 A calibration laboratory shall provide in the annex to their application the list of calibration methods by sites, name and identification for each method, calibration item, scope of calibration and calibration capability and the number of calibrations a year. In addition, they shall submit the records of measurement standards, the traceability chart for each unit of measurement and analysis of the results of interlaboratory calibrations. Guidance on description of the desired scope of accreditation for the calibration laboratories is given in the document EAK VJ3.

2.1.2.2 A testing laboratory shall provide in the annex to their application the list of testing methods by sites, name and identification of methodology for each method, test item (i.e. material or product to be tested), indicator to be measured, measuring principle, measurement

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range, uncertainty of measurement /measurement capability and the number of tests a year. Guidance on description of the desired accreditation scope for the testing laboratories is given in the document EAK VJ5¹, while for the medical laboratories in EAK VJ6¹ and for the measurement instruments verification laboratories in EAK VJ8¹ respectively.

2.1.2.3 An organizer of interlaboratory comparison shall provide in the annex to their application the name and identification, precise item, parameters and measurement range and relevant site for each interlaboratory comparison scheme.

2.1.2.4 Inspection bodies shall describe in the annex to the application the type of independence, inspection range, legal acts, standards or specifications in compliance with which inspections are performed.

Guidance on description of the desired accreditation scope for the inspection bodies is given in the document EAK VJ9¹.

An inspection body performing audits of electrical installations shall follow the provisions of the document EAK VJ7¹ when defining the scope of accreditation.

2.1.2.5 A certification body shall describe in the annex to the application the standards and normative requirements or legal acts in compliance with which certifications of products, services, processes, persons and management systems are performed. If relevant, it is necessary to add information on the category of industrial sector, product or person.

A certification body of quality, environmental, occupational health and safety management systems shall submit the description of their scope of accreditation based on the NACE rev 2 codes and a certification body of food safety management systems based on categories/subcategories.

Guidance on description of the desired accredited scope for the different kind of certification bodies is given in the documents EAK VJ1¹, VJ2¹ or VJ4¹ respectively.

2.1.3 A conformity assessment body that is applying for the status of a notified body after granted accreditation shall make a relevant notation on the application template.

When describing the scope of accreditation, the body applying for notification shall:

- refer to relevant clauses of relevant directives and legal acts;
- describe the conformity assessment module or system applied;
- list the normative documents used at conformity assessment.

2.1.4 When submitting the application, the body will also submit the management system documentation and other additional documents listed on the application template.

2.1.5 On receipt of the application in the EAK, the assistant will register the application and check whether the application and questionnaire are completed correctly and are accompanied by all required additional documents.

2.1.6 If required, the assistant will inform the applicant of the omissions and will appoint a time limit for correcting of omissions (up to one month). If the omission is not corrected in a timely manner, the EAK may refuse to review the application.

2.1.7 The assistant will register the additional documents submitted with the application on the accreditation registration template AD 02², stating the decision made in further processing of application. The assistant will then forward the registered application with annexes to the head of accreditation responsible for the relevant area.

2.1.8 Processing of application starts from the moment when the application and questionnaire are filled in and all required additional documents submitted. Processing of the application involves resource review, decision by the Member of Management Board on starting processing, appointment of lead assessor and technical reviewer and first contact with the body.

2.1.9 If in the course of processing of application or initial assessment it becomes evident that a member of top management or a person involved in the respective conformity assessment

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activity has been found guilty of fraud or the body has intentionally provided false information or concealed information, the EAK will reject the application or terminate the accreditation process.

2.2 Resource review

2.2.1 The head of accreditation will perform the review of the EAK resources aimed at determining if the EAK is ready to perform the assessment requested. At that they assess at least the following:

- availability of required competence in the EAK (i.e. whether the EAK has earlier assessed the given scheme);
- compliance of the application with the EAK policies (possibility to accredit the scheme, demand of Estonian market);
- availability of competent assessors/experts and access to them (in the EAK assessors register, etc);
- available time (concerning both lead and specialist assessors);
- lack of applicant’s indebtedness to the EAK (if appropriate).

2.2.2 As a result of review the head of accreditation will make a decision on the availability of resources in the EAK. The results of review are recorded on the accreditation registration template.

2.2.3 After that the head of accreditation will forward the application with annexes (if necessary) and results of review to the Member of Management Board for making the decision to start processing the application.

2.2.4 If the Member of Management Board decides to start the processing of application, she/he will return it to the head of accreditation. If the Member of Management Board decides to refuse to start processing the application or extend the time of processing the application because of insufficient resources in the EAK, unpaid invoices by the body, etc, the applicant will be informed in writing by the Member of Management Board or head of accreditation.

2.2.5 The head of accreditation responsible for the area will send to the applicant the invoice containing the fee for reviewing the application that will cover the costs of the EAK work until the decision is made to start processing the application. The invoice with the fee for initial review of the application is presented for reviewing the application for initial accreditation and extension to the scope of accreditation (for the new conformity assessment scheme or testing area).

2.2.6 After starting processing of the application the head of accreditation will appoint a qualified lead assessor concerning the relevant accreditation standard and will forward the applicant’s documents to him/her. In addition, the head of accreditation will appoint a qualified lead assessor concerning the relevant accreditation standard to be the technical reviewer of assessment.

2.2.7 The lead assessor who was appointed as the leader of assessment team will open a file of the new body (both for paper and digital documents) for gathering all materials related to processing and assessment of the application of the body in question.

2.3 Preparation for assessment

2.3.1 Program for initial assessment

2.3.1.1 The lead assessor will draw up an initial assessment program in a free form. The program will take into account the risks associated with the applicant’s activities, locations and personnel (re: Annex 4) and will include all assessment activities to be performed during initial

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assessment: review of documents, on-site assessment, including carrying out witnessing. The risks considered will be also fixed in the program.

2.3.1.2 The program will cover the assessment of all locations of the body where at least one of key activities listed in Annex 2 is carried out. When assessing bodies who operate internationally and which have locations of key activities in different countries, in addition the requirements of guides EA-2/13 and IAF MD 12 (re: chapter 12) are followed.

2.3.2 Review of documents

2.3.2.1 Assessment starts with review of documents, in the course of which it is possible to make a preliminary visit of the body. The purpose of the review of documents is to determine the readiness of the body for assessment and if necessary, to clarify the scope of accreditation they are seeking.

2.3.2.2 The lead assessor will conduct the review of documents of the body.

2.3.2.3 The objectives of review of documents are to:

- review the documented information of the management system of the body;
- review the status of the body and their understanding of the requirements, processes, objectives and of the standard;
- obtain necessary information on the scope of the management system (locations, personnel, processes and equipment used, applicable regulatory requirements) for determination of the competence of the assessment team and ensuring effective performance of assessors, focussing only on the assessment of the area in their scope of accreditation.

2.3.2.4 If the submitted documents are unclear or the accreditation body has doubts concerning the competence of the body and operation of the management system, the lead assessor, if necessary, and in coordination with the body, may conduct a preliminary visit to the body, taking into account the following:

2.3.2.4.1 The maximum time of the preliminary visit is one day.

2.3.2.4.2 The preliminary visit will enable the lead assessor to explain requirements provided for the specific conformity assessment activity to the representatives of the body and clarify the scope of accreditation they are applying for. In the course of the preliminary visit the lead assessor shall avoid providing any consultancy to the body.

2.3.2.4.3 During preliminary visit the observations and/or shortcomings that have become evident will be explained to the management of the body.

2.3.2.4.4 The observations and/or shortcomings found during preliminary visit shall be recorded in the assessor report and no due date shall be determined for their elimination. The body may take corrective action for eliminating of observations and/or shortcomings before start of on-site assessment.

2.3.2.5 If shortcomings are found in the activities or management system of the body during review of documents, the body shall be informed of them and, if appropriate, they shall be recorded in the detailed report.

2.3.2.6 The results of the review of documents are recorded on the template AR 02.

2.3.3 Planning of witnessing

2.3.3.1 The EAK will witness conducting of a number of conformity assessments before making the decision on granting accreditation to the applicant. The witnessed conformity assessments shall demonstrate that the body has an efficient system for selecting competent calibrators/testers/auditors.

2.3.3.2 When planning witnessing of persons performing conformity assessment activities it is necessary to consider the complexity and risk level of different types of conformity assessment

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activities, as well as the frequency they are carried out, required competence level of calibrators/testers/inspectors/auditors, the total number of employees and newly employed people, training system of the body and the efficiency of the internal monitoring program of employees.

2.3.3.3 In defining the number of witnessing and of activities to be witnessed the following shall be considered:

2.3.3.3.1 At least one methodology for each measuring principle in the scope of accreditation should be covered in a laboratory. While planning assessments, additionally sectorial guidance VJ3¹ is followed in calibration, VJ5¹ in testing, VJ6¹ in medical and VJ8¹ in verification laboratories.

2.3.3.3.2 In case of inspection, certification of products, services, processes or persons at least one witnessing should be conducted for each certification/inspection area and/or product group that is included in the application of the body. If a product certification scheme includes also inspection activities, one witnessing will cover both activities. In case of a body applying for notification the most complicated module is selected for witnessing in each area they are applying for. Guidance on planning the witnessing of inspection activities is given in the document EAK VJ9¹, while for the persons and products certification activities in EAK VJ1¹ and EAK VJ4¹ respectively.

2.3.3.3.3 When witnessing the audits of management system certification bodies, the EAK is proceeding from IAF guides MD 16 and MD 17 and from guidelines provided in sectoral guide of EAK VJ2¹ in addition.

2.3.3.3.4 When witnessing the activities of inspection bodies conducting audits of electrical installations the guidelines provided in guide EAK VJ7¹ are taken into account in addition.

2.3.3.3.5 When witnessing the activities of attestation bodies of greenhouse gas emissions, the EAK is proceeding from the Regulation No 2018/2067 of the European Commission.

2.3.3.3.6 When witnessing is conducted separately from on-site assessment, the body shall agree the witnessing time with the EAK at least a month before the witnessing takes place, to allow the EAK to provide necessary resources for conducting witnessing.

2.3.3.6 In order to plan witnessing at a client’s site of the body, the body shall submit necessary information related to the specific witnessing, including:

- assessment plan, drawn up by the body, including the time and place of assessment,
- information on persons conducting assessment at client’s site,
- client’s management system,
- reports of previous conformity assessments,
- evidence documents of the competence of assessment team.

2.3.3.7 The final decision on the conformity assessment activities and employees of the body to be witnessed during assessment is made by the lead assessor.

2.3.3.8 In cases when the body refuses to make witnessing possible (including when the client of the body refuses to allow to perform witnessing), the EAK will not be able to accredit the specific conformity assessment activity.

2.3.4 Appointment of assessment team and tasks of team members

2.3.4.1 The task of the assessment team is to review the documents submitted by the body and carrying out on-site assessment, including witnessing.

2.3.4.2 The lead assessor will make a proposal to the head of accreditation (if the head of accreditation is the lead assessor, to the Member of the EAK Management Board) for including
2.3.4.3 In the selection of assessors the lead assessor will proceed from the requirement that the assessment team as a whole will represent necessary competence for assessment (i.e. all areas of conformity assessment activities shall be covered by competent assessors).

2.3.4.4 The lead assessor will select the members of assessment team from among the assessors entered in the EAK assessors register, considering their approved competence range and data on their CV on qualifications and work experience. If required, the lead assessor will contact the assessor before that to specify his/her competence and/or information presented in CV. In addition, the lead assessor will verify the conformity of each assessor’s compliance with the requirements of clauses 5.6 and 5.7 of EAK J10¹.

2.3.4.5 In case of each member of the assessment team the impartiality concerning the body to be assessed has to be ensured. It is not allowed to appoint an assessor to be a member of the assessment team who has personal interests in relation to the body to be assessed or who has participated in the development and implementation of system(s) to be assessed. Before appointment to the assessment team an assessor is obliged to notify the lead assessor of each possible conflict of interests related to assessment of the specific body. It is not allowed to appoint a person to be assessor who has had employment relationship with the body to be assessed in the two last years. In addition, it is necessary to avoid a situation when an employee of body A participates as an assessor in the assessment of body B, an employee of which in turn was an assessor in assessing A (re: cl. 4.4.2 of J10).

2.3.4.6 The members of assessment team and observers, if any, and their workplaces are communicated to the body normally two weeks in advance before the start of on-site assessment. The body has a right to reject the appointed lead assessor and/or assessor(s) for valid reasons and on such an occasion the EAK shall offer alternative options. If it is impossible to find a suitable replacement or the reasons for refusal are not justified, the EAK may use the initially selected assessors. The objections of the body concerning the members of the assessment team or observers shall be in the reproducible format. If the body does not respond to the suggestion of assessment team members, the EAK will interpret it as consent on behalf of the body.

2.3.4.7 The members of assessment team, their approval by the body to be assessed and confirmation of the members of the assessment team by the head of accreditation or the Member of EAK Management Board (if the head of accreditation is the lead assessor) is recorded on the template AD 01².

2.3.4.8 The task of lead assessor is to ensure following the assessment plan and management of the work of assessment team, including supplying assessors with guides which provide accreditation requirements and procedures, documents of previous assessment, report templates used at assessment and documents submitted by the body, as well as assigning of tasks and advising assessors in handling the issues arising in the course of assessment.

2.3.4.9 Each member of assessment team shall ensure that they use current revisions of relevant legal acts, standards, guides (including EAK guides) and report templates.

2.3.4.10 Each member of assessment team can ask for additional materials necessary for preparation for assessment, e.g. work instructions, validation reports, etc from the body, using the lead assessor as the intermediary.

2.3.4.11 The assessment team shall document the review of documents before on-site assessment in the assessor’s questionnaire or assessor report.

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2.3.5 Plan for on-site assessment

2.3.5.1 After preparatory activities the lead assessor will develop the plan for on-site assessment (time schedule), as a rule proceeding from the program for initial assessment and taking into account the risks associated with the applicant’s activities, locations and personnel (re: Annex 4). The assessment plan is drawn up for planning the on-site assessment, incl. determination of assessment activities, time schedule and participants. The plan comprises also the assignment given to the assessment team members.

2.3.5.2 The assessment plan is drawn up in the appropriate form for planned assessment, considering the information shown in Annex 5.

2.3.5.3 In the course of development of the plan for on-site assessment they calculate the assessment time required for on-site assessment. The circumstances and parameters to be considered in the calculation of the duration of assessment time are listed in Annexes 3 and 6.

2.3.5.4 The dates and plan of on-site assessment are coordinated with the body and members of assessment team before the start of on-site assessment.

2.3.6 Preparation of accreditation agreement

2.3.6.1 Before on-site assessment the lead assessor will prepare the accreditation agreement (template AC 02). The planned assessment time is determined in the calculation of the costs of services which will serve as the annex to the accreditation agreement.

2.3.6.2 The lead assessor will draw up the agreement with the calculation of the costs of services and will send it to the applicant. Before the start of assessment, the accreditation agreement will be signed by the Member of EAK Management Board and the representative of the applicant body.

2.3.6.3 The lead assessor will also manage the development and making of agreements for services of assessors (template AC 01a) and, when appropriate, signing the declarations of confidentiality by assessors.

2.4 On-site assessment

After preparations and formation of the assessment team, on-site assessment of the body is conducted. The goal of on-site assessment is to find evidence that the body is competent in the accreditation scope they are applying for and meets accreditation criteria.

2.4.1 Opening meeting

2.4.1.1 On-site assessment starts with opening meeting where members of the assessment team and representatives of the body participate. The purpose of opening meeting is for the assessment team and representatives of the body to get acquainted, to define the purpose of the assessment team, to confirm the assessment plan and to explain what is expected from the body to be assessed.

2.4.1.2 The lead assessor will chair the opening meeting and the agenda will include as a minimum the recommendations given in Annex 7.

2.4.2 Assessment – obtaining and verifying information

2.4.2.1 The opening meeting is followed by assessment of the activities of the body. In the course of assessment evidence on compliance with accreditation requirements is gathered, using the assessment techniques presented in Annex 2.

2.4.2.2 The assessors shall get an overview of the general competence of the body and the appropriateness of used processes during assessment. Assessors will evaluate professional competence of the personnel in the application of methods and use of equipment and performance of their management system.

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2 Referred documents and templates are available in the relevant register on EAK intranet
2.4.2.3 During assessment they verify whether the management system covers regular observation of the activities of all their calibrators/testers/inspectors/auditors and other relevant personnel and maintenance of records.

2.4.2.4 Next is the evaluation of conformity assessment activities conducted by the body and determination whether they meet accreditation requirements or not. Assessors will select from the scope of accreditation sought conformity assessment activities performed earlier, proceeding from the complexity of activities and their percentage in the body’s activities and will review documentation describing those activities and reports/certificates granted in the area to determine the conformity of those with the management system and accreditation requirements.

2.4.2.5 Compliance is also verified with guidance documents of IAF/ILAC/EA and EAK, referred to in EAK J1, the requirements of which are complementary to the requirements of the accreditation standard.

2.4.2.6 During on-site assessment the lead assessor will use the questionnaire template\(^2\) of the specific standard to ensure that all accreditation requirements are addressed in the course of assessment.

2.4.3 Witnessing of conformity assessment activity

2.4.3.1 As a rule during on-site assessment the conformity assessment activities of the body are also witnessed to determine if the practical (routine) work of the body is carried out according to the procedures, their personnel are competent, and work is conducted in compliance with accreditation requirements.

2.4.3.2 If witnessing is impossible during on-site assessment, witnessing will be carried out at a different time from on-site assessment, suitable time for witnessing is to be agreed. See also cl. 2.3.3.5.

2.4.3.3 Witnessing of conformity assessment activities at the client’s site of the body assumes that the body will inform their client on the intention of the EAK to take part in a specific conformity assessment before actual performance of conformity assessment, will explain the procedure of witnessing to their client and shall get consent from the client.

2.4.3.4 The body should not make changes in their audit team, audit plan or duration of the audit because of witnessing. When such changes take place, the body shall submit justifications to the EAK.

2.4.3.5 When the EAK assessment team is witnessing the conformity assessment activities, e.g. inspection or certification activities at the client’s site of the body, they proceed from the following:

2.4.3.5.1 During witnessing the assessor has the role of an observer and will not interfere when the body is conducting assessment. The assessors should ensure that clients of the inspection or certification body would not perceive their presence and witnessing activity as interference but would consider it positive.

2.4.3.5.2 Before witnessing the lead assessor shall inform the body of the objectives of witnessing and of the processes of witnessing, feedback and reporting. All interested parties shall understand that the assessor is not assessing the management system of the client of the body since that is the task of the body.

2.4.3.5.3 Direct questioning of the clients of an inspection or certification body during assessment by the assessors is not allowed. Assessors are not allowed to express any opinions to the clients of an inspection or certification body. In addition, it is necessary to make sure that the assessor will not influence the results of the audit of the body and will avoid giving any evaluation to the body or to the body’s client. This does not mean that the assessor is not

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1 *Refused documents and templates are available on EAK website*

2 *Refused documents and templates are available in the relevant register on EAK intranet*
allowed to ask explanations or additional information during planned breaks. Discussions between the assessor and body shall be conducted without the presence of the client.

2.4.3.5.4 At the request of assessors they are to be given immediate access to the documents examined by the auditing team of the inspection or certification body.

2.4.3.5.5 The assessment team will only evaluate work of the body, not that of their client, paying attention to the following to ensure that:

- the procedures and guidelines of the body are followed;
- representatives of the body behave in a correct, competent and purposeful way;
- representatives of the body have necessary technical competence, keeping in mind the specific features of client’s activities;
- each question concerning the characteristics of conformity assessment activities is thoroughly dealt with;
- representatives of the body are capable to communicate with the client in a manner that enables to obtain sufficient and correct information;
- the outcome of conformity assessment is timely and clearly presented;
- conclusions made by the representatives of the body are based on evidence gathered during assessment.

2.4.3.5.6 After the audit team has drawn conclusions and after the closing meeting, and in the absence of the client of the inspection or certification body, the lead assessor shall give the audit team feedback on the performance of the inspection or certification body (including on findings/nonconformities identified during witnessing). The feedback should include an outline of the reporting process of the accreditation body, answering/response process of the inspection or certification body and of the decision-making process of the accreditation body. When possible, the feedback should be given also to the management of the inspection or certification body.

2.4.3.6 The witnessing results of conformity assessment activities are documented on the relevant witnessing or assessment template and identified nonconformities on the template of detailed report. When recording the witnessing results the following is taken into account:

2.4.3.6.1 An assessor will complete his/her witnessing report only after having read the report, including conformity assessment results presented to the assessor.

2.4.3.6.2 A witnessing report shall present the conclusions and opinion of the assessment team as to the implementation of the process of conformity assessment, the suitability and performance of the audit team and the overall competence of the body for carrying out conformity assessment activities.

2.4.3.6.3 If the assessor was not present throughout the whole conformity assessment activity, the witness report should outline in detail which audit activities were witnessed. The report should identify e.g. auditing of which parts of the audit plan and of which requirements of the management system standard were witnessed.

2.4.3.6.4 Witness report should avoid presentation of information which was already provided in the conformity assessment activities report drawn up by the body.

2.4.3.6.5 If an assessor made observations during witnessing which were not noticed by the body in the course of the conformity assessment activity, but which should qualify as nonconformities, the assessor will inform the body of the fact after witnessing and will document his/her observations as a nonconformity(ies).

2.4.3.7 If witnessing is not conducted during on-site assessment, the findings identified during witnessing, including nonconformities, are processed following the description of clauses 2.5 and 2.6.2. In addition, the findings documented during witnessing and their processing will be addressed during the next assessment of the body.

¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet
2.4.3.8 Any information collected during an audit is confidential and shall be treated by the members of the assessment team accordingly. The witnessing report is given to the customers at their requests.

2.4.4 Occupational safety at on-site assessment and witnessing

2.4.4.1 During on-site assessments the body has the obligation to inform the EAK assessment team in advance of all the applicable safety requirements.
2.4.4.2 During witnessing the client of the body has the obligation to inform the EAK assessment team in advance of all the applicable safety requirements.
2.4.4.3 The assessors shall conform to all safety rules made known to them either by the body or the body’s client.
2.4.4.4 In case of threat the assessors shall take immediate action to avoid injuries, including leaving the area or the premises of the organisation.
2.4.4.5 If at any time during witnessing an audit the assessor observes a potential condition he/she considers to be an immediate risk of high severity (e.g. health and safety and the environment), the assessor shall immediately request a private meeting with the audit team leader to inform him/her of the potential threat, with the expectation that the audit team leader will address the threat with the client in accordance with the organisation’s process and any legal obligation.

2.4.5 Identification, documentation and classification of findings

2.4.5.1 Assessment findings that conclude conformity and specify nonconformity are identified, documented and classified.
2.4.5.2 Assessment findings are classified into three categories: findings which confirm conformity, nonconformities and observations.
2.4.5.3 Findings confirming conformity are documented in assessor reports and in detail in questionnaires, assessment, witness and detailed reports that serve as bases for assessor reports (see cl. 2.6.1).
2.4.5.4 Nonconformity means not complying with accreditation requirements or a situation in which objective evidence indicates noncompliance with requirements and which requires taking corrective action. For example, nonconformity is a situation when the accreditation requirement is not addressed in the management system of the body, practical performance of the body is different from the requirements of the management system or the performance practice does not meet the expected results.
2.4.5.5 A nonconformity is critical when it:
   - influences the conformity assessment results of the body,
   - refers to significant shortcomings in the competence, impartiality or integrated performance of the body or in the extent of implementation of the management system.
2.4.5.6 Examples of the grading of nonconformities depending on their effect on the reliability of the conformity assessment results, and their extent are given in the informative Annex 8.
2.4.5.7 All nonconformities identified in the course of assessment shall be documented with a reference to accreditation requirements (including the clause of the standard which requirements the situation does not meet) and objective evidence concerning the actual situation identified during assessment (including the fact, what was wrong and location/situation/part of system where the failure was identified).
2.4.5.8 Identified nonconformities are discussed and their degree of severity assigned at the meeting of assessment team.
2.4.5.9 Nonconformities are documented on the relevant template of detailed report² (at the discretion of lead assessor) that will make with witnessing report and assessment report the

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¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet
objective basis for completing assessor reports\(^1\) and the summary report of assessment \(^2\) and making recommendations.

2.4.5.10 The detailed report shall reflect nonconformity with the EAK requirements that is based only on objective evidence and the nonconformity shall be formulated in a way that it is unambiguously understood also after some time has passed. The lead assessor’s responsibility is to guide members of assessment team in finding, formulating and grading nonconformities.

2.4.5.11 The detailed report shall include as a minimum the following:

- formulation of the content/nature of nonconformity (based on facts, precise, objective, traceable);
- place of identification of nonconformity (e.g. a specific laboratory or client);
- conformity assessment activity evaluated;
- definition of the relevant documentation of the body;
- clause of accreditation requirements the situation does not comply with;
- names and signatures of representatives of assessor and body (representative accompanying the assessor, etc).

2.4.5.12 In addition to nonconformities it is possible to record also observations in the detailed report, i.e. circumstances identified during assessment which indicate opportunities of improvement in the body’s documents and/or practices or may cause occurrence of nonconformities.

2.4.5.13 The description and presentation of nonconformities and observations shall not include recommendations or advice to the body.

2.4.6 Preparation of the results and conclusions of on-site assessment

2.4.6.1 When the assessment team has finished the assessment, they will normally have their meeting for drawing conclusions of the assessment.

2.4.6.2 The assessment team will review the objective evidence collected during assessment and other relevant information obtained during assessment and will compare it to the assessment scope and criteria and will formulate the assessment findings.

2.4.6.3 In case of identified nonconformities they evaluate their degree of severity and reach their common conclusion on the conformity of the body with accreditation requirements.

2.4.6.4 When the on-site assessment lasts several days, the assessors will hold a short meeting at the end of each day where they discuss details that have arisen and the need for making changes in the plan for on-site assessment. If needed, the plan will be amended, and the body informed of that.

2.4.6.5 Each member of the assessment team will fill out the standard assessor report (see cl. 2.6.1).

2.4.6.6 Before closing meeting the lead assessor will complete the summary report (template ASR 01\(^2\)), which will briefly present the work results of the assessment team. The report will provide:

- short comments of the assessment team on the competence of the body,
- confirmation of the continuing suitability of the accreditation scope or agreements and recommendations regarding changes to the accreditation scope,
- statement on the adequacy of the organization and procedures adopted by the body to give confidence in its competence, and
- conclusions of the assessment team regarding conformity with the accreditation requirements and the recommendation to the EAK on the accreditation of the body.

In addition, the summary report will present, if required:

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\(^1\) Referred documents and templates are available on EAK website

\(^2\) Referred documents and templates are available in the relevant register on EAK intranet
• a recommendation on the isuse of a new annex to the accreditation certificate if, in the course of assessment, a need appeared for specification of the accreditation scope, or changes had occurred in the name, location, persons, etc. of the body,
• agreements and expectations regarding any witnessing outside assessment,
• special aspects or deviations from the assessment plans,
• schemes/methods, for which the body shall immediately stop working until the nonconformities are removed (e.g. “work performed regarding nonconformity X shall be stopped until the nonconformity is removed, and it is closed by the EAK”).

2.4.6.7 When the assessment team prepare their recommendation, they take into account the content, extent and degree of severity of identified nonconformities, considering the following:

2.4.6.7.1 If nonconformities were not identified, the assessment team, as a rule, will recommend the EAK to grant accreditation to the body in the assessed scope.

2.4.6.7.2 If nonconformities were identified, the assessment team will recommend on granting accreditation after the EAK has received (in a format which can be reproduced) objective evidence on resolving of nonconformities and has approved the evidence.

2.4.6.7.3 If a critical nonconformity is present in only one area of conformity assessment activities and the general system is functioning satisfactorily, the assessment team may recommend accreditation, leaving the area of nonconformity out of the scope of accreditation.

2.4.6.7.4 If the number and nature of identified nonconformities prove that the whole management system of the body and their organization does not function appropriately, the assessment team may recommend refusing granting accreditation.

2.4.6.8 If the members of the assessment team do not reach a common understanding in case of compliance of some identified finding or meeting of accreditation requirements, the lead assessor would normally refer to the relevant head of accreditation or another competent and experienced lead assessor of the same area to apply for his/her position in the disputed question, having, if necessary, an additional discussion in the assessment team, taking the position into account.

2.4.7 Closing meeting

2.4.7.1 On-site assessment is finished with closing meeting, in which the members of assessment team and representative(s) of the body participate and the purpose of which is to allow the members of assessment team to give an overview of assessment results to the representatives of the body and introduce the recommendations the assessment team plans to give to the EAK for making a decision. The detail report(s) and the summary report are signed at the closing meeting by the members of assessment team and representatives of the body.

2.4.7.2 The lead assessor will chair the closing meeting and the agenda will include as a minimum the recommendations given in Annex 9.

2.5 Follow-up activities of the assessed body after on-site assessment

2.5.1 In case of identification of critical nonconformities during conformity assessment activities the body shall immediately suspend activities in the nonconforming work (area), shall immediately take necessary action for correction of nonconformity, shall perform the analysis of root causes of nonconformity/nonconformities and shall take relevant corrective action to eliminate the cause(s) of nonconformity and prevent their recurrence.

2.5.2 After closing meeting, normally in five working days, the body will submit to the lead assessor the following information concerning all identified nonconformities:
• correction – description of actions taken for resolving of nonconformities;

1 Referred documents and templates are available on EAK website
2 Referred documents and templates are available in the relevant register on EAK intranet

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- analysis of the causes and extent of nonconformities – investigating for what reason the nonconformity had occurred and to what extent it is present, e.g. is it a single instance or a systematic failure;
- plan of corrective action – description of planned measures for eliminating of causes of nonconformity and prevention of recurrence (what action is planned).  

2.5.3 The body shall submit the following information concerning all identified nonconformities to the lead assessor within the agreed time limit (at surveillance/reassessment up to one month and at initial assessment up to three months):
- description of taken corrective action (what was done for eliminating the causes and prevention of recurrence of nonconformities);
- objective evidence records on correction of nonconformity and taking of corrective action (records which show that action has been taken with references to the names of files, pages, chapters, etc).

2.6 EAK activities after on-site assessment

2.6.1 Drawing up of an assessor report

2.6.1.1 Each member of the assessment team will fill out the written assessor report (template AR 01²) either on-site or within five days after on-site assessment and will submit it to the lead assessor for approval.

2.6.1.2 The assessor report shall be an accurate, concise and comprehensive evidence document for making the accreditation decision and shall include or refer to the following:
- names of the assessor and persons accompanying him/her (e.g. names of the interpreter or observer);
- date of assessment and locations where assessment activities were carried out (on-site or elsewhere, at a permanent or temporary location);
- name of the body and of the representative of the body;
- assessment type (e.g. initial, surveillance or reassessment or special assessment);
- accreditation criteria;
- assessment scope, i.e. the part of accreditation scope assessed by a concrete assessor;
- number of detected nonconformities;
- areas that were assessed and collected objective evidence and assessment findings confirming conformity in these areas;
- if required and appropriate, deviations from the assessment plan and the reasons of deviations;
- all unsolved problems, if they were identified;
- assessor’s conclusion and recommendation;
- witness and assessment reports and detailed reports and/or questionnaires prepared by the assessor.

2.6.1.3 The information presented in the column “Assessor’s comments” in the assessor report:
- what was assessed – to define in detail the areas/chapters of the criteria, including e.g. personnel, resources/equipment, procedures of the body, methodologies, performed conformity assessments, reference to accreditation, management system, etc;
- collected objective evidence in the assessed areas/chapters – i.e records, stating of facts or other information concerning assessment criteria that can be verified. If objective evidence is recorded in questionnaires or in the report of method assessment, it is not duplicated in the assessor report;

¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet
• findings which confirm the conformity identified in the assessed areas/chapters – i.e. results of the comparison of collected objective evidence and criteria which confirm conformity; and
• references to nonconformities.

2.6.1.4 The information presented in the column “Assessor’s conclusion”:
• conclusions based on findings or final outcome of assessment after taking into account assessment objectives, criteria and all findings, including evaluation of the conformity with accreditation requirements and
• recommendation on granting/not granting/continuing of accreditation.

2.6.2 Review of corrective actions

2.6.2.1 Depending on the nature of nonconformity and the correction and corrective action taken it is possible to be convinced of their performance after examining the relevant documents presented to the EAK and/or having additional on-site assessment by a member of assessment team.

2.6.2.2 Having received correction, analysis of the cause and extent, plan of corrective action and objective evidence documents from the body, the lead assessor may introduce them, if required, to assessors to get their evaluation on the appropriateness of planned and implemented measures.

2.6.2.3 Notations about correction, cause analysis, plan of corrective action and appropriateness of corrective action measures are provided in the detailed report. The lead assessor will record the decision on the closing of each nonconformity in the detailed report and on the closing of all nonconformities in the summary report. If necessary, the assessors will perform an additional assessment in the body to verify that the nonconformities were resolved.

2.6.2.4 If the body does not submit correction, cause analysis, plan of corrective action and objective evidence documents on resolving of nonconformities by agreed due date or submits inappropriate or insufficient materials, the lead assessor will send a relevant reminder to the body within a week and will set an additional time limit (as a rule one week). If the body still does not submit necessary and appropriate materials after that, the lead assessor can make a proposal to the Member of EAK Management Body to finish the accreditation process or to continue it in the limited scope of assessment.

2.6.3 Drawing up of final report

2.6.3.1 The lead assessor will draw up a final report based on the information gathered during assessment. The final report will reflect conformity of the body with the relevant accreditation criterion. The final report shall include as a minimum the following:
• assessment dates;
• members of assessment team;
• names and addresses of all assessed locations;
• short overview of other activities of the body;
• assessed scope of accreditation or reference to it;
• reference to records proving conformity with accreditation criteria;
• confirmation of closing nonconformities;
• other information on the applicant’s professional competence;
• conclusion on the conformity with accreditation requirements;
• proposal for making the accreditation decision;

1 Referred documents and templates are available on EAK website
2 Referred documents and templates are available in the relevant register on EAK intranet

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• explanations about any differences of the information presented to the body at the closing meeting.

2.6.3.2 The report shall not contain any additional nonconformities that were not discussed at the closing meeting of the on-site assessment or those introduced to the representatives of the body during witnessing of practical activities beyond on-site assessment which were not recorded in nonconformity reports. The report may be sent to the assessed body at their request.

3. MAKING ACCREDITATION DECISION

The EAK decision-making has two stages, consisting of technical review and decision.

3.1 Technical review

3.1.1 The lead assessor shall submit all assessment materials, i.e. a thorough assessment report² (re: cl. 2.6.3) with summary report, assessor reports² and detailed reports² and the drafts of accreditation decision and its annex to the technical reviewer for assessment within ten working days starting from closing of nonconformities (re: cl. 2.2.6).

3.1.2 Technical review is conducted in 7 working days starting from the receipt of materials from the lead assessor. The technical reviewer will conduct assessment review aimed at verifying that the assessment was performed according to valid procedures and it covered all relevant accreditation requirements. Among other things the review will determine whether:

- the initial assessment programme (in case of extension and reassessment, the assessment programme of the accreditation cycle) prepared according to cl. 2.3.1 was updated and implemented;
- the competence of assessment team covered the whole scope of assessment (based on assessors` register and CVs);
- the assessment was performed according to valid procedures (this guide, etc);
- the assessment covered all appropriate accreditation requirements (applicable legal acts, the EAK accreditation criteria, accreditation standard and its implementation guides);
- all identified nonconformities were processed as required and are closed;
- the recommendation of assessment team is based on the assessment results;
- the description of the scope of accreditation coincides with the assessed scope;
- all the time spent for assessment is registered in the Toggl time-registering program.

3.1.3 The review results are recorded on the report template ARR1². The report will be introduced to the lead assessor who conducted assessment and who, if necessary, will make necessary adjustments or additions to assessment materials, and if required, will contact the body for getting additional documents. When all the remarks made by the reviewer have been taken into account, the lead assessor will submit the assessment materials to the Member of EAK Management Board for making the decision.

3.2 Accreditation decision

3.2.1 Following the lead assessor’s suggestion and approval of assessment by the technical reviewer the Member of EAK Management Board will make the decision on granting or not granting accreditation to the body (CAB) in the defined scope of conformity assessment activities.

3.2.2 The decision is made within a month starting from the moment when all the necessary documents and information were submitted to the EAK and nonconformities were closed by the EAK.

3.2.3 The assessment summary is recorded on the accreditation registration template.

¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet

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3.2.4 The accreditation decision is forwarded to the assessed CAB by one of the following ways:

- If the decision on granting accreditation is positive, without any restrictions limiting the CAB’s activities, the accreditation certificate with annex will be sent to the CAB (re: cl. 3.3.4);
- If the decision on granting accreditation is positive, but includes restrictions limiting the CAB’s activities, apart from the certificate with annex also the decision will be sent to the CAB;
- If the decision on granting accreditation is negative, the relevant decision will be sent to the CAB.

3.3 Accreditation certificate

3.3.1 When drawing up the accreditation certificate the provisions of cl. 7.8.1 of ISO/IEC 17011 are followed. The certificate is made up according to the relevant template². Each certificate bears an unique number consisting of the symbol of the type of a conformity assessment body and succession number of an accreditation granted. Symbols of the different types of conformity assessment bodies are as follows:

- K – calibration laboratory;
- L - testing laboratory;
- M – medical laboratory;
- I – inspection body;
- PEC – persons’ certification body;
- PC – products/processes/services certification body;
- MSC- management systems certification body;
- V – verification body.

3.3.2 The provisions of cl. 7.8.3 of ISO/IEC 17011 are used when the annex to the certificate is drawn up, considering the additional requirements coming from relevant legal acts. In the annex to the accreditation certificate² the scope of voluntary and mandatory (regulated by legal acts) certification is presented separately, in the latter case with references to appropriate legal acts and standards. In case of inspection bodies, the type of independence of the body and in case of verification bodies of measuring instruments the list of qualified verifiers by types of measuring instruments are also recorded in the annex.

3.3.3 The accreditation certificate and its annex(es) are prepared on paper. The certificate is signed by the Member of Management Board and its annexes are signed both by the Member of Management Board and lead assessor (on the last page). The certificate is marked with the EAK embossing seal impression and all pages of the annex(es) of certificate by colour seal (re: EAK JSP ²).

3.3.4 The assistant will send the signed certificate and its annex(es) to the accredited body (as a rule) by post and she will enter the data of body (including a short description of the scope of accreditation) and the detailed scope of accreditation described in the annex to the certificate (as a digital file) into the list of accredited bodies on the EAK website.

4. PREPARATION OF THE ASSESSMENT PROGRAM OF THE ACCREDITATION CYCLE

4.1 After initial assessment the lead assessor will prepare the assessment program for the body for the whole accreditation cycle. The goal of the assessment program is to ensure that a representative sample of all conformity assessment activities in the scope, of different locations

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¹ Referred documents and templates are available on EAK website
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and personnel were assessed and witnessed during the whole accreditation cycle. The program
is based on the initial assessment program, taking into account the risks arising from the sources
listed in Annex 4 and additions resulting from the successive assessments or defining necessary
changes for the future assessments (scope, time or dates, surveillance frequency, competence
of assessment team).
4.2 The assessment program includes the assessment of all sites of the body during the cycle
where at least one of the key activities listed in Annex 3 is carried out. When the organisation
is operating internationally and has sites of key activities in different countries, in addition the
requirements of EA-2/13 ja IAF MD 12 are to be followed (see chapter 12).
4.3 The program covers the assessment team composition, conformity assessment activities of
different fields and groups to be assessed and witnessed by locations and (if required) by
performers of conformity assessment activities and the time of on-site assessments, including
that of witnessing. Thereby also the risks arising from the CAB’s activities, locations and
personnel considered (re: Annex 4) will be fixed.

5. FILE OF THE BODY

5.1 When the initial assessment is finished and the accreditation decision is made and the
assessment program of the accreditation cycle prepared, the lead assessor will collect all
records gathered and developed into the file of the body (re: cl. 2.2.7). The digital documents
shall be referred to in the paper folder. Agreements and invoices are collected into a special
folder of invoices.
5.2 The files of an accredited body include (on paper or in a computer file) as a minimum the
following documents drawn up during initial assessment:
- standard format application of the body with annexes (except quality manual);
- accreditation registration form²;
- assessment team appointment form²;
- report of document review²;
- preliminary visit report (if necessary);
- initial assessment program (re: cl. 2.3.1);
- on-site assessment plan (re: cl. 2.3.5);
- reports of witnessing and assessment of conformity assessment activities²;
- detailed reports²;
- assessor(s) reports² (re: cl. 2.6.1);
- (lead) assessor’s questionnaire²;
- summary assessment report² (re: cl. 2.4.6.6);
- thorough assessment report (re: cl. 2.6.3);
- records proving correction of identified nonconformities;
- records giving evidence of corrective action taken;
- report of technical review of assessment²;
- accreditation decision;
- accreditation certificate and its annex(es);
- assessment program of the accreditation cycle;
- relevant excerpt from the Toggle time-registering program.

¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet
6. SURVEILLANCE ASSESSMENT

6.1 Surveillance management

6.1.1 The objective of periodical surveillance is to determine whether the body continuously meets the accreditation requirements. Accreditation surveillance means regular assessment visits to the accredited body.

6.1.2 Surveillance of an accredited body includes:

a) regular assessment in the body and at least once in the accreditation cycle in each location of the body covered by accreditation;

b) assessment and witnessing of conformity assessment activities; the frequency of the assessment or witnessing of a specific conformity assessment activity depends on the situation but the objective is to cover all accredited areas of activities during the accreditation cycle;

c) other surveillance activities (e.g. gathering information from various sources on the activities of the body covered by accreditation).

6.1.3 If a body within 12 months did not perform conformity assessment according to a scheme or method belonging to its accreditation scope, it shall demonstrate to EAK its continuous competence by performing a dummy assessment, participation in interlaboratory comparisons, training or other relevant means. In addition, the body shall enable to perform witnessing referred to in cl. 6.1.2 b according to the programme of accreditation cycle.

6.1.4 The principles described in chapter 2 and 3 shall be followed during surveillance.

6.2 Surveillance frequency

6.2.1 Surveillance normally takes place once a year.

6.2.2 The first on-site surveillance assessment is conducted 12 months after the on-site initial assessment at the latest. The periods between the following surveillance assessments shall not exceed 14 months of the previous on-site assessment until the surveillance frequency of $n \times (12 \pm 2)$ months is reached from the accreditation or reassessment decision date, whereas $n$ is the number of succession of an on-site assessment within the accreditation cycle. If necessary, e.g. occurrence of a critical nonconformity in the body, the time interval between on-site assessments will be reduced.

6.2.3 Starting from the second accreditation cycle (i.e. after reassessment) the accredited body may apply for increasing the surveillance interval to 18 months as a maximum, provided the body meets the following criteria:

- the body has been accredited at least for one accreditation cycle, i.e. five years as a minimum, and has successfully passed reassessment;
- identified nonconformities were always closed and the evidence records submitted to the EAK by the agreed due date;
- during two last assessments no critical nonconformities with accreditation requirements were found;
- the body performs management system audits and reviews on the established dates and according to established procedures;
- the body has participated in interlaboratory comparisons according to the EAK accreditation criteria;
- there have not been any significant changes concerning the owners and structure, number of personnel nor key persons, work intensity, equipment and measuring instruments and in the scope of accreditation and there are no plans to change the scope of accreditation;
- in the last two years the body has paid all invoices for provided assessment services presented by the EAK in a timely manner.

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1. Referred documents and templates are available on EAK website
2. Referred documents and templates are available in the relevant register on EAK intranet
If the nonconformities will be identified, the assessment team will be entitled to refuse the recommendation on increasing the surveillance interval.  
6.2.4 In order to extend the time interval between surveillances the body will submit a relevant application to the EAK in free format not later than 3 months before the month of accreditation decision and the planned surveillance assessment. The head of accreditation will make the decision on the extension of the time interval in compliance with the relevant conclusions of the lead assessor on the conformity of the body with the criteria provided in cl. 6.2.3. If the head of accreditation was the lead assessor during the assessment of the body in question, the decision will be made by the Member of EAK Management Board. The conclusion and decision are documented on the assessor report template. The lead assessor will inform the body of the decision made. The decision will be valid for one accreditation cycle as a maximum, i.e. until the next reassessment, provided the criteria set down in cl. 6.2.3 are continuously met.  
6.2.5 In case of certain exceptional circumstances (e.g. moving of the body) it is possible to apply for one-time extension of the surveillance interval up to 18 months at the request of the body. The next surveillance will still take place at the earlier planned time.  
6.3 Extension or transition to new version of standard in the course of surveillance  
6.3.1 The body may apply for the assessment of the extension to the scope of accreditation during surveillance. If the body applies for extension to the scope of accreditation before periodical surveillance assessment, the assessment of the new scope can be aligned with surveillance assessment. However, the assessment of new scope shall be conducted like initial assessment, in accordance with the provisions of chapter 2. If the new scope applied for refers to a different area of former scope, it will be necessary to involve an assessor of the corresponding area.  
6.3.2 The body may apply for the assessment of transition to the new version of a standard during surveillance. In such case the assessment, incl. decision process, will be carried out in accordance with the provisions of the relevant transitional guide of EAK, if any, and the chapters 2-3.  
6.4 Preparation for assessment  
6.4.1 Document review  
6.4.1.1 Before surveillance assessment the body will submit to the lead assessor the new updated quality manual (in case of significant changes), changes that took place during the last year (including changes concerning measurement range and uncertainty of measurement of the method) and the minutes of the last management review, in addition, in case of a laboratory, information on participation in interlaboratory comparison and in case of a certification body, the list of issued certificates, and in case of the certification body of management systems the data required by IAF MD 15, in case of an inspection body data on the number of inspections performed by areas, and other documents considered necessary by the lead assessor or other members of assessment team.  
6.4.1.2 Review of documents is recorded in the assessor questionnaire.  
6.4.2 Assessment program  
6.4.2.1 Before each on-site surveillance assessment the lead assessor will amend the assessment program prepared for the accreditation cycle according to cl. 4, considering changed circumstances (e.g. extension to the scope of accreditation or information on changes submitted by the body) and risks arising from the sources listed in Annex 4. Both the changed circumstances and risks considered will be fixed in the program.

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1 Referred documents and templates are available on EAK website  
2 Referred documents and templates are available in the relevant register on EAK intranet
6.4.2.2 Data on all earlier assessment activities that were carried out during the accreditation cycle will be registered in the assessment program.

6.4.3 Assessment team
6.4.3.1 On-site surveillance assessment is normally conducted by the assessment team appointed for initial assessment. If necessary, the lead assessor may include other competent assessors of the area from the EAK assessors register into the assessment team. The changes in the composition of the assessment team will be coordinated with the body to be assessed and are registered on the template AD 01².

6.4.3.2 The lead assessor will send the materials submitted by the body to the members of assessment team for examining. Each member of the assessment team may ask for additional necessary materials for preparation for the on-site assessment, such as work instructions, validation reports, etc, using the lead assessor as an intermediary.

6.4.4 Plan for on-site assessment
6.4.4.1 When drawing up a plan for on-site assessment the experience gathered during previous assessments and the risks arising from the sources listed in Annex 4 will be taken into account. The risks considered will be fixed in the program. The parameters to be considered for calculation of the duration of on-site surveillance assessment are indicated in Annex 6.

6.4.4.2 The time and plan of on-site surveillance assessment will be prior to the assessment harmonized with the body.

6.4.5 Preparation of surveillance agreement
Before on-site assessment the lead assessor will prepare the surveillance agreement (template AC 04²) with the calculation of the cost of services and will send it to the body. The agreement is signed by the Member of EAK Management Board and representative of the body. The lead assessor will manage the concluding of agreements for services with assessors (template AC 01a²).

6.5 On-site assessment
Management of on-site surveillance assessment and following of the assessment plan are the responsibilities of the lead assessor. On-site assessment is conducted similarly to initial assessment as described in chapter 2, considering the specifications of this section.

6.5.1 Opening meeting
On-site assessment starts with opening meeting which is chaired by the lead assessor and in the course of which the issues indicated in Annex 7 are addressed.

6.5.2 Assessment – obtaining and verifying information
6.5.2.1 During surveillance assessment the assessors will assess the compliance of the competence of the body with accreditation requirements, assess and/or witness conformity assessment activities at the location of the body and witness conformity assessment activities (re: cl. 2.4.3) in a certain part of conformity assessment area in the scope of accreditation, considering that the activities of the body in each area of conformity assessment in the scope of accreditation and the representative sample of calibrators/testers/inspectors/auditors is covered by witnessing by an assessor during the 5-year accreditation cycle.

6.5.2.2 During on-site surveillance assessment special attention is paid to the following:
- changes in the management system documents of the body;
- results of internal audits and management system reviews;
- changes of their personnel (especially concerning responsible persons), management structure, etc;

¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet
- coverage and effectiveness of the in-house monitoring of calibrators/testers/inspectors/auditors;
- compliance of testing/measuring equipment;
- use of subcontracting;
- meeting the impartiality requirement;
- handling of complaints and appeals;
- review and verifying of records related to conformity assessment activities performed in the scope of accreditation *(including issued reports, certificates)*;
- following of the body’s procedures;
- following the interlaboratory comparisons plan and results;
- assessment of the efficiency of implemented corrective action to resolve the nonconformities identified at earlier assessments;
- use of the EAK accreditation symbol and reference to the body’s accreditation;
- in case of extended surveillance interval *(re: cl. 6.2.4)* the continuous compliance of the body with the requirements stated in cl. 6.2.3.

6.5.2.3 Proceeding from the surveillance assessment plan each assessor will verify compliant implementation of some procedure and activity in the body in a great detail. The results of conformity assessment activities are documented on the appropriate template and identified nonconformities and observations on the detailed report template.

6.5.2.4 To ensure that all relevant accreditation requirements are addressed during an accreditation cycle the lead assessor will use an appropriate questionnaire for the relevant accreditation standard. Thereby, during surveillance and reassessment the questionnaire may be filled in only partly, providing that during the accreditation cycle all clauses of the relevant standard will be embraced.

6.5.3 Witnessing of conformity assessment activities

6.5.3.1 Witnessing of conformity assessment activities is carried out according to the assessment programme of the accreditation cycle.

6.5.3.2 When the body refuses to make witnessing possible *(including the refusal of the client of the body to allow witnessing)* and the EAK does not consider the refusal to be justified, the guidelines provided in chapter 9 will be applied to suspend the validity of accreditation.

6.6 Identification, documentation and classification of findings

6.6.1 Identification, documentation and classification of assessment findings are done according to the provisions of cl. 2.4.5.

6.6.2 In case of occurrence of recurrent nonconformities they are graded as critical nonconformities.

6.7 Preparation of the results and conclusions of on-site assessments

6.7.1 Preparation of assessment results and conclusions is carried out in accordance with provisions of cl. 2.4.5, considering the specifications below.

6.7.2 To present the conclusions and recommendations concerning maintaining of accreditation each assessor will give his/her evaluation. If on-site surveillance included the assessment of the extension to the scope of accreditation *(re: cl. 6.3)*, the results of that assessment are also reflected in the reports. Based on his/her assessment results and those of other assessors participating in assessment the lead assessor will draw up the summary assessment report on template ASR 01.

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1 *Referral documents and templates are available on EAK website*

2 *Referral documents and templates are available in the relevant register on EAK intranet*
6.7.3 In the summary report of surveillance assessment the lead assessor will make a **suggestion** on the maintaining of accreditation of the body. Depending on the identified nonconformities the lead assessor will suggest that the accreditation should:

a) continue unchanged without reservations (**in case no nonconformities were identified**);
b) continue, on condition that there is assurance that the identified nonconformities have been resolved and corrective action taken;
c) continue with reduced/extended scope of accreditation (**after resolving of identified nonconformities**);
d) be suspended up to six months (**including partial suspending scope**), during which period the body shall resolve critical nonconformities and submit objective evidence on the implementation of planned corrective actions. When the validity of accreditation has been suspended, it is necessary, as a rule, to have a follow-up visit to identify if the nonconformities were resolved and to determine restoring of accreditation (**re: chapter 8**). After six months of the suspending decision at the latest the decision will be made on the restoring of accreditation, continuing of suspending or withdrawing accreditation (**re: cl. 10.3**);
e) be withdrawn, which means among other things that if the body wants to restore accreditation, they shall undergo the whole accreditation process again (**i.e. initial assessment**).

6.7.4 In case of simultaneous surveillance assessment and assessment of extension to the scope of accreditation (**re: cl. 6.3**) the recommendations for both are given separately for each assessment.

6.8 Closing meeting

On-site surveillance assessment is finished with closing meeting which is conducted according to provisions of cl. 2.4.7 and in the course of which the issues listed in Annex 9 are addressed.

6.9 Follow-up activities of the assessed body after on-site assessment

Follow-up activities of the assessed body after surveillance assessment are described in cl. 2.5.

6.10 EAK activities after on-site assessment

6.10.1 Drawing up of assessor report

6.10.1.1 Drawing up of assessor reports is done in accordance with provisions of cl. 2.6.1 and cl. 6.5.2.2, providing additional information on the following:

- significant changes which took place after the last assessment;
- reference to the EAK accreditation;
- proof of effectiveness of corrective action taken concerning previously identified nonconformities, if applicable.

6.10.1.2 The procedures assessed and witnessed in detail are recorded in the assessor report and witnessing/assessment results on the appropriate witnessing/assessment report template.

6.10.2 Review of corrective actions

In review of corrective actions, the provisions of cl. 2.6.2 are followed.

6.10.3 Decision on continuing of accreditation

6.10.3.1 Considering the suggestion of the lead assessor the Member of EAK Management Board will approve maintaining of the body’s accreditation, which is documented in free format in the summary assessment (**template ASR 01**). If extension to the scope of accreditation was assessed during surveillance, the Member of EAK Management Board will make a

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¹ **Refereed documents and templates are available on EAK website**
² **Refereed documents and templates are available in the relevant register on EAK intranet**
decision in accordance with provisions of chapters 3 and 9. The decision will be made within 40 days starting from the final date of on-site assessment, provided all necessary documents and information for decision-making have been submitted to the EAK in a timely manner.

6.10.3.2 The body will be informed of closing nonconformities and finishing of assessment in writing (as a rule by e-mail) and if necessary, a new accreditation certificate and/or its annex will be issued which will reflect changes in the scope of accreditation of the body or data of the body.

6.10.4 Updating of assessment program

The lead assessor will update the assessment program of the accreditation cycle and register the assessment activities performed, following the provisions of chapter 4 and cl. 6.4.2. Thereby also the risks associated with the activities, locations and personnel (re: Annex 4) considered in the course of updating of the program will be fixed.

6.11 Additions to the file of the body

6.11.1 When the surveillance assessment is completed and the decision on the continuing of accreditation is made, the lead assessor will collect all assessment materials gathered and developed during assessment into the folder developed during initial assessment (paper folder and server). Agreements and invoices are gathered into a special folder of invoices.

6.11.2 The lead assessor will add to the folder of the materials of initial assessment (re: cl. 5.2) at least the following documents:

- plan of on-site assessment;
- copies of the reports of the body’s management system reviews;
- data on the participation of the laboratory in interlaboratory comparison with cause analysis of deviations and descriptions of improvement measures;
- data on the number of certificates issued by the certification or inspection bodies in different fields of activity;
- copies of correspondence bearing on accreditation between the EAK and the body (e.g. on communication of the accreditation decision or changes of the name or owner of the body, etc);
- assessment program of the accreditation cycle;
- surveillance assessment reports²;
- technical review report of the assessment of extension² application (if appropriate);
- data on the activity or behaviour of the body in solving the complaints and appeals made.

7. REASSESSMENT

7.1 To ensure continuity of accreditation a body shall submit the application for reassessment as a rule three months before the end of the validity of the accreditation certificate to make sure that the body would have enough time after reassessment to take possible corrective action.

7.2 Reassessment is conducted based on the body’s standard format application and it contains assessment of the management system and conformity assessment activities of the body, similarly to initial assessment. When making the plan of reassessment, including plan for witnessing, the results of previous assessments and risks arising from the sources listed in Annex 4 are taken into account. If possible, the members of assessment team are rotated.

7.3 During reassessment the principles that were described in chapters 2 – 5 are followed, just reading “reassessment” instead of “initial assessment”.

7.4 No initial assessment programme according to cl. 2.3.1 will be prepared for reassessment.

7.5 When plans are made and implemented for witnessing conformity assessment activities, the guidelines provided in cl. 2.3.3 will be followed and it has to be ensured that all areas

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¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet

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defined in the assessment plan of the accreditation cycle will be covered during reassessment (including those not covered by surveillance).

7.6 When drawing up a plan for on-site assessment the provisions of cl. 6.4.4 are followed, taking into account the experience of the assessments performed during an accreditation cycle and risks associated with the activities, locations and personnel of the body (re: Annex 4). The risks considered are fixed in the program.

7.7 In addition to the provisions of cl. 3.1.2, following of the assessment programme of the whole accreditation cycle is verified during the technical review, including that required witnessing of conformity assessment activities was planned and implemented.

7.8 The new accreditation decision is not made before the EAK has received convincing evidence that the body has resolved all nonconformities identified during reassessment. The start time of the validity of the certificate will be stated on the EAK website.

8. EXTRAORDINARY ASSESSMENT

8.1 The need for extraordinary (out of the program) assessment may arise on the following occasions:

- to verify that the nonconformities identified during assessment were resolved (re: cl. 2.6.2.1);
- to restore the validity of suspended accreditation (re: cl. 6.7.3 d and 10.2.3);
- to assess continuing compliance of the accredited body after significant changes in the body (re: chapter 11);
- to verify the circumstances after the EAK had received a complaint on the body’s activities;
- to assess transition to a new version of the standard applied for by the body (re: cl. 6.3.2).

8.2 Special assessment is conducted at the time agreed with the body similarly to the on-site surveillance assessment (re: cl. 6.5).

9. ASSESSMENT OF THE EXTENSION TO THE SCOPE OF ACCREDITATION

9.1 An accredited body may apply for the extension to its scope of accreditation by submitting an application on the appropriate EAK template or by a letter from the body. The application will include a detailed description of the scope of accreditation to be extended and in addition management system documents addressing the scope they are applying for and other documents considered important by the lead assessor or other members of the assessment team.

9.2 Assessment of the extension to the scope of accreditation is conducted similar to initial assessment as described in chapter 2 and it may be combined with the surveillance assessment (re: cl. 6.3) or be conducted separately.

9.3 The extension to the scope of accreditation may involve additional assessment in the body’s permanent location and witnessing/assessment of the body performing conformity assessment. During assessment of the extension the risks associated with the activities and locations (re: Annex 4) embraced with the extension are taken into account.

9.4 If it is extension to scope in the range of the measurement method or measuring principle or e.g. within a product group, category or cluster already covered by accreditation, the lead assessor may conduct extension assessment based on the review of documents, involving, if necessary, speciality assessors. For that purposes the body shall submit at least the following documents to the EAK: documents giving evidence of the competence of personnel and performing of (demonstration) task(s), relevant work instructions/procedures, validation and verification reports (if necessary), traceability schemes of measuring and calibration results and quality control data. Assessment is documented in accordance with provision of chapters 2-5.

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1 Referred documents and templates are available on EAK website
2 Referred documents and templates are available in the relevant register on EAK intranet

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9.5 The assessment of the extension to the scope is conducted and the results are documented in line with the provisions of chapters 2 and 3, considering the following differences: report on document review is not to be compiled, the assessment may be carried out by a technical assessor alone, the final report is not to be drawn up, the results of technical review are recorded on the template ARR2² and the assessment program for accreditation cycle will be updated, if relevant.

9.6 The EAK cannot make the decision on the extension to the scope of accreditation, including conforming of the meeting of accreditation requirements, before the body has resolved all nonconformities in the scope of accreditation, including those which were identified during regular surveillance, special assessment or reassessment.

10. SUSPENDING, WITHDRAWING AND REDUCING ACCREDITATION

10.1 General procedure

10.1.1 Pursuant to the requirements of Regulation (EC) No 765/2008 (Art. 5 cl. 4) and standard ISO/IEC 17011 (cl. 7.11) the EAK shall suspend the validity of accreditation or withdraw accreditation if the body cannot consistently meet the accreditation requirements or does not follow the accreditation criteria.

10.1.2 Pursuant to the requirements of Regulation (EC) No 765/2008 (Art. 5 cl. 4) and standard ISO/IEC 17011 (cl. 7.11) the EAK shall reduce the scope of accreditation and remove from the scope of accreditation those conformity assessment activities in case of which the body could not consistently meet the accreditation requirements, including requirements for competence.

10.1.3 When the EAK has received evidence during periodical surveillance or some other way, e.g. in the course of processing a complaint against the activities of the body, that the accredited body does not meet the accreditation requirements any more, the EAK can suspend the validity of granted accreditation (re: cl. 10.2), withdraw accreditation (re: cl. 10.3) or reduce the scope of accreditation (re: cl. 10.4).

10.1.4 If the suspending, withdrawing or reducing takes place on the EAK initiative and/or happens because of the results of accreditation assessment, the decision-making process will follow the provisions of chapter 3.

10.1.5 The decision shall provide (or refer to) all relevant justifications and considerations.

10.1.6 Concerning the decision draft the body will be offered an opportunity to be heard, except when it is necessary to take immediate action to prevent damage resulting from delay or it is necessary to protect public interests or when the body itself has applied for suspending, withdrawing or reducing accreditation or when the body has been given an opportunity to be heard regarding the decision on suspension, preceding the decision on withdrawal, and in the decision on suspension the specific circumstances bringing about the withdrawal have been listed.

10.1.7 When accreditation is suspended or withdrawn, the decision on suspending or withdrawal will declare the last granted accreditation certificate invalid.

10.1.8 The Member of Management Board or the head of accreditation will inform the body in writing of the EAK decision to suspend, withdraw or reduce accreditation. The copy of the decision with the explanation of limitations brought about by the change in the accreditation status and, if appropriate, on the conditions of restoring accreditation will be sent to the body. The change in the accreditation status of the body will be recorded in the list of accredited bodies published on the EAK website.

10.1.9 The body shall immediately stop using the EAK accreditation symbol and reference to accreditation from the moment of enforcement of the decision.

10.1.10 The body has a right to challenge the decision within a month of its receipt.

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¹ Referred documents and templates are available on EAK website

² Referred documents and templates are available in the relevant register on EAK intranet

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10.2 Suspending accreditation

10.2.1 The accreditation of a body is suspended for up to six months on the following occasions:

- if the body applies for suspending;
- when scheduled surveillance assessment or special assessment are not made possible;
- if the body refuses to enable EAK to perform a witnessing of the conformity assessment activity;
- at identification of critical nonconformity;
- the body has not resolved nonconformities in a timely manner;
- the accreditation invoice was not paid in a timely manner;
- breach of the conditions of accreditation agreement, including when the body does not fulfil the facilitation obligation or does not cooperate with then EAK, does not satisfy the requirement of the EAK for submitting documents, does not inform the EAK of significant changes taken place in the body concerning accreditation;
- systematic misuse of accreditation symbol;
- based on the processing results of complaints received on the activities of the body;
- if the documents or evidence submitted by the body to prove meeting of accreditation requirements after accreditation decision turn out to be incorrect;
- on other justified occasions when not suspending accreditation may damage the accreditation system and trustworthiness of the EAK or will endanger persons’ life, health or property.

10.2.2 When the body applies for suspending accreditation, the lead assessor will prepare an appropriate draft decision and present it to the Member of EAK Management Board. No technical review is conducted.

10.2.3 When accreditation is suspended, the accreditation can be restored after meeting the conditions indicated in the suspending decision and/or determination of the resolving of nonconformities during special assessment.

10.2.4 The decision on restoring of accreditation is made according to the provisions of chapter 3. When the reason for suspending accreditation is non-payment of invoice, the restoration of the validity of accreditation will require confirmation of the accountant on the payment of the invoice and the accreditation may be restored without technical review.

10.2.5 A new accreditation certificate of the date of restoration of accreditation is issued to the body together with the decision on restoration of the validity of accreditation.

10.3 Withdrawing accreditation

10.3.1 Accreditation of a body is withdrawn on the following occasions:

- if the body applies for withdrawing;
- when the maximum time has passed (six months) from suspending accreditation;
- if the accredited body has not paid the accreditation invoice within six months of the due date on the invoice;
- at liquidation of the body;
- if the body goes bankrupt;
- in case of fraudulent behaviour by the body or intentional provision of false information or concealing of essential information by it;
- on other justified occasions when not withdrawing accreditation may damage the accreditation system and trustworthiness of the EAK or will endanger persons’ life, health or property.

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¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet

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10.3.2 If six months have passed from suspending accreditation and during that period the body has not changed the circumstances based on which accreditation was suspended, has not informed the EAK of their wish to restore accreditation or has not made possible conducting of special assessment, the accreditation will be withdrawn. The decision-making process will follow the provisions of chapter 3, except no technical review will be conducted.

10.3.3 If the body applies for withdrawing accreditation, the lead assessor will prepare an appropriate draft decision and present it to the Member of EAK Management Board. No technical review is conducted.

10.3.4 Withdrawing accreditation involves also the termination of the accreditation agreement. The data of the body in the list of accredited bodies published on the EAK website will be maintained but without accreditation scope and with added remark on withdrawal of accreditation. In case of withdrawing the accreditation the folder of the company will be sent to the EAK documents archive.

10.4 Reducing the scope of accreditation

10.4.1 Reducing the scope of accreditation is partial withdrawing of accreditation (re: cl. 10.3).

10.4.2 The scope of accreditation is reduced on the following occasions:

- if the body applies for reducing;
- when a critical nonconformity is identified;
- if the body has not resolved nonconformities by the set due date;
- when the maximum time has passed (six months) from suspending accreditation;
- on other justified occasions when not reducing the scope of accreditation may damage the accreditation system and trustworthiness of the EAK or will endanger persons’ life, health or property.

10.4.3 If the body applies for reducing the scope of accreditation, the lead assessor will prepare an appropriate draft decision and the amended annex to the accreditation certificate and will present it to the Member of EAK Management Board. No technical review is conducted.

11. HANDLING OF CHANGES THAT TOOK PLACE IN ACCREDITED BODIES

11.1 Reporting of changes

11.1.1 Pursuant to the accreditation agreement accredited bodies are obliged to inform the EAK immediately of all significant changes in their legal status, structure, owners, top management, key persons, courses of action and scope, resources (funds, equipment), locations of operation, etc.

11.1.2 If changes communicated by the body or information on changes from other sources give sufficient basis to question the continuing conformity of the body with accreditation requirements, the EAK can ask the body for additional documents, explanations and/or to conduct special assessment of the body.

11.1.3 If during regular surveillance assessment it appears that the body has not informed the EAK of changes that took place in a timely manner, this will be considered as the breach of the provisions of the accreditation agreement that is essentially equivalent to critical nonconformity (re: cl. 2.4.5).

11.2 Presentation of changes on accreditation certificates

If a decision is made to issue a new accreditation certificate to reflect the changes that had taken place in the body, the same decision will declare the last issued certificate invalid starting from the date of issue of the new certificate.

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1 *Referred documents and templates are available on EAK website*

2 *Referred documents and templates are available in the relevant register on EAK intranet*
If a decision is made to issue a new annex to accreditation certificate to reflect the changes that had taken place in the body, the lead assessor after technical review compiles a draft decision and presents it to the Member of EAK Management Board. A new annex to accreditation certificate is issued, without conducting technical review, in the following cases:

- elaboration of measurement capability of a calibration laboratory at its request;
- change of the name of accredited body/laboratory;
- change of the address of an operational location of accredited body/laboratory;
- implementation of a new version of the standard referred to in accreditation scope;
- change of a legal act or normative document referred to in accreditation scope;
- change of the type of an inspection body (from A to B or C) at the body’s request.

A new annex to accreditation certificate is issued without conducting technical review nor the decision by the Member of Management Board in the following cases (the lead assessor formulates the reason for change in the summary report):

- change of address of the body/laboratory without changing its operational locations, provided that the body/laboratory has presented the relevant documentation;
- formal adjustments in the annex (e.g. specifying the method/procedure);
- change of the list of verifiers of measurement instruments.

All documentation serving for justification of the changes shall be retained in the electronic or paper file of the respective body/laboratory. The reason for issuing a new annex to accreditation certificate is presented in the annex.

12. FLEXIBLE SCOPE OF ACCREDITATION

12.1 The EAK offers accredited laboratories an opportunity to apply for flexible scope of accreditation.

12.2 Starting from reassessment an accredited laboratory has an opportunity to apply for using flexible scope of accreditation for certain defined measuring principles. In the application for flexible scope of accreditation it is necessary to proceed from the provisions of this guide, taking into account the provisions of guides EA-2/15 and EAK J19¹.

13. CROSS-BORDER ACCREDITATION

13.1 Accreditation of cross-border activities of Estonian bodies

13.1.1 Accreditation is conducted according to the procedures established in this guide in cooperation with the local (national) accreditation body (re: cl. 13.3).

13.1.2 All key activities of the body (including those abroad) are covered during on-site initial assessment and at least once during the accreditation cycle in future.

13.1.3 When assessing the conformity assessment activities of the body in key locations abroad it will be verified that the conditions listed in chapter 5 of guide EA-2/13 and in IAF MD 12 are followed.

13.2 Accreditation of foreign bodies

13.2.1 When the EAK receives an accreditation application from a body operating in an EU member state or operating in the so-called EA region, the EAK will check that it is in accordance with the provisions of Article 7 (1) of Regulation 765/2008/EC before making a decision on processing the application.

13.2.2 Accreditation is conducted according to the procedures established in this guide in cooperation with the local (national) accreditation body (re: cl. 13.3).

¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet
13.3 Cooperation with accreditation bodies of foreign countries
During assessment of conformity assessment activities which are performed in foreign countries the EAK has cooperation with local (national) accreditation bodies that includes the following:
- information to the local accreditation body of the planned assessment with proposal to involve their observer;
- information to the body assessed on the participation of the representative of the local accreditation body at assessments and asking for consent from the body;
- use of services of the local accreditation body for conducting on-site assessment or witnessing (if necessary).

14. ACCREDITATION OF BODIES APPLYING FOR NOTIFICATION

14.1 Accreditation of conformity assessment bodies which apply for notification is carried out according to the requirements of an Estonian legal act and/or the requirements of the standard defined as preferred in the guide EA-17 (tables 2 and 3) for the relevant conformity assessment module and directive.

14.2 Accreditation is conducted according to the procedures established in this guide, while in addition to accreditation requirements the requirements listed in the guide EA-2/17 and the requirements provided for notified bodies in the relevant directive are taken into account. To specify the field of activity in the accreditation certificate of a notified body the term “conformity assessment” is used.

14.3 Once in six months a report on the assessment results of the notified bodies is submitted to the notifying body Technical Surveillance and Consumer Protection Agency. The Technical Surveillance and Consumer Protection Agency is informed immediately when changes take place in the notified accreditation scope of the body or when the accreditation status of the notified body changes.

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1 Referred documents and templates are available on EAK website
2 Referred documents and templates are available in the relevant register on EAK intranet

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Annex 1: Description of accreditation process
The stages of accreditation process are described in the flow chart below.

Submission of application
↓
Review of application
↓
Resource review
↓
Decision on starting accreditation process
↓
Initial assessment¹
↓
Accreditation decision²
↓
Drawing up of cycle’s assessment programme
↓
Surveillance once a year³
↓
Reassessment⁴

¹ Appointment of lead assessor
   Drawing up of assessment programme
   Document review
   Appointment of assessment team
   On-site assessment
   Review of corrective action and closing of nonconformities

² Certificates are issued for five years

³ On-site assessment
   Review of corrective action and closing of nonconformities
   Updating of cycle`s assessment programme

⁴ Submission of application
   Review of application and resources
   Decision on starting accreditation process
   Appointment of lead assessor
   Drawing up of reassessment programme
   Document review
   Appointment of assessment team
   On-site assessment
   Review of corrective action and closing of nonconformities
   Reassessment’s decision

¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet
Ref 1: Referred documents and templates are available on EAK website

Ref 2: Referred documents and templates are available in the relevant register on EAK intranet

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### Annex 2: Assessment techniques used in accreditation *(in Estonian)*

**The following techniques are used in accreditation assessments:**

<table>
<thead>
<tr>
<th>Name of the assessment technique</th>
<th>Description of the assessment technique</th>
<th>Circumstances in which the technique is used</th>
</tr>
</thead>
</table>
| Dokumentide ülevaatus
| Tõendusdokumentide ülevaatus
*Record review* | Asutuse JS funktsioneerimist ja vastavushindamistegevuse läbiviimist tõendavate dokumendid ülevaatust assessori poolt. Võib sisaldada ka dokumendi ülevaatust ja intervjuud. | Enne igat hindamist vaatab assessor läbi kõik labori poolt esitatud tõendusdokumendid ja annab neile hinnangu. Näiteks juhtkonnapoolse ülevaatuse protokoll, verifitseerimisprotokoll jms. Tõendusdokumentide ülevaatus on eriti oluline siis, kui hinda-

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1. *Referred documents and templates are available on EAK website*
2. *Referred documents and templates are available in the relevant register on EAK intranet*
<table>
<thead>
<tr>
<th>Name of the assessment technique</th>
<th>Description of the assessment technique</th>
<th>Circumstances in which the technique is used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervjueerimine</td>
<td>Asutuse töötajate küsitlemine hindamise käigus</td>
<td>Intervjuusid kasutatakse tõendite otsimiseks JS ja protséduride rakendatuse ning kompetentsi kohta. Intervjuu abil saab assessor hinnata, kas protséduuridest on aru saadud, kas töötajad teavad, kus juhised asuvad jne.</td>
</tr>
<tr>
<td>Kohapealne hindamine</td>
<td>Asutuse vastavushindamise tegevuse hindamise asutuse</td>
<td>Akrediteerimisotsuse tegemiseks tõendite otsimise, et asutuse</td>
</tr>
<tr>
<td>Name of the assessment technique</td>
<td>Description of the assessment technique</td>
<td>Circumstances in which the technique is used</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>On-site assessment</td>
<td>füüsilises asukohas/tegevuskohas.</td>
<td>vastavushindamistegevus vastab akrediteerimiskriteeriumitele.</td>
</tr>
<tr>
<td></td>
<td>Kombinatsioon intervjuudest, dokumentide ja tõendusdokumentide ülevaatusest ning vaatlusest.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sisaldab dokumentide ja tõendusdokumentide ülevaatust ning intervjuud. Ei sisalda vaatlust.</td>
<td>Täskli jooksul hinnatakse reeglina toimikute põhjal kõiki ulatuses olevaid valdkondi vastavalt EAK VJ-des toodud ulatuste kirjeldustele.</td>
</tr>
<tr>
<td></td>
<td>Valitakse esinduslik arv läbiviidud sertifitseerimisi/inspekteerimisi/tõendamisi, et anda hinnang konkreetselt protseduuri/vastavushindamisskeemi vastavuse kohta.</td>
<td></td>
</tr>
<tr>
<td>Meetodi hindamine Method assessment</td>
<td>Konkreetselt mõõtmise läbiviimise süviti hindamine vastavalt mõõtemetoodikale, mille käigus täidetakse vastav EAK metoodika hindamise vorm.</td>
<td>Kasutatakse konkreetselt meetodi puhul tõendite hankmiseks, et kõik akrediteerimisnõuded on labori poolt täidetud.</td>
</tr>
<tr>
<td></td>
<td>Sisaldab dokumentide ja tõendusdokumentide ülevaatust, intervjuusid ja vaatlust.</td>
<td>Reeglina hinnatakse kõik meetodid, kuid suurte ulatuste puhul valitakse hindamiseks esinduslik arv konkreetsel meetodeid. Selle valimi põhjal antakse hinnang kogu akредiteerimisulatuse kohta.</td>
</tr>
<tr>
<td></td>
<td>Meetodi hindamisel valitakse esinduslik arv mõõtmisi, et anda hinnang selle konkreetsel meetodi vastavuse kohta.</td>
<td></td>
</tr>
</tbody>
</table>

1 Referred documents and templates are available on EAK website
2 Referred documents and templates are available in the relevant register on EAK intranet

Rev 23.10.2019
<table>
<thead>
<tr>
<th>Name of the assessment technique</th>
<th>Description of the assessment technique</th>
<th>Circumstances in which the technique is used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meetodi hindamine on oma olemuselt vertikaalne.</td>
<td>Kasutatakse asutuse kompetentsi ning protseduuride asjakohasuse ja rakendamise hindamisel. Võib toimuda asutuse kliendi juures või asutuse ruumides, kus paraskajagu vastavushindamist läbi viiaakse.</td>
<td></td>
</tr>
<tr>
<td>Vertikaalne audit</td>
<td>Vertikaalne audit keskendub kogu protsessile ja hindab kogu vastavushindamistegevuse läbirääkimise algusest lõpuuni. Labori korral hinnatakse kogu konkreetset mõõtmist alates tellimusest/proovi saabumisest laborisse kuni tulemuse väljastamise kliendiile. Sert/inspekteerimisassutuse puhul hinnatakse kogu protsessi taotlusest sertifikaadi väljastamises. Kombinatsioon intervjuust ja tõendusdokumentide ülevaatusest</td>
<td></td>
</tr>
</tbody>
</table>

1 Referral documents and templates are available on EAK website 2 Referral documents and templates are available in the relevant register on EAK intranet
<table>
<thead>
<tr>
<th>Name of the assessment technique</th>
<th>Description of the assessment technique</th>
<th>Circumstances in which the technique is used</th>
</tr>
</thead>
</table>
| Assessor valib üldistuste tegemiseks esindusliku hulga näiteid konkreetse nõude rakendamise kohta. Laborites hindab assessor näiteks mõõtuseadmete kalibrieeritust ja kontikki, tööjuhendite vormistust, kinnitamist ja ülevaatust, mõõte-tulemuste vormistust. Inspekteerimis-/sertifitseerimisasutustes hindab assessor näiteks taotluse läbivaatust, üleminekueelset ülevaatust, aruannete koostamist, otsuse tegemist jms. Kombinatsioon intervjuust ja tõendusdokumentide ülevaatusest | vuse nõuetekohasuse hindamiseks. |}


| Measurement audits | | |

| Kaughindamine | Vastavushindamisasutuse füüsilises asukohas või virtuaal-tegevuskohas toimuvate teguvuste hindamine, kasutades info- ja kommunikatsioonitehnoloogilisi lahendusi [nt nutitelefonid, droonid, videokaamerad, tehisintellektid, arvutid jne]. | Kasutatakse hindamisel tõendite kogumiseks, et asutuse vastavushindamistegevus on nõuetekohaselt läbi viidud ja veendumaks, et kogu protsess on jälgitavalt dokumenteeritud. Võimaldab optimeerida hindamise efektiivsust, toetab |

| Remote assessment | | |

---

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2 Referred documents and templates are available in the relevant register on EAK intranet
<table>
<thead>
<tr>
<th>Name of the assessment technique</th>
<th>Description of the assessment technique</th>
<th>Circumstances in which the technique is used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Näited:</td>
<td>Näited: koosoleku läbiviimine telekonverentsivahendite abil, sh heli-, video- ja andmevahetuse kaudu; dokumentide ja andmete ülevaatus kaughaldusvahendite abil (nii reaalajas kui asünkroonselt); info ja tõendusmaterjalide salvestamine heli- ja videotehniliste vahendite abil; eemalasetsevate või potentsiaalselt ohtlikele tegevuskohtadele ligipääsu võimaldamine audio-visuaalse infovahenduse abil.</td>
<td>hindamisprotsessi terviklikkust, säästab aega ja transpordikulusid ning võimaldab ligipääsu mujalasuvale personalile.</td>
</tr>
</tbody>
</table>

1 Referred documents and templates are available on EAK website
2 Referred documents and templates are available in the relevant register on EAK intranet
Annex 3: Key activities of conformity assessment

1. **Key activities of a laboratory:**
   - order and agreement review;
   - qualification of personnel and assigning responsibility;
   - sampling/calibration/testing;
   - approval of calibration certificates/test reports.

2. **Key activities of an inspection body:**
   - formulation of policies;
   - process and/or procedure development;
   - procedure for initial selection of inspectors;
   - agreement review;
   - planning of conformity assessments;
   - review and approval of conformity assessments.

3. **Key activities of a certification body of products, processes and services:**
   - formulation and approval of policies;
   - development and approval of a process and/or procedure;
   - initial assessment of competence and approval of technical personnel and subcontractors;
   - management of the competence monitoring process of personnel and subcontractors;
   - agreement review which includes technical review of agreement and defines technical requirements for a certification activity in new or not spread areas;
   - certification decision which also includes technical review of assessment.

When defining the need for on-site assessment and assessment time the following shall be considered in addition:
   - effectiveness of planning of conformity assessment activities;
   - availability of documents (including records) and information electronically, through a web conference or in some other way without on-site visit;
   - opportunity to interview relevant personnel over phone or through a web conference or in some other way without on-site visit;
   - cooperation with market operator and schemes to avoid duplicating of activities and to ensure effective use of available competence.

4. **Key activities of a certification body of management systems:**
   - formulation of policies;
   - process and/or procedure development;
   - initial approval, control and training of personnel conducting audits;
   - continuous monitoring of personnel conducting audits;
   - application review;
   - authorisation of personnel conducting audits;
   - control of surveillance and recertification audits;
   - review of final report and approval of certification decision.

5. **Key activities of a certification body of persons:**
   - formulation and approval of policies;
   - development and approval of the necessary processes and/or procedures of the certification system of persons, which also involves selection and authorisation of examiners;
   - review of applications and agreements related to certification of persons;
   - development, assessment and management of exams and recertification;
   - making of certification decisions on persons, including signing or approval of certificates;
   - development and approval of necessary policies, processes and procedures for solving of complaints and appeals on the certification process or criteria which were received from applicants, candidates, certified persons and their employers or other parties;
   - final decision on complaints and appeals.

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1. *Referred documents and templates are available on EAK website*
2. *Referred documents and templates are available in the relevant register on EAK intranet*
Annex 4: Risk sources in conformity assessment activity

1) **Associated with activities:**
- Change in volume of work
- New equipment
- Internal quality control
- Large scope of accreditation
- Earlier assessment experience
- Realization of the witnessing plan, embracing of the entire scope
- Subcontracting
- Impartiality
- Complaints and appeals
- Mergers and cross-border extensions

2) **Associated with location:**
- Rooms
- Different locations
- Facilities/equipment
- Extension to new location
- Location of key activities
- Changes in personnel or activities
- Risks resulting from a geographical location
- Complaints

3) **Associated with personnel:**
- New personnel
- Changes
- Competence
- Sufficiency of personnel
- Recruitment
- External personnel
- Complaints
- Impartiality

---

1. Referred documents and templates are available on EAK website
2. Referred documents and templates are available in the relevant register on EAK intranet
Annex 5: Content of an assessment plan

Initial/surveillance/reassessment plan

Body assessed:
Locations to be covered by assessment:
Type of assessment: initial/surveillance/reassessment/extension
Assessment team:
  Lead assessor:
  Assessor(s), incl. their current job:
  Speciality expert(s), incl. their current job:
  Observer(s), incl. their current job:

Accreditation criteria:

Scope of assessment:

Activities to be assessed:
  Lead assessor:  [standard(s), clauses]
  Assessor(s)/expert(s):  [methods, products, EA/NACE codes, etc.]

Representatives of the body whose presence is necessary:

Time schedule of assessment (model):

<table>
<thead>
<tr>
<th>Date(s)</th>
<th>Time</th>
</tr>
</thead>
</table>
| Opening meeting                    | ......-.......
| Interviews with responsible persons and review of documents | ......-.......
| Lunch break                        | ......-.......
| Interviews with responsible persons and review of documents | ......-.......
| Preparation for closing meeting (assessment team) | ......-.......
| Closing meeting                    | ......-.......

Time schedule can be changed due to the local circumstances

Dates for audit/inspection/testing witnessing:  Dates or in accordance with the CAB’s work schedule

Lead assessor
Date

In case of objections to the composition of the assessment team, the justified arguments shall be presented to the EAK within two working days at the latest!

1 Referred documents and templates are available on EAK website
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Rev 23.10.2019
Annex 6: Principles for calculation of the duration of on-site assessment

1. When planning the duration of on-site assessment of a laboratory the rules below are considered:

The duration of lead assessor’s on-site assessing in each location of the laboratory is at least one working day (basic duration 8 h), provided it does not exceed the following limits:
   a) 1-2 speciality assessors/experts are involved in assessment, including not more than one expert;
   b) the total number of methodologies assessed is not over 20 (or up to 15 per assessor/expert);
   c) the number of employees in the laboratory is not over 4.

The duration of necessary on-site assessment is adjusted depending on the following factors:
   a) if two or three of the limits indicated are exceeded, the duration of on-site assessment will increase in comparison to the baseline duration proportionally to the limits given in the paragraphs a) to c); if one limit is exceeded, the lead assessor will decide whether it is necessary to extend the duration of on-site assessment;
   b) if a laboratory is applying for notification and simultaneous interpretation is used at assessment, or an earlier review of documents refers to inconsistent implementation of the management system, the duration of on-site assessment can be increased twofold as a maximum;
   c) if the number of assessed methodologies is much lower than the limit and one assessor/expert is involved in assessment, the management system of the laboratory is integrated with the management system of the organization and the laboratory is cooperative, the duration of on-site assessment can be decreased to half a working day (4 h).

The duration of a speciality assessor’s/expert’s on-site assessment in each location of laboratory is at least one working day (basic duration 8 h), provided it does not exceed the following limits:
   a) the total number of methodology groups assessed (covers similar methodologies, in the assessment of which it is possible to be limited to the witnessing of the performance of one representative methodology) is not over 3;
   b) the total number of methodologies assessed is not over 15;
   c) the number of employees of laboratory in the area assessed is not over 4.

The duration of necessary on-site assessment is adjusted depending on the following factors:
   a) if the above-mentioned limits are exceeded, the duration of on-site assessment will increase in comparison to the baseline duration proportionally to the limits given in the paragraphs a) to c);
   b) if simultaneous interpretation is used at assessment, or the earlier review of documents indicated that the laboratory personnel has little experience and the methodologies have not been sufficiently elaborated, the duration of on-site assessment can be increased twofold as a maximum;
   c) if the number of assessed methodologies is much lower in comparison to the limit (e.g. they form only one methodology group), the laboratory has only 1-2 employees in the given area and the laboratory is cooperative during conducting of assessment and organizing witnessing of practical work, the duration of on-site assessment can be decreased to half a working day (4 h).

¹ Referred documents and templates are available on EAK website
² Referred documents and templates are available in the relevant register on EAK intranet

Rev 23.10.2019
2. When planning the duration of on-site assessment of an **inspection body** (*basic duration 8 h*) the following circumstances are considered:

   a) the number of persons (also external) involved with inspection activities;
   b) the number of inspection methods and procedures in the scope of accreditation;
   c) the volume of activities, e.g. the number of inspection reports and certificates;
   d) the number of locations;
   e) whether it is a notified body;
   f) additional requirements from legislation;
   g) use of unaccredited subcontractors;
   h) if the tests are accredited or not;
   i) language of assessment;
   j) the level of complexity of the body’s management system, e.g. their management system is integrated with the management system of a large corporation;
   k) the degree of maturity of the body’s management system and knowledge of management systems;
   l) earlier experience of the body’s willingness to cooperate during on-site assessment;
   m) the size of assessment team: as a maximum two technical assessors and one technical expert on one assessment day and one place.

3. When determining the duration of on-site assessment of a **certification body of products, processes and services** (*basic duration 8 h*) the following circumstances are considered:

   a) the number of persons (also external) involved with the certification process;
   b) the number of certification schemes in the scope of accreditation;
   c) the volume of activities, e.g. the number of certificates/valid certification agreements;
   d) the number of locations;
   e) use of unaccredited subcontractors;
   f) whether it is a notified body;
   g) additional requirements from legislation;
   h) language of assessment;
   i) the level of complexity of the body’s management system, e.g. their management system is integrated with the management system of a large corporation;
   j) the degree of maturity of the body’s management system and knowledge of management systems;
   k) earlier experience of the body’s willingness to cooperate during on-site assessment;
   l) the size of assessment team: as a maximum two technical assessors and one technical expert on one assessment day and at one place.

4. When determining the duration of on-site assessment of a **certification body of management systems** (*basic duration 8 h*) the following circumstances are considered:

   a) the number of persons (also external) involved with the certification process;
   b) the number of certification schemes and NACE codes in the scope of accreditation;
   c) whether it is a notified body;
   d) the volume of activities, e.g. the number of certificates/valid certification agreements;
   e) the number of locations;
   f) language of assessment;
   g) the level of complexity of the body’s management system, e.g. their management system is integrated with the management system of a large corporation;
   h) the degree of maturity of the body’s management system and knowledge of management systems;

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i) earlier experience of the body’s willingness to cooperate during on-site assessment;

j) the size of assessment team: as a maximum two technical assessors and one technical expert on one assessment day and at one place.

5. When determining the duration of on-site assessment of a **certification body of persons** *(basic duration 8 h)* the following circumstances are considered:

a) the number of persons (also external) involved with the certification process;

b) the number of certification schemes in the scope of accreditation;

c) the volume of activities, e.g. the number of certificates/valid certification agreements;

d) the number of locations;

e) whether it is a notified body;

f) additional requirements from legislation;

g) language of assessment;

h) the level of complexity of the body’s management system, e.g. their management system is integrated with the management system of a large corporation;

i) the degree of maturity of the body’s management system and knowledge of management systems;

j) earlier experience of the body’s willingness to cooperate during on-site assessment;

k) the size of assessment team: as a maximum two technical assessors and one technical expert on one assessment day and at one place.
Annex 7: Content of an opening meeting

The topics and activities addressed at the opening meeting are given in the following table:

<table>
<thead>
<tr>
<th>Initial assessment and reassessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Introductions of assessment team and participants from the body;</td>
<td>• Introductions of participants;</td>
</tr>
<tr>
<td>• presentation of conditions of accreditation agreement and calculation <em>(if necessary)</em>;</td>
<td>• presentation of surveillance agreement and calculation <em>(if necessary)</em>;</td>
</tr>
<tr>
<td>• presentation of accreditation requirements;</td>
<td>• presentation of accreditation requirements;</td>
</tr>
<tr>
<td>• explanation of goal of assessment, including goal of on-site assessment and tasks of each</td>
<td>• presentation of the goal and plan of on-site surveillance assessment;</td>
</tr>
<tr>
<td>assessor and assurance of following confidentiality requirements;</td>
<td>• presentation of the tasks of each member of assessment team;</td>
</tr>
<tr>
<td>• description of assessment process, including explanation of possible results and nonconformities;</td>
<td>• presentation of time schedule of visit and work methods;</td>
</tr>
<tr>
<td>• presentation of review of documents and *(if appropriate) results of preliminary visit;</td>
<td>• assigning of body’s representatives;</td>
</tr>
<tr>
<td>• specification of scope of conformity assessment activities provided in accreditation application;</td>
<td>• presentations by body’s representatives of changes that have taken place in their management system and/or activities in the period between assessments.</td>
</tr>
<tr>
<td>• agreement of on-site assessment plan *(including breaks and lunch) and organizational aspects <em>(meeting room, copying, etc)</em>;</td>
<td></td>
</tr>
<tr>
<td>• assigning an escort* to each assessor from the body and explanation of the role of escorts;</td>
<td></td>
</tr>
<tr>
<td>• agreement on content, place and time of closing meeting;</td>
<td></td>
</tr>
<tr>
<td>• answering to relevant questions of body’s representatives.</td>
<td></td>
</tr>
</tbody>
</table>

*Note*: Each assessor shall be accompanied by representative(s) assigned by the body’s management and having responsibility for the assessed area, the person of representative may change during assessment.

---

1 *Referred documents and templates are available on EAK website*

2 *Referred documents and templates are available in the relevant register on EAK intranet*
Annex 8: Examples of the degrees of severity of nonconformities

The examples of grading the nonconformities given in the following table should be considered within the context of discovering of a particular nonconformity

<table>
<thead>
<tr>
<th>No</th>
<th>Area/aspect</th>
<th>Critical nonconformity</th>
<th>Nonconformity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Competence of personnel</td>
<td>Can have direct impact on the results of conformity assessment (e.g. competence requirements not determined or inadequate, competence evaluation of personnel not documented, inspectors or other employees connected with conformity assessment not monitored)</td>
<td>No direct impact on the results of conformity assessment (e.g. not all employees monitored according to plan, part of the training plan of employees not fulfilled)</td>
</tr>
<tr>
<td>2</td>
<td>Internal audit</td>
<td>Ineffective audit (e.g. incompetent internal auditors, audit findings do not reflect reality)</td>
<td>Some mandatory aspect or audit criterion not covered by audit</td>
</tr>
<tr>
<td>3</td>
<td>Management review</td>
<td>Procedures missing or ineffective review (e.g. review findings do not reflect reality)</td>
<td>Some mandatory input or output not covered by review</td>
</tr>
<tr>
<td>4</td>
<td>Corrective action</td>
<td>Procedures missing or not implemented (e.g. some nonconformity not identified or not processed, missing records)</td>
<td>Cause analysis of corrected nonconformities or analysis of effectiveness of action taken not documented</td>
</tr>
<tr>
<td>5</td>
<td>Availability of testing/measuring equipment</td>
<td>Measuring/test has direct impact on test results of laboratory</td>
<td>Measuring/test has no direct impact on test results of laboratory</td>
</tr>
<tr>
<td>6</td>
<td>Traceability of measurements/calibrations</td>
<td>Measuring with traceably not-calibrated measuring instrument, if it has direct impact on test results of laboratory</td>
<td>Measuring with not traceably calibrated measuring instrument if it has no direct impact on test results of laboratory</td>
</tr>
<tr>
<td>7</td>
<td>Uncertainty of measurement</td>
<td>Uncertainty of measurement of test/measuring results not estimated</td>
<td>When estimating uncertainty of measurement not all significant components were considered</td>
</tr>
<tr>
<td>8</td>
<td>Quality assurance in laboratory</td>
<td>Laboratory does not take part in interlaboratory comparison or does not analyse results of taking part in interlaboratory comparison</td>
<td>Laboratory has not precisely followed the plan for taking part in interlaboratory comparison</td>
</tr>
<tr>
<td>9</td>
<td>Records control</td>
<td>Records control procedures not established, when data corrected in workbooks, repeatedly evidential signatures and/or dates missing in workbooks, source data not documented</td>
<td>Evidential signature and/or date missing at correction of data in workbook, records control procedures are incomplete, retaining of records does not meet requirements</td>
</tr>
</tbody>
</table>

1. Referred documents and templates are available on EAK website
2. Referred documents and templates are available in the relevant register on EAK intranet
<table>
<thead>
<tr>
<th></th>
<th>Certification documents of management system (MS)</th>
<th>Elements required by relevant standard are not reflected on certificate</th>
<th>Misprint in certificate text, scope of certification not defined unambiguously, certificates of body having several locations miss references to all covered locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Testing/calibration method</td>
<td>Established methodology not followed, non-standard methodology not validated</td>
<td>Verification report of methodology can be related to standard but not to methodology; no information in methodology how the results issued to clients are calculated</td>
</tr>
<tr>
<td>11</td>
<td>Test report/calibration certificate</td>
<td>Mandatory information according to standard requirements repeatedly missing on reports/certificates, thus traceability of results no ensured <em>(connection to source data)</em></td>
<td>Missing page numbers on reports/certificates, reference to the source of limits missing, original version of amended report not retained, reference to the grounds for presenting opinions missing</td>
</tr>
<tr>
<td>12</td>
<td>MS documentation</td>
<td>Whole documentation, processes, systems, records, etc have no reference or connection to MS documentation</td>
<td>Organization chart in MS manual not updated, personnel has no access to MS documents at any time</td>
</tr>
<tr>
<td>13</td>
<td>Use of accreditation symbol</td>
<td>Use of EAK symbol on reports/certificates does not meet requirements established in EAK J9 guide and/or is misleading concerning scope of accreditation <em>(e.g. use of EAK logo on their website, accreditation symbol is on report that does not present accredited results or does not distinguish them from unaccredited results)</em></td>
<td>Formal deviation from EAK J9 requirements <em>(e.g. concerning reference to image of symbol or accreditation)</em> that is not misleading concerning accreditation</td>
</tr>
<tr>
<td>14</td>
<td>Control of impartiality of certification activity</td>
<td>Certification body does not document impartial assessment during application review</td>
<td>Assessment of impartiality is not documented for some clients</td>
</tr>
<tr>
<td>15</td>
<td>Certification process of a person</td>
<td>Not following scheme requirements <em>(e.g. no theory examination carried out that is established by certification scheme)</em></td>
<td>Rotation of examination questions is insufficient</td>
</tr>
<tr>
<td>16</td>
<td>Certification process of products</td>
<td>Some process stages provided by relevant standard not gone through</td>
<td>Reviewer assigned at receipt of application has ordered laboratory to carry out test and thus participated in assessment process</td>
</tr>
<tr>
<td>17</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 *Referred documents and templates are available on EAK website*

2 *Referred documents and templates are available in the relevant register on EAK intranet*
|   | Impartiality and independence of inspection body | Risks on impartiality of inspection body are currently not identified; inspection body does not follow requirements established for the specific type of impartiality | In risk assessment some factors of impartiality are not covered |

1. Referred documents and templates are available on EAK website
2. Referred documents and templates are available in the relevant register on EAK intranet
Annex 9: Content of a closing meeting

The topics and activities addressed at the closing meeting are given in the following table:

<table>
<thead>
<tr>
<th>Initial assessment and reassessment</th>
<th>Surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• It is emphasized that assessment did not cover all aspects in body’s activity and thus there could be nonconformities in the body’s activities not documented by assessment team;</td>
<td>• Short summary of assessment results;</td>
</tr>
<tr>
<td>• meaning of severity degree of nonconformities is explained;</td>
<td>• description of all identified nonconformities and their degree of severity;</td>
</tr>
<tr>
<td>• each assessor is allowed to present findings confirming conformity and nonconformity and evaluate the conformity of specific sector with accreditation requirements;</td>
<td>• explanations of possible nature of documents giving evidence of resolving of nonconformities and determination of time limit for presenting them (as a rule up to 20 working days);</td>
</tr>
<tr>
<td>• actions to be taken by body to stop immediately nonconforming work and resolving nonconformity are confirmed;</td>
<td>• information on need of possible follow-up check;</td>
</tr>
<tr>
<td>• final summary, conclusions and recommendations for granting accreditation are presented;</td>
<td>• giving conclusions and recommendation for maintaining accreditation and (if necessary) on changes of scope of accreditation;</td>
</tr>
<tr>
<td>• activities planned for resolving of nonconformities found or the time limit for presenting plan of activities are agreed with the body;</td>
<td>• body is allowed to discuss the course and results of assessment;</td>
</tr>
<tr>
<td>• explanations of possible nature of documents giving evidence of resolving nonconformities and determination of due date for presenting them;</td>
<td>• body’s representatives sign finalized detail reports and summary report;</td>
</tr>
<tr>
<td>• information on need of possible follow-up check;</td>
<td>• copies of signed reports are given to body’s management;</td>
</tr>
<tr>
<td>• body is allowed to discuss the course and results of assessment;</td>
<td>• time and manner are agreed for submitting unfinished assessor reports.</td>
</tr>
<tr>
<td>• get signatures from body’s representatives on finalized detail reports and summary report;</td>
<td></td>
</tr>
<tr>
<td>• give copies of all signed reports to body’s representative;</td>
<td></td>
</tr>
<tr>
<td>• inform that assessor reports not finished by closing meeting will be sent to body for information as a rule within five working days;</td>
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<tr>
<td>• explain rules of referring to accreditation.</td>
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2 Referred documents and templates are available in the relevant register on EAK intranet

Rev 23.10.2019
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<th>Confirmation</th>
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