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Order N\_\_\_8-KH\_\_\_

**MANAGEMENT SYSTEM**

**ACCREDITATION PROCEDURE AND GENERAL REQUIREMENTS**

**PR-7**

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**“*The present document represents the English version of the document under reference at the specified revision. In case of conflict, the Armenian version will prevail*”**

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# Scope

**1.1** The present procedure defines the process of accreditation handled by the the “National Accreditation Body” SNCO (hereinafter ARMNAB).

The accreditation procedure and general requirements according to accreditation schemes are defined in the following documents, which are separate annexes to this procedure:

Annex PR-7/ATL-01 Accreditation of testing laboratories

Annex PR-7/ACL-01 Accreditation of calibration laboratories

Annex PR-7/ACB-01 Accreditation of product, service, process certification bodies

Annex PR-7/ACB-02 Accreditation of management systems certification bodies

Annex PR-7/ACB-03 Accreditation of persons certification bodies

Annex PR-7/AIB-01 Accreditation of inspection (including verification) bodies

Annex PR-7/APT-01 Accreditation of PT providers.

**1.2** The present procedure is developed to meet the requirements of the GOST ISO/IEC 17011-2018 (ISO/IEC 17011:2017, IDT) standard and ISO/EA/IAF/ILAC documents.

# 2. Normative references

The referenced documents with no-date shall be applicable only by the latest edition. This document contains references to the following documents:

GOST ISO/IEC 17000, Conformity assessment. Vocabulary and general principles

GOST ISO/IEC 17011, Conformity assessment. General requirements for bodies accrediting conformity assessment bodies

«Law on Accreditation», February 8, 2012

“Order on approval of size and procedure on accreditation services provided by National accreditation body on the basis of contract signed between National accreditation body and Conformity assessment body, payments made by Conformity assessment body against appraisals and annual membership fee of conformity assessment body”, order N311-N of Ministry of Economics of the RA, March 6, 2015

“The list of the members of Accreditation Council of the National Accreditation Body and the conditions of its operation”, order N646-A of Ministry of Economics of the RA, May 19, 2015

RA Government Decree No 152-N, dated 13 February 2020, “On inclusion of the accredited conformity assessment bodies (including the certification bodies and testing laboratories (centers)) in the EEU Unified Registry of Conformity Assessment Bodies, and the operation and maintenance thereof” (EEC Council Resolution No 100, dated 05 December 2018)

K-02 Provision of accreditation committees activities

K-03 Provision for application of logo and accreditation symbol of the National Accreditation Body

K-04 Provision for activities of appeal committee and consideration of appeals

K-06 Provision on operation of advisory technical committees

K-07 Provision on inclusion of conformity assessment bodies in the national part of the Unified Register of the Eurasian Economic Union (EAEU)

K-08 Provision on payment for work performed by an accreditation expert (assessor)/ technical expert

AC-4.6 General Accreditation criteria and list of documents

PL-02 Policy on cab objection to the structure of assessment team

PL-08 Policy of impartiality, managing conflicts of interests and ensuring objectivity in accreditation activity

PL-09 Policy on cross-border accreditation

PR-4.4 Procedure on Risk management

PR-4.6.3 Evaluation criteria and procedure for new conformity assessment scheme(s)

PR-4.6.4 Procedure for developing, extending or terminating accreditation schemes

PR-03 Updating of the accreditation scope of accredited conformity assessment bodies

PR-6.1.3 Procedure for Monitoring of NAB Personnel

PR-7.8 Requirements for the content, issuance, as well as the re-issuance of the accreditation certificate

PR-7.10-7.11 Procedure of extending or reducing accreditation

PR-7.12 Procedure on consideration of complaints

Documents developed by EAEU, EA, ILAC, IAF, which are mentioned in document AC-4.6.

EAEU, EA, IAF, ILAC documents are posted on the following websites, respectively:

EAEU: http://www.eurasiancommission.org,

EA: http://www.european-accreditation.org/,

ILAC: http://www.ilac.org,

IAF: http://www.iaf.nu.

# 3. Terms, Definitions, and abbreviations

The present procedure applies the following terms and definitions as defined by Law on accreditation, GOST ISO/IEC 17000, GOST ISO/IEC 17011 standards:

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

**National Accreditation Body** - state non-commercial organization established by the Government of the Republic of Armenia, vested with exclusive powers in the field of ensuring accreditation as prescribed by Law on Accreditation and other legal acts.

**Accreditation certificate** - formal document or a set of documents, stating that accreditation has been granted for the defined scope.

**Scope of accreditation**- specific conformity assessment services for which accreditation is sought or has been granted.

**Accreditation symbol** - symbol issued by an accreditation body to be used by accredited conformity assessment bodies to indicate they are accredited.

**Accreditation scheme** - rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply

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

**Conformity assessment activity** - activity conducted by a conformity assessment body when assessing conformity

Note: In the context of this document, activities covered by *accreditation* include, but are not limited to, testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification. For simplicity, these are referred to as conformity assessment activities being performed by conformity assessment bodies.

**Conformity assessment body** - body that performs conformity assessment activities and that can be the object of accreditation.

Note: Whenever the term “conformity assessment body” is used in the text, it applies to both the applicant and accredited conformity assessment bodies, unless otherwise specified.

**Extending accreditation** - adding conformity assessment activities to the scope of accreditation.

**Reducing accreditation** - cancelling part of the scope of accreditation.

**Suspending accreditation** - putting temporary restrictions in place for all or part of the scope of accreditation.

**Withdrawing accreditation** - cancelling accreditation for the full scope.

**Assessment technique** - method used by an accreditation body to perform an assessment.

Note: Assessment techniques, can include, but are not limited to:

— on-site assessment;

﻿— remote assessment;

— witnessing

— document review;

— file review;

— measurement audits;

— review of performance in proficiency testing and other interlaboratory comparisons;

— validation audits;

— unannounced visits;

— interviewing.

**Accreditation expert (assessor) (assessor)** – a natural person registered in the Register of Accreditation Experts (Assessors), having been appointed by the National Accreditation Body to carry out the assessment of the Conformity Assessment Bodies management system.

Note: In this procudure and all ARMNAB documents the term “Accreditation expert (assessor)” corresponds to clause 3.30 «assessor» of GOST ISO/IEC 17011.

**Technical accreditation expert (assessor) (hereinafter - Technical assessor) –** a natural person registered in the Register of Accreditation Experts (Assessors), who provides specific knowledge in a specific field of accreditation, appointed by the National Accreditation Body to carry out the assessment of the Conformity Assessment Body.

Note: In this procudure and all ARMNAB documents the term “Technical Accreditation expert (assessor)” corresponds to clause 3.30 «assessor» of GOST ISO/IEC 17011.

**Team leader** - assessor who is given the overall responsibility for the management of an assessment.

*Notes:*

*1 – ARMNAB's internal assessors are the team leaders.* *ARMNAB doesn’t have external team leaders.*

*2 – In this procedure and all ARMNAB documents the term “Team leader” means assessor who is given the overall responsibility for the management of an assessment. The term „ Team leader“ corresponds to clause 3.31 of GOST ISO/IEC 17011.*

**Technical expert –** a natural person registered in the Register of Technical Experts and possessing sufficient professional knowledge and skills in the field of accreditation subject to assessment, who has been appointed by the National Accreditation Body to participate in the assessment of the Conformity Assessment Body.

The technical expert is a team member providing technical consultancy services, but is not considered technical assessor.

*Note: By definition, therefore, technical experts, without a basic understanding of the standard used for accreditation and the accreditation body’s relevant policies and procedures, must always be escorted by the accreditation experts (assessors) (“Escorted” means close supervision throughout the assessment activity).*

**Assessor-in-trainee** - new employee, approaching process of recruitment for assessor.

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

*Note:* *assessments performed by ARMNAB (initial, supplementary, surveillance, programmed and extraordinary, extension, reaccreditation) for the purpose of granting, maintenance, extension and renewal of accreditation.*

**Reaccreditation -** assessment performed to renew the accreditation cycle.

**Surveillance** - set of activities, except reassessment, to monitor the continued fulfilment by accredited CABs of requirements for accreditation.

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

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

**Nonconformity -** deviation of the fulfillment of accreditation criteria (requirements), which has or may have a direct impact on the results of conformity assessment activities.

**Major nonconformity** (MJN) – non-fulfillment of accreditation criteria (requirements), which has principal importance for the outcomes of activities.

**Minor nonconformity (MN)** – deviation from the fulfillment of accreditation requirements (minor mistake), which does not affect the outcomes of CAB’s activities.

**Correction -** action initiated to eliminate the identified nonconformity.

*Note 1: Correction may be implemented in combination with a corrective action.*

**Corrective action -** action initiated to eliminate the cause of the identified nonconformity or another undesirable situation.

*Note 1: Nonconformity may be caused by several reasons.*

*Note 2: Corrective action is initiated to prevent the reoccurrence of an incident, whereas preventive action aims to prevent the occurrence of the incident.*

*Note 3: There is a difference between correction and corrective action.*

**3.2 Acronyms**

|  |  |
| --- | --- |
| ARMNAB | “National Accreditation Body” SNCO |
| CAB | Conformity Assessment Body |
| AC | Accreditation Committee |
| ATC | Advisory Technical Committee |
| ISO | International Organization for Standardization |
| EAEU | Eurasian Economic Union |
| EA | European Cooperation for Accreditation |
| GOST | Interstate standard |
| AST | Standard of the Republic of Armenia |
| ILAC | International Laboratory Accreditation Cooperation |
| IAF | International Accreditation Forum |

# 4. REQUIREMENTS AND INFORMATION FOR ACCREDITATION

# 4.1 General information

4.1.1. Any person/CAB may send to ARMNAB a request – written, verbal or electronic – to find out about accreditation.

Upon receipt of the request, ARMNAB gives the website address – [www.armnab.am](http://www.armnab.am) – where it can download the list of ARMNAB documents.

When necessary, it is possible to arrange a preliminary meeting at ARMNAB’s office to explain the accreditation process to the interested person/CAB. These meetings do not involve any commitment by either party and they shall not involve any form of consultancy.

**4.1.2** The CAB registered in the Republic of Armenia is not allowed to apply to the accreditation body of another state, if the ARMAB can carry out the accreditation of the given scope, taking into account the requirements of regional and international accreditation organizations (cross border).

**4.1.3** If ARMNAB receives an application for accreditation by CAB located abroad, Regulation (CE) 765/2008 is applicable as well as the ARMNAB PL-09 “Policy for Cross border accreditation” and also the relevant EA/IAF/ILAC documents.

**4.1.4** The applicant CAB shall be a legal entity. Is considered to be a legal entity also the public legal person (e.g.: regions, provinces and commons, public economic entities, public institutional entities such as universities, etc).

For foreign CABs the definition of a legal entity applied in the country in question is applicable as per the national legislation.

Physical persons shall not present an application for accreditation.

**4.1.5** A legal entity seeking accreditation submits a separate accreditation application with attached documents to the ARMNAB through the electronic accreditation system, and in case of its impossibility, by e-mail.

**4.1.6** CABs are accredited to carry out conformity assessment activities in voluntary and/or regulated fields in accordance with the requirements of their applicable standards and other documents specified in the scope of accreditation.

**4.1.7** In all cases where the scheme is not based on an official standard or on para- or pre-normative documents issued by official standardization bodies the scheme shall be presented to ARMNAB by the scheme owner. ARMNAB, prior to starting accreditation or extension activities carries out a thorough review of the new scheme in conformity with the procedure PR-4.6.3.

# 5. General provisions

**5.1** Assessment of the CAB competency by the ARMNAB covers the following stages:

1. Acceptance of application for accreditation; Resource’s review, decision-making on application; Review of the set of documents submitted with the application and registration (if sufficient);
2. Conclusion of a contract for a preliminary visit, preliminary visit (upon the request of an applicant in case of initial accreditation) and preparation of a report;
3. Preparation and signing of a pre-accreditation contract, Documents and records review, review of amended documents (if necessary), preparation of a report;
4. Preparation for assessment (assessment team formation, assessment plan development and agreement with CAB), on-site assessment (including witnessing), additional on-site assessment (if necessary), analysis of the assessment results and preparation of the report;
5. Decision-making on granting of accreditation/reaccreditation, registration of Accreditation certificate, signing of accreditation contract, issuance of accreditation certificate scope and accreditation symbol;
6. Surveillance of the accredited bodies.

**5.1.1** In justified cases (inability to work, planned leave, business trip, postponement of the dates set by the PT provider, repairs, etc.), on the recommendation of the CAB or ARMNAB, clause 5.1 of this procedure 1), 3), 4), 5) the period of each stage defined by sub-paragraphs may be extended no more than 1 month, but the total period of extension of the specified stages may not exceed 2 months.

# 5.2 Duration of accreditation process

# 5.2.1 The process of accreditation/reaccreditation/extension should be completed no later than 16 months starting from the day of application registration, except for the cases defined by the "ARMNAB goals" document.

# 5.2.2 The accreditation process and deadlines are set out in Annex D.

**5.3 Accreditation application, documents**

# 5.3.1 For the purpose of accreditation, the CAB submits the accreditation application and attached documents to ARMNAB (at the time of extension of accreditation, only those documents related to the extension of accreditation are attached to the application) according to the forms established by ARMNAB, which are posted on the official website [www.armnab.am](http://www.armnab.am).

# NOTE: After the launch of the automation of accreditation (e-accreditation) program and the transition period provided to the CABs, in accordance with the policy of ARMNAB P-01-02 "On transition to electronic accreditation (e-Accreditation) of accreditation subjects in the field of conformity assessment", accredited/seeking accreditation legal entities shall apply to ARMNAB for accreditation through the electronic accreditation system, and in case of its impossibility, by e-mail.

**5.3.2** The forms of application and attached documentsare available in document annexes PR-7/ATL-01, PR-7/ACB-01, PR-7/ACB-02, PR-7/ACB-03, PR-7/ACL-01, PR-7/AIB-01, PR-7/APT-01.

For each CABs, the ARMNAB has developed a separate form for application and attached documents.

**5.4 Acceptance of documents attached to the accreditation application, resources review, registration of the accreditation application**

# 5.4.1 Within 8 working days the ARMNAB's Team leader, selected through the electronic accreditation system or by Deputy Director, checks the completeness of application and related documents according to Annex PR-7-08, as well as reviews resources in line with annex PR-7-10.

**5.4.2** In case of not conforming to established templates of ARMNAB or incompleteness of application package, ARMNAB notifies to CAB within 5 days submit the updated documents, otherwise the registration of application is rejected.

**5.4.3** Resource reviews is performed during accreditation, re-accreditation and accreditation extension.

The Team leader reviews the resources.

The resource review includes:

- review of the draft scope of accreditation;

- evaluation of ARMNAB’s ability to carry out accreditation in the required volume and within the scope of ARMNAB activity;

- evaluation of ARMNAB ability to carry out accreditation within the deadlines stipulated by this procedure;

- review of availability and accessibility of Accreditation experts (assessors), including technical assessors, technical experts.

After the Team leader’s positive decision, the "Resource Review" form is signed by the head of the Accreditation department and Deputy director.

**5.4.4** The resource review includes verification of ARMNAB ability to conduct an assessment in a timely manner. In case of absence of resources, additional conditions are set (for example, extension) under which the ARMNAB may involve a foreign assessor(s)/ technical expert(s) in the accreditation process. After discussion with the CAB, ARMNAB considers the accreditation application accepted or rejects it notifying the CAB within 3 working days.

If, as a result of resource review, there is a need to expand the scope of ARMNAB activity, this is done in accordance with PR-4.6.4.

# 5.5 Preparation for the assessment

**5.5.1** After registration of the application for accreditation, a pre-accreditation contract is signed between ARMNAB and CAB in accordance with the form approved by ARMNAB (Appendix PR-7-01), which stipulates the payment for the documents review (according to the procedure for calculating the prices of accreditation works, order N 311-N, Minister of Economy), the accreditation process begins.

**5.5.2** Failure to make the payment specified in the contract is a basis for rejecting the accreditation of the CAB.

**5.5.3** After signing the pre-accreditation contract and making the payment by the CAB, within 5 working days ARMNAB forms an assessment team consisting of the Team leader, who is a full-time employee of the ARMNAB and appropriate number of accreditation expert (assessor), technical assessor and technical expert corresponding to the CAB scope. The selection of technical assessors/experts is done in such a way that their competence covers the entire scope of accreditation. The number of members included in the assessment team depends on the complexity and volume of the accreditation scope.

**5.5.4** The team may also include newly recruited employees of ARMNAB as trainee assessors and/or observer.

Observers are also members of the expert assessment team consisting of assessors of accreditation bodies of other countries for the purpose of concluding bilateral/multilateral recognition agreements, the representative(s) of the ARMNAB (for monitoring and other purposes).

**5.5.5** For the formation of assessment team the team leader conducts a written and/or oral inquiry to the accreditation experts (assessors), technical assessors and technical experts, from the relevant registers, taking into account the following criteria:

− knowledge of the accreditation requirements applied to the CAB;

− knowledge of the fields (technical activity) of the scope applied for accreditation;

− experience in conducting assessments;

− their availability.

# NOTE: After the launch of the on-line accreditation (e-accreditation) program, the assessment team leader and members will be randomly selected by an automated system based on their scope of competence, employment, monitoring results, impartiality risks and other factors.

**5.5.6** The candidate for the assessment team agrees to participate in the assessment, taking into account the risks affecting impartiality (according to PL-08) and confirming that:

a) during the last three years:

1. not provide consultancy to the CAB;

2. not have joint contracts, including the organization with the organization;

3. not have common real estate;

4. not have common management;

b) not have any friendship and kinship with the management and staff of an accredited/accrediting CAB.

**5.5.7** After obtaining approval from all selected candidates to the assessment team, prepares a draft of the assessment team composition in order to send it to the CAB for agreement.

In case of a positive answer received from more than 2 candidates with the same knowledge, the member of the assessment team is selected by the Deputy director, taking into account the criteria specified in 5.5.5.

**5.5.8** The ARMNAB should informs the CAB on the members of assessment team in order to give opportunity to object in written form against the appointment of the assessors or technical experts with justification. CAB submits its consent within 3 working days after receiving the notification or, for reasonable reasons, objects to the appointment of a specific assessor and/or expert, but not more than twice, in accordance with ARMNAB policy PL-02.

If the CAB does not receive a response within 3 working days, it is considered that there is no objection to the assessment team.

**5.5.9** If the justification by the ARMNAB is valid the member(s) of the assessment team, the replacement is confirmed with the CAB.

**5.5.10** The team leader selects a new candidate in accordance with paragraph 5.5.5 of this procedure.

**5.5.11** In case of absence of accreditation expert (assessor), technical assessors and technical experts, in the relevant registers by the proposal of ARNBAB and agreement of the CAB in assessment team may be included foreign assessor/technical expert.

**5.5.12** In case of necessity to involve foreign assessor/technical expert in the assessment team, the deadlines may be subject to change.

**5.5.13** During the assessment stages, if necessary, the composition of the assessment team can be changed (increased or reduced) based on the results of the assessment of the CAB’s accreditation scope and related documents.

**5.5.14**  All assessments (surveillance, extraordinary, etc.) carried out during the accreditation cycle of the CAB are carried out through the same assessment team, if for any valid reason (for example, incapacity, employment, vacation, etc.) they refuse to participate in the assessment. In such a case, the accreditation expert (assessor), technical assessor/expert is replaced by another evaluator/expert with the same knowledge/competence.

**5.5.15** The assessment team members sign Declaration of impartiality and confidentiality, according to Annex A, according to which they are obliged to follow the requirements of impartiality, independence, confidentiality and absence of conflict of interest.

**5.5.16** **The ARMNAB doesn’t provide assessments through subcontracting**.

# 5.6 Preliminary visit

**5.6.1** The preliminary visit is not an obligatory stage of the accreditation process. Prior to starting the on-site assessment process, with the agreement of the CAB, it is possible to conduct a preliminary visit. The preliminary visit is done within 5 working days after the registration of the application and signing of a relevant contract (Annex PR-7-00) between the parties. The visit is done after the submission of the document evidencing the payment of the fee provisioned by the contract.

**5.6.2** The preliminary visit can be carried out by the ARMNAB accreditation expert (assessor) alone, and if necessary (depending on the complexity of the accreditation scope), an assessment team is formed within 1 working day in accordance with clause 5.5.5 of this procedure.

**5.6.3** Assessment team leader develops a plan for preliminary visit (PR-7-06), which includes the list of issues to be discussed and the timeframe of the visit.

**5.6.4** Assessment team leader/assessment team conduct document review within 2 working days.

**5.6.5** The on-site assessment starts with the opening of the meeting, which reflects on:

- purpose of the visit;

- criteria of accreditation;

- introduction of assessment team members.

**5.6.6** The preliminary visit helps to identify the consistence of the CAB management system to accreditation requirements, as well as correspondence of the technical equipment available in the organization to the requirements set for the scope of accreditation.

**5.6.7** During the preliminary visit, the provision of advice by evaluators/experts should be excluded, as they may be included in the accreditation process of the respective CAB.

**5.6.8** After the preliminary visit the team leader prepares a report (Annex PR-7-PR) and provides it to the CAB within 1 working day. No corrective action is required by the CAB.

**5.6.9** After receiving the report, the CAB can withdraw the accreditation application by submitting a letter on the termination of the accreditation process and paying for the work done until then, or continue the accreditation process.

**5.6.10** All documentation related to the preliminary visit (application for preliminary visit, list of assessment team members, report, plan of the preliminary visit) are kept with the assessment team leader and are taken into consideration during the CAB accreditation process.

# 6. ACCREDITATION PROCESS

# 6.1 Document review

**6.1.1** According to the order of ARMNAB director, begins the CAB's document reviw stage.

**6.1.2** Document reviw is carried out electronically and (or) through a meeting of assessment team members and is coordinated by the team leader. The team leader distributes the amount of work on the document review among the team members.

**6.1.3** The assessment team reviews the CAB’s documentation within 30 working days to evaluate its conformity with the relevant standard and accreditation requirements, as a result of which a report/conclusion is compiled (according to annexes ACB-01-01-DR, ACB-02-01-DR, ACB-03-01-DR, ATL-01-01-DR, ACL-01-01-DR, AIB-01-01-DR, AIB-02-01-DR, APT-01-01-DR).

Accreditation experts (assessors), technical assessors submit reports in the forms approved by the ARMNAB, and technical experts in the voluntary forms (signed, scanned versions are accepted).

**6.1.4** During the review, it may become necessary to obtain additional materials and information from the CAB. In this case, the team leader sends the request (in any convenient way) to the CAB for additional documents/records.

**6.1.5** As a result of document review, a report is drawn up and submitted to the CAB. If the nonconformities found as a result of the document review don’t affect the continuation of the assessment (they are minor), then after receiving the agreement from the CAB and making the payment for the on-site assessment, the process of preparing the on-site assessment begins. In that case, checking of the effectiveness of elimination of nonconformities found during the document review is carried out during the on-site assessment or after.

**6.1.6** ARMNAB verifies the payment specified in the pre-accreditation contract (in terms of carrying out the on-site assessment process) through the treasury online system. In case of non-fulfilment within the period specified by the pre-accreditation agreement, the accreditation of the CAB is rejected.

**6.1.7** If the CAB is not ready to accept the assessment team or as a result of the document review, such nonconformities are found that may affect the continuation of the assessment (major), then a 50-working day period is given to eliminate the nonconformities and provide the amended documents to the ARMNAB. The failure to submit complete/compliant version of the documents may be deemed as ground to rejecting the accreditation.

**6.1.8** Upon submitting the complete version of application by the CAB, the assessment team holds additional examination of the documents within 20 working day and prepares a report on the results of examination according to Annexes ACB-01-02-DR, ACB-02-02-DR, ACB-03-02-DR, ATL-01-02-DR, ACL-01-02-DR, AIB-01-02-DR, AIB-02-02-DR, APT-01-01-DR.

Accreditation experts (assessors), technical assessors submit reports in the forms approved by the ARMNAB, and technical experts in the voluntary forms but only with those points where nonconformities were found (signed, scanned versions are accepted).

**6.1.9** In case of negative results (report) of the additional examination of the documents within 10 working days, the AC makes a decision on the rejection of accreditation and the CAB is notified about it.

# 6.2 Assessment

**6.2.1** In case of positive results of the document review the assessment team leader jointly with the assessment team members drafts an on-site assessment plan (Annex PR-7-06) within 5 working days approved by the ARMNAB director.

**6.2.2** ARMNAB takes into account the risks associated with the assessment activities, the locations of those activities, and the staff being evaluated within the accreditation scope (see point 7.2.1). To identify risks that may lead to improper assessment, before the assessment, the team leader and the assessment team members fill out the sheet "Assessment of impartiality risks".

**6.2.3** The scope, schedule, and functions of all members of the assessment team are determined by the team leader through the preparation of an assessment plan (program) in accordance with Annex PR-7-06.

The assessment plan includes the activities to be evaluated, the place(s) of the activity to be performed, the staff to be evaluated, assessment techniques, including witnessing (if necessary). If during the assessment period it is not possible to organize witnessing activity (in the absence of applicant for certification, inspection), a simulation is indicated. If it is not possible to organize witnessing of the activities of the CAB during the assessment period (in case of absence of certification, technical control application(s) by the applicant), the CAB shall be accredited on the condition that it shall inform the NAB for the latter to perform witnessing upon accepting the first application, but no later than within a year (before the next surveillance), at least one representative sample (scheme, object of surveillance, etc.) shall be assessed in line with the accreditation scope. During the accreditation cycle, the number of witnessing of the activities of the CAB and staff is set to assess the entire scope of accreditation/extension.

**6.2.4** The assessment plan shall be agreed with the CAB within 3 working days. If the CAB doesn’t send a response within 3 working days, it is considered that there is no objection to the assessment plan.

**6.2.5** The assessment is carried out in accordance with this procedure and depending on accreditation schemes according to PR-7/ATL-01, PR-7/ACL-01, PR-7/ACB-01, PR-7/ACB-02, PR-7/ACB-03, PR-7/AIB procedures, in order to confirm the conformity of the management system and the technical competence of the CAB with the accreditation requirements.

The assessment includes the following steps:

– opening meeting;

– assessment of the CAB competence according to the accreditation scheme;

– closing meeting.

**6.2.6** All locations where the CAB carries out conformity assessment activities, CAB staff, directions of conformity assessment activities are assessed. The selection of objects to be evaluated (representative sample) is carried out in accordance with the clause 7.2.1 and Annex B.

**6.2.7** Prior to the assessment, the team leader shall ensure that all members of the assessment team have up-to-date versions of the documents setting out the accreditation criteria required for the assessment, informing them of the results of previous assessments (if available).

**6.2.8 Opening meeting**

**6.2.8.1** Assessment begins with a preliminary meeting that is attended by the members of the assessment team (according to the time schedule of the assessment plan) and representatives of the CAB and observers (if any).

**6.2.8.2** At the preliminary meeting, the objectives of the assessment and the criteria for accreditation are clearly established; the plan and scope of the assessment are confirmed.

**6.2.8.3** At the preliminary meeting, the team leader:

− represents the members of the assessment team and their functions;

− informs the CAB about the objectives of assessment, accreditation criteria, assessment procedures, documentation of assessment results;

− provides information on the appeal procedure;

− communicates the assessment plan to the representatives of the CAB, makes sure that the plan is correctly understood; the plan and scope are confirmed;

− clarifies the time schedule for assessment;

− agrees on the methods of interaction of the assessment team with the representatives of the CAB;

− clarifies the date, time and participants of the final meeting with the representatives of the CAB, if necessary, dates and time of other meetings;

− informs the CAB about the observance by all the members of the assessment team of confidentiality of the information received during the CAB assessment;

− transfers to the present members of the assessment team and observers a confidentiality statement for signing (Annex A);

− gives the floor to the representatives of the CAB for an opportunity to ask questions of interest or express their opinion;

− draws up the minutes of the preliminary meeting in the form specified in Annex PR-7.11.

**6.2.8.4** If necessary, the assessment plan may be adjusted at the opening meeting. When making adjustments to the assessment plan, the necessary additions and amendments are specified by the team leader in the minutes of the preliminary meeting.

The representative of the CAB informs the assessment team of up-to-date information on its activities, including information on the activities of the organization, which includes the CAB (if any).

**6.2.8.5** In the absence of some members of the assessment team at the preliminary meeting (according to the time schedule of the assessment plan), a meeting with them (interim meeting according to the assessment plan) is held immediately upon their arrival at the CAB in the presence of the representatives of the CAB.

**6.2.8.6** In case of refusal by the CAB (at the preliminary meeting) to conduct assessment, assessment does not continue, the team leader draws up the minutes of the preliminary meeting, which indicates this information, prepares documents for consideration by the AC for decision making regarding the CAB.

**6.2.9 CAB’s competence assessment**

**6.2.9.1** The assessment in the accreditation process is based on the standard, requirements of EAEU, IAF, ILAC, EA and ARMNAB and the requested scope of accreditation. The ARMNAB assesses the CAB in respect of the technical competencies and the management system, paying attention to the CAB’s impartiality and independence and ensuring reliability of the conformity assessment services.

**6.2.9.2** The Technical expert(s) shall carry out the assessment under the supervision of the assessment team leader or technical assessor(s).

**6.2.9.3** In assessments ARMNAB applies one or a combination of the following assessment techniques:

a) **Document review** – checking of the CAB’s application and documentation.

Document review is an assessment of one process from its beginning to its completion.

The document review is used to assess the effectiveness of the functioning of individual elements of the CAB’s management system.

During document review assessors assess in detail how each of procedure is conducted, without being distracted by interrelated processes. The advantage of this assessment is the ability to assess in detail all the actions of one process, all accompanying documentation on this process, all the personnel involved in this process.

During initial accreditation and re-accreditation, a document review of all elements of the CAB’s management system is carried out.

During surveillance of competency the following elements of the CB management system are included in the assessment plan: impartiality requirements, resource requirements, complaints and appeals, management reviews, internal audits, nonconformities, and corrective actions, as well as organizational changes and MS documents changes.

When extending accreditation, besides team leader, technical assessors/experts who are competent for the activities subject to extension are also included in assessment team and the CAB assessment is carried out for those elements of the management system that have been amended as a result of the expansion of accreditation and for the entire additionally declared area of accreditation.

In case of an extraordinary assessment of competence, the assessment plan shall include those elements of the CAB management system which are affected by the appeal which requires unscheduled assessment.

During the preliminary assessment of competency, the following elements of the CB management system are included in the assessment plan: impartiality requirements, resource requirements, organizational structure, complaints and appeals, management review, internal audits, nonconformities and corrective actions, document control.

**b) File (Case) review** - checking of the CAB’s reports and related documents (in papers and/or electronic).

File (Case) review is a complete assessment of all aspects of testing/calibrations/inspections/certifications/declarations registration for the selected representative test/calibration/inspection/certifications/declaration registration sample/ method/scheme.

File (Case) review is used to assess the technical competence of the CAB in carrying out the test/calibrations/inspections/certifications/declaration registration for the selected representative sample/method/scheme and assessment of the performance of the CAB’s management system regarding the selected representative method.

Case review includes competency assessment of the CAB in carrying out tests/calibrations/inspections/certifications/declaration registration for a selected representative sample/ method/scheme in practice using various combinations of assessment techniques (interview, record review, analysis of participation in proficiency testing programs and interlaboratory comparisons).

During case review, the assessment team carries out a record review of the CAB regarding the testing/calibration/inspection/certification/declaration registration of the selected representative sample/method/scheme.

The file review technique is used when conducting the CAB surveillance.

- the number of conformity assessment documents issued/registered by the CAB in one object/technical regulations/product group, etc., defined by the scope of accreditation in case of 1-3, then all documents are analyzed;

- if the number of conformity assessment documents is 4-11, then no less than 3 documents are analyzed not less than 2;

- if the number of conformity assessment documents is 11 or more, no less than 4 documents are analyzed.

*Note: In the event of nonconformities found in the records (case) analysis, the assessment team may request additional files to detect recurring discrepancies.*

**c) On-site assessment** – visiting of CAB’s working area/branch, sites.

During initial accreditation and extending accreditation, the assessment is conducted at all sites of the CAB’s activities in the scope applied for accreditation. Remote assessment is possible only in justified cases.

During the preparation for surveillance and re-accreditation, in the presence of several locations of the CAB, the assessment team selects the sites for the assessment, taking into account selected representative test/calibrations/inspections/ certifications/declaration registration samples/methods/schemes.

During surveillance and re-accreditation, the assessment is carried out in the main office of the CAB, as well as in the production facilities of the CAB, where test/calibration/inspection/certification/declaration registration activities are carried out for selected representative samples/methods/schemes/.

During selecting of the assessment locations, the results of previous assessments are taken into account so that during the accreditation cycle all sites of the CAB’s activities in the scope applied for accreditation were assessed at least once (the main site of activity is assessed at each assessment, additional sites at least once during the accreditation cycle).

**d) Witnessing** - observation by the accreditation body of a CAB carrying out conformity assessment activities within its scope of accreditation.

Witnessing of tests/calibrations/inspections testing can be carried out using:

- real samples of testing/calibrations/inspections when performing the current activities of the CAB;

- product specimen (for testing) sampled in the presence of a technical assessor/expert or provided by assessment team;

- standards (for calibration laboratories).

This technique can be used in combination with measurement audit technique.

During sampling for witnessing, it is possible to credit the results of participation in the PT and ILC, provided that the laboratory provides documentary evidences. In case of positive results of participation in the PT by a representative methods are not carried out.

Witnessing rule products, management systems and persons certification bodies are set out accordingly in PR-7/ACB-01, PR-7/ACB-02, PR-7/ACB-03, for inspection bodies - in PR-7/AIB-01, for PT provider – in PR-7/APT-01.

The witnessing technique shall not be used during the process of declarations registration. Only the techniques of document review, records review, conducting interviews and on-site assessment shall be used.

If there are no certification/inspection applications during the assessment period, a simulation is indicated before the first application is received. Upon receipt of the first application for certification/inspection, the CAB shall apply in writing to the ARMNAB to arrange Witnessing.

**e) Interviewing** – conversation with the CAB's personnel.

Interviewing is the competency assessment of the CAB personnel, the assessment of their knowledge and skills, carried out by direct oral communication of the assessor with the CAB personnel.

During accreditation, periodic assessment of competence, extending accreditation, re-accreditation, assessment of a CB by applying interviewing technique is usually carried out in combination with other techniques: witnessing and (or) file review.

**f) Remote assessment** - assessment of the physical location or virtual site of a TL using electronic means (e. g. Skype, Viber, etc.).

Remote assessment can be carried out in the following cases:

- when on-site assessment is not possible due to unforeseen, Epidemic diseases, force majeure situations related to the current inability to physically visit the CAB (due to a threat to the safety of members of the assessment team, travel restrictions, etc.);

- if it is necessary to conduct additional assessments, but there is difficulties to implement trips in a short time.

- other justified cases.

The remote assessment is carried out by the team leader after analyzing the risks and making a positive decision according to the Annex PR-7-14.

Remote assessment is not carried out in the following cases:

- initial accreditation/re-accreditation, extension of accreditation;

- changes in accreditation criteria, changes in the CAB location (for laboratories);

- changes in the main staff of the CAB;

- if remote assessments are not permitted for a given standard or conformity assessment scheme;

- if the assessment objectives cannot be achieved through remote assessment.

Conducting a remote assessment, as well as taking notes during a remote assessment, is carried out in accordance with this procedure and requirements set out in the IAF MD 4, IAF ID 12 documents, provided that the CAB makes available electronically documented information to the assessment team and provides virtual interactions, including audio and video recordings as well as resources (personnel and tools).

If during the remote assessment, the assessment team determines that the assessment objectives cannot be achieved, the remote assessment process is stopped and an on-site assessment is organized.

**g) Analysis of participation in proficiency testing programs (PT), interlaboratory comparisons (ILC) and other measures** – assessment testing/calibration results through interlaboratory comparisons (ILC), PT providers or other measures.

During the assessment of the competence of laboratories for the representative method selected for assessment, ARMNAB takes into account the results of participation in the PT, ILC and other measures taking into account PL-05, ILAC P9 Polices and EA 4/18.

During sampling for witnessing, it is possible to credit the results of participation in the PT, ILC and other measures provided that the laboratory provides documentary evidences:

- obtaining positive results of participation in the PT, ILC, other measures by a representative method;

- participation plan in the PT, ILC and other measures (taking into account the ARMNAB Policy on the frequency of participation in the PTs, ILCs and other measures);

- Information on staff participating in PT, ILC and other measures.

**h) Validation audits** - Assessment, during which the validation processes carried out in the CAB are evaluated, as well as reports published as a result of validation, and decisions made.

This assessment technique can be carried out both in the examination of documents and in the on-site assessment.

**i) Measurement audits** – a measurement audit is the assessment carried out by comparing the results obtained during testing/calibration/inspection of the assessed CAB with the results of the reference CAB taking into account the measurement uncertainties assigned to the reference value and the measurement uncertainty reported by the assessed CAB.

In this case, the witnessing of testing/calibrations/inspections/proficiency testing can be carried out using:

- certified reference material with known values;

- samples with specified parameters/characteristics (encrypted samples) provided by the assessment team, while the person to be assessed does not know the parameters/characteristics specified (mutual application of measurement audit techniques).

**j) unannounced visits -** is carried out without prior planning and informing the CAB. An assessment is carried out in the event that ARMNAB receives a complaint about the activities of the CAB or in case of reasonable suspicions by ARMNAB, which may have an impact on the reputation and accreditation results of ARMNAB.

The unannounced visit shall at least include an assessment of compliance with the requirements stated in the information received.

**6.2.9.4** The assessment duration depends on the CAB evaluation objectives, scope (number of conformity assessment methods to be evaluated, places, resources, evaluation criteria (relevant standard (s), etc.).

**6.2.9.5** When conducting assessments, the members of the assessment team should not request copies of the documents to be analyzed, evaluated from the CAB, except when it is necessary to present objective evidence of nonconformities or objections by the CAB. In such cases, copies of the documents are attached to the nonconformities sheets. The assessment team shall keep the documents of the CAB that are documents attached to the application, the sampling acts recorded as a result of assessment the activities of the CAB and analyzing the records, test reports, conclusions, certificates, declarations, qualification inspection reports, statistical analyses, etc.

**6.2.9.5.1 Team leader:**

- manages the entire assessment process;

- assesses the CAB management system, through which it is possible to confirm and demonstrate the continuous fulfillment of the requirements of the standard(s) and/or other regulatory (normative) documents, which define the activities of the CAB and the quality assurance of the work performed within the scope of accreditation,

- in order to be included in the EAEU joint register, they also assess the compliance of the Government of the Republic of Armenia February 13, 2020 Annex to Decision N 152-N (Decision No. 100 of the EAEU Council of 5 December 2018) and K-07 requirements;

- check correct use of the ARMNAB accreditation symbol (in case of re-accreditation, surveillance, extraordinary assessment).

**6.2.9.5.2** The accreditation expert (assessor) assesses the part of the documented management system of the CAB, which is not assessed by the team leader (those points of the management system are indicated in the report prepared by ARMNAB).

**6.2.9.5.3 Technical assessors:**

- assess the competence of the relevant staff, the adequacy of the facilities, equipment, systems and support services needed to carry out activities in the scope of accreditation;

- assess compliance with CAB staff selection, training and monitoring requirements;

- assess the knowledge, skills and abilities of CAB staff in accordance with their powers as defined in their documents;

- assess the availability of materials provided by CAB documents, the awareness of staff eligible to work in the field of accreditation, including those who submit, analyze the results of conformity assessment, provide feedback, make decisions, approve results, develop, modify, test, check, validate methods,

- check the measuring instruments, ensure the metrological traceability (according to PL-06),

- carry out with the CAB activities from sampling/sample preparation to recording/ recording of results (protocol/report/certificate/conclusion/sampling act, etc.);

- check the accuracy of the results of the accredited/accredited CAB compliance activities (protocol/report/certificate/conclusion/sampling act, etc.);

- assess the process of cooperation with inquiries, applications, tenders, contracts, bidders or their representatives, including the correct application of methods for the implementation of CAB activities, to assess measurement uncertainty, if necessary;

- analyze the results of CAB (where applicable) PT tests, interlaboratory or other comparisons, used as a tool to assess the quality of CAB work;

- check the validity of the applied regulations, methods, other documents, their accessibility to the CAB staff,

- check the records corresponding to the CAB processes, etc.

**6.2.9.5.4** A technical expert works under the responsibility of the team leader or technical assessor and shall be competent and able to prove from a technical point of view representative objects selected for the purposes of the assessment.

**6.2.9.6** Assessment also includes the witnessing of conformity assessment activities by members of the assessment team (e.g. certification process, testing, inspection, sampling, etc.) to determine CAB competence and the results are included in ATL-01-TWR, ACL-01-CWR, ACB-01-PWR, ACB-02-MWR, ACB-03-AWR, AIB-01-WR, AIB-02-WR, APT-01- In WR reports.

**6.2.9.7** Witnessing of conformity assessment activities may also be carried out separately from the assessment period (if no applications were received during the assessment period) in accordance with the CAB letter.

**6.2.9.8** Prior to the closing meeting, the assessment team, without the presence of representatives of the CAB, conducts an analysis of all the information and objective evidence collected from the analysis of documented information and assessment to determine the competence of the CAB based on its conformity with the accreditation requirements; makes a decision on the classification of findings, draws up a sheet(s) of nonconformities, discusses the information that will be announced by the assessment team at the closing meeting.

**6.2.9.9** In case of nonconformities are drawn up nonconformities sheets (point 1 of Annex PR-7-NCR is filled).

Any nonconformity stated must be related to the requirements of a standard or another document containing the accreditation requirements.

The nonconformities are classified into two types: major and minor.

The assessment team may provide **suggestions for improvement**, which do not involve counseling. If the suggestions for improvement are not accepted by the CAB, they may be classified as a minor non-conformity during the next assessment.

A description of the classification of nonconformities, ARMNAB and CAB operations is given in Annex C.

**6.2.9.10** Sheet(s) of nonconformities (if any) are drawn up in copy and signed by the members of the assessment team and/or team leader who identified the nonconformity. Point 1 of the nonconformities sheets is completed during the assessment and agreed with the representative of the CAB. The copy of the nonconformities sheet shall be provided to the CAB and an original to the team leader.

**6.2.9.11** In case of refusal to sign the sheet(s) of nonconformities by the CAB representative, the team leader will enter this information into the minutes of the final meeting (Annex PR-7-12) for discussion in ARMNAB.

**6.2.9.12** During the assessment, the activities of the members of the assessment team can be monitored according to the PR-6.1.3 procedure.

**6.2.9.13 Closing meeting**

**6.2.9.13.1** At the closing meeting, the following persons should be present:

− members of the assessment team (according to the time schedule of the assessment plan);

− representatives of the CAB, including the management and quality manager (the composition of those present is determined by the CAB);

− observers (if any).

**6.2.9.13.2** At the final meeting:

− the team leader informs the management of the CAB about the results of the assessment, including information on the implementation of the assessment plan, presents positive aspects and achievements of the CAB, comments;

− members of the assessment team present findings (if any) identified during the assessment and explain the importance of all identified nonconformities/risks, receive confirmation of a full understanding of the identified nonconformities/risks by the CAB.

The representative of the CAB is provided with an opportunity to ask questions about the identified nonconformity(s), to receive clarifications on the finding, including, if any, nonconformities and their justification.

The team leader summarizes the results of the assessment, agrees on the development and submission deadline for the approval of corrective actions/corrections (within 10 working days after receiving the ARMNAB report), as well as the deadline for the implementation of corrective actions/corrections to eliminate the nonconformities (within 50 working days after receiving the ARMNAB report) identified during the assessment from the date their coordination with the team leader.

The team leader informs the representatives of the CAB that they need to fill in, sign and send the nonconformities sheets item 2 (cause of the nonconformity and corrections/corrective actions) to ARMNAB in electronic version.

The team leader explains the interaction between the representatives of the CAB and the accreditation body after the assessment and draws up the minutes of the final meeting in the form specified in Annex PR-7-12, which is signed by the members of the assessment team and the representatives of the organization/CAB.

**6.2.9.14 Analysis of results and reporting**

**6.2.9.14.1** After closing meeting, assessment team within 5 working days (in case of surveillance, extraordinary assessment - 3 working days) submit their reports/conclusions to the team leader.

Accreditation experts (assessors), technical assessors submit reports in the forms approved by the ARMNAB, and technical experts in the voluntary forms (signed, scanned versions are accepted).

**6.2.9.14.2** The team leader analyzes the results of the assessment within 10 working days following the term provided by the assessment plan (program), taking into account the reports/conclusions of the assessors/experts (accepted prepares the signed assessment report) prepares the on-site assessment report according to Annexes ACB-01-R, ACB-02-R, ACB-03-R, ATL-01-R, ACL-01-R, AIB-01-R, AIB-02-R, APT-01-R, in 2 copies - one of which is provided to the CAB, the other is kept in the CAB accreditation folder.

Ungrounded, unsubstantiated conclusions of technical experts the team leader may not be included in the final report.

**6.2.9.14.3** In case of identification of nonconformities by the assessment team the CAB within 10 working days develops and submits to the ARMNAB a corrective actions program (according to Annex PR-7-09) composed on the basis of nonconformity lists.

After receiving the nonconformity sheets filled out by the CAB within the specified period, the team leader agreed with the assessors/experts who found the nonconformities the correct wording of the causes of the nonconformities filled by the CAB, the sufficiency of the corrections/corrective actions and the deadlines for eliminating the nonconformities, the team leader filled the corresponding column of corrective actions program.

If the members of the assessment team do not agree with the corrections/corrective actions and/or deadlines, appropriate notes are made in the "Note" column of corrective actions program and the team leader informs the head of the CAB about the need to revise the corrective actions. The nonconformities (content) of corrections/corrective actions is re-formulated by the CAB and provided to the ARMNAB for approval. The revision by the CAB and coordination with the ARMNAB should not exceed the deadline of 10 working days after receiving the report.

**6.2.9.14.4** 50 working days are given after the report is provided to the CAB to eliminate nonconformities (in the case of surveillance, extraordinary assessments - 25 working days are provided for the development of corrections/corrective actions by the CAB, submission to ARMNAB, agreement, elimination of nonconformities) regarding them to submit the report with attached evidence as per Annex PR-7-CA developed by ARMNAB. The failure to submit information on the elimination of nonconformities within the set period of time is deemed as a ground to refuse the accreditation by the ARMNAB.

**6.2.9.14.5** After receiving the report on the elimination of nonconformities with the attached evidence within the specified period, ARMNAB provides it to the assessment team. Within 10 working days (including surveillance, extraordinary assessments), the assessment team conducts an additional assessment by studying the received information and, if necessary, conducts an additional on-site assessment.

If the actions undertaken by the CAB to eliminate nonconformities are insufficient, the assessment team may require additional information.

**6.2.9.14.6** Additional on-site assessment is carried out if:

- for some reason, not all measures planned in the evaluation plan were implemented,

- it is impossible to assess the elimination of inconsistencies based on documentary evidence,

- the results of monitoring the activities of the CAB are insufficient,

- it is necessary to verify the effectiveness of the corrective actions/corrections of the CAB.

In the above cases, assessment team members in the nonconformities sheet(s) should indicate the need for additional on-site assessment.

**6.2.9.14.7** In order to carry out additional assessment, the team leader shall develop an additional on-site assessment plan (Annex PR-06), which shall be provided to the CAB.

In additional on-site assessment team are included only those assessors/experts who have identified nonconformities during the on-site assessment in the assessment team.

**6.2.9.14.8** Following the additional assessment the team leader prepares an additional report (according to annexes ACB-01-AR, ACB-02-AR, ACB-03-AR, ATL-01-AR, ACL-01-AR, AIB-01-AR, AIB-02-AR, APT-01-AR). Accreditation experts (assessors), technical assessors submit reports in the forms approved by the ARMNAB, and technical experts in the voluntary forms (signed, scanned versions are accepted).

**6.2.9.14.9** If the report on the assessment results differs from the results of the presented report, the team leader shall detail this difference in the final report provided to the CAB.

**6.2.9.14.10** ARMNAB is responsible for the assessment reports, including the nonconformities mentioned in the report.

***6.2.10 Witnessing***

**6.2.10.1** Witnessing of conformity assessment activities is carried out by ARMNAB within scope of accreditation in the places of CAB applicants' (calibration, certification process, testing, inspection, etc.) and in the CAB’s premises (testing, calibration, medical laboratories, PT providers, etc.). The purpose of witnessing CAB activity is to practically evaluate conformity assessment activities.

**6.2.10.2** Witnessing of CAB activities is part of the assessment process. Witnessing should be coordinated with the CAB and then included in the assessment plan. During the assessment, the number of witnessing CAB and staff's activities is defined so as to cover the whole scope of accreditation/extansion.

**6.2.10.3** Witnessing of conformity assessment activities may also be carried out separately from the assessment period (if no applications were received during the assessment period) in accordance with the CAB letter/program, on the basis of which an assessment team is established by the order of the ARMNAB director or this process is carried out by the accreditation expert (assessor)/technical assessor alone.

**6.2.10.4** The assessment team is formed in accordance with clauses 5.5.4-5.5.12 of this procedure, taking into account the scope of activities defined in the scope of accreditation, according to the information provided by the CAB.

**6.2.10.5** The process of witnessing CAB activities shall be carried out in accordance with sub-clause d) of 6.2.9.3 of this procedure.

**6.2.10.6** After the witnessing activity, the assessment team or accreditation expert (assessor) analyzes the results, based on which it prepares a report within 5 working days - 2 copies and provides to the CAB (paper-electronic).

**6.2.10.7** Within 5 working days of receiving the report, the CAB prepares and submits Item 2 (Corrections/Corrective actions part) of the completed nonconformities sheet (Annex PR-7-NCR) to ARMNAB based on the completed nonconformities sheets. The assessment team analyze the accuracy of the dates of planned corrective actions.

**6.2.10.8** The CAB is provided with a deadline no more than 20 days to eliminate nonconformities.

**6.2.10.9** After receiving the report on elimination of nonconformities with the attached evidence (in accordance with the form PR-7-CA) within the specified period, ARMNAB submits it to the assessment team. The assessment team examines the received information within 5 working days and informs the team leader if it is satisfactory.

If the corrective actions of the CAB are considered insufficient, the members of the assessment team may request additional information or, if necessary, carry out an additional on-site assessment, based on the results of which the team leader or the accreditation expert (assessor)/technical assessor prepares an additional report.

**6.2.10.10** The failure to submit information on the elimination of nonconformities within the set period of time is deemed as a ground to refuse the accreditation by the ARMNAB.

**6.2.10.11** Based on the negative results of the witnessing, the AC makes a decision on reducing, suspending, withdrawing of accreditation.

# 6.3 Accreditation decision-making

**6.3.1** The decision on accreditation is made by the Accreditation Committee (AC) in accordance with K-02 procedure. The CAB is gets accredited, if it meets accreditation requirements, eliminates the nonconformities identified during the assessment, and completes the corrective actions.

**6.3.2** The ARMNAB within 4 working days after providing the report to the CAB, prepare and present accreditation related all documents (including assessments reports) to the AC. The AC shall review the submitted documents within 4 working days and make a decision on accreditation, refusal, suspension, renewal, reduction, extension, withdraw of accreditation.

When questions arise on CAB accreditation documents in the course of decision making on accreditation, the AC may refer to the Technical Advisory Committee under the ARMNAB and/or the assessment team having performed the assessment of the given CAB. In that case, the decision may be delayed for other 2 working days.

The representatives of the accredited CAB may be invited to the session.

**6.3.3** Upon the end of each stage of accreditation the CAB has a right to appeal to the commission within 10 working days with a request to revise any unfavorable decision made by the ARMNAB. The procedure of grievance appeal is defined in K-04.

**6.3.4** In case of adopting a positive decision on accreditation, the ARMNAB shall, within 10 working days:

(1) include the CAB in the appropriate register of accredited CABs and shall conclude an accreditation contract (Annex PR-7-02). A CAB shall be deemed to be accredited from the moment of inclusion in the register;

(2) issue an accreditation certificate to the CAB (PR-7.8) and the scope(s) of accreditation. The validity of the accreditation certificate begins on the date of adoption of the AC decision on accreditation or on the next day.

(3) provide an accreditation symbol to the CAB the procedure for the use whereof shall be established by the Board (K-03).

**6.3.5** The results of the session of the AC are recorded in the minutes and decision. In case of rejection of the accreditation, within 10 working days, ARMNAB informs the CAB in writing about the decision, stating the reasons for the rejection.

**6.3.6** Accreditation decisions are not carried out by ARMNAB through a subcontractor, all accreditation works are carried out through ARMNAB.

**6.3.7** The accreditation/re-accreditation/accreditation extension process diagram and timelines are set out in Annex PR-7-04.

# 7. Accreditation cycle

**7.1** The accreditation cycle starts from the date or next day of the decision of the AC on accreditation or reaccreditation. Initial accreditation and reaccreditation period 4 years.

The accreditation cycle cannot exceed 5 years.

**7.2** From the moment of issuing the accreditation certificate ARMNAB constantly monitors the activities of the accredited body in accordance with the scope of accreditation at the relevant locations according to the program of periodic assessments of competence and reaccreditation (Annex PR-7-07). The assessment program is designed for the accreditation cycle, taking into account the risks of the CAB activity. Assessment program shall be developed together with the assessment team’s technical assessors/experts. The assessment program is drawn up for the accreditation cycle, that the CAB's all locations, entire management system and scope of accreditation be assessed throughout the accreditation cycle. During each accreditation/reaccreditation, extension of accreditation, the team leader carries out an assessment of risks related to the accreditation (extension) of the CAB, according to the Annex PR-7-13, in order to determine the frequency of periodic assessments after drawing up the surveillance plan. The frequency of the surveillance may change depending on the scope of the CAB’s activities, the results of nonconformities and other factors.

**7.2.1 The criteria and rules of selecting representative criteria and samples**

The assessment plan and the surveillance program for the accreditation cycle shall be prepared by the assessment team leader, taking into account the technical assessors’/experts’ recommendations and the following risks associated with the activity mentioned in the accreditation scope:

* activities in the regulated (mandatory) field;
* the complexity and the principle of application of the testing / calibration / inspection method /certification scheme;
* the sampling process, in case of testing laboratories which perform sampling;
* sensory tests are always assessed during the first accreditation;
* opinions and interpretations which are applicable for the testing/calibration laboratory, are assessed during the first accreditation or accreditation extension as stipulated by GOST ISO/IEC 17025;
* frequency of performing tests/calibrations/verifications/certification/ surveillance;
* the use of non-standard/internal methods is a higher risk factor than that of standard methods as a process of methods validation and verification is required;
* availability of PT, ILC, RM, activities aimed at ensuring quality. The availability of internal/external quality control is one of the indirect tools of assessing accredited activities. It is necessary to select the representative sample for those technical scopes in which the possibility of participating in PT, ILC is small or non-existent;
* for certification bodies, the peculiarities (e.g., the number and significance of product batches, regulations and schemes, number of places subject to assessment, voluntary or regulated (mandatory) fields) of the certification scheme (procedure) shall be taken into account;
* the number of appeals and complaints;
* personnel changes, etc.

The CAB shall be informed in advance about the tests (representative samples) only in case:

- it is necessary to prepare the sample before the on-site assessment visit

- presence of certain environmental conditions is necessary (e.g. out-of-location tests, sampling, or long preparation of the sample),

- tests shall be performed on those samples which are typically inaccessible in the laboratory.

**7.3** During the accreditation cycle, the program may be amended/supplemented in relation to the elements of the CAB’s management system planned for the assessment, CAB’s activities, and the places of assessment due to:

– extending of accreditation;

– reducing accreditation;

– changes that have occurred in CAB.

If it is necessary to make changes/additions to the program, the team leder makes the appropriate changes/additions to the program, signs it with the new date and stored in the CAB’s file (case).

**7.4** The ARMNAB shall, accepting as a basis the accreditation contract concluded with the CAB, during the entire validity period of the accreditation certificate of the CAB carry out:

- surveillances;

- extraordinary assessments, unannounced visit;

- witnessing (in case of absence of certification/inspection applications by the CAB's applicant during the period of accreditation, reaccreditation, surveillance).

# 7.4.1 Surveillance

**7.4.1.1** According to the information provided by ARMNAB assessors, the Deputy Director forms the annual plan of periodic assessments for the given year, which is posted on the internal network of ARMNAB.

**7.4.1.2** In the case of the initial accreditation of the CAB, ARMNAB carries out the surveillance no later than once within 12 months of accreditation, and in the case of re-accreditation - once no later than within 18 months. The next surveillance is carried out no later than 18 months after the previous surveillance - once.

If on-site assessment is not applicable, ARMNAB uses a different assessment technique to achieve the same objective as the on-site assessment being replaced and justifies the use of such techniques.

**7.4.1.3** The purpose of the surveillance is to assess if:

- the accredited CAB meets the current accreditation requirements for the scope of accreditation;

- the corrective/preventive actions taken to resolve nonconformities stated during the previous ARMNAB assessment have been effectively implemented;

- the accredited CAB complies with the provisions of the Accreditation contract (among others, application of the accreditation symbol, referring to the accreditation status, notifying the ARMNAB about significant changes, etc);

- competencies of the accredited CAB are continuously improved.

**7.4.1.4** After accreditation or reaccreditation, the first surveillance shall be performed by the members of the same assessment team for verifing the effectiveness of the nonconformities found during accreditation or reaccreditation. In justified cases, by the order of the director of the ARMNAB, the team leader and members may be changed, if they can’t participate in the surveillance due to leave, incapacity, dismissal, employment or other reasons.

**7.4.1.5** At least 10 working days prior to the scheduled periodic assessment, the CAB shall submit by email the following documents to the ARMNAB:

- list of the amended documents, and the documents;

- Information on conformity assessment activities within the scope of accreditation, as from the previous assessment, according to ARMNAB's forms.

**7.4.1.6** In order to carry out the surveillance, the assessment team and assessment plan forms on the basis of the surveillance program in accordance with 5.5.2-5.5.13 of this procedure.

**7.4.1.7** Prior to carrying out surveillance the director of the ARMNAB shall, within 3 working days, reach an agreement in writing with the CAB on the assessment plan.

**7.4.1.8** The assessment is carried out in accordance with clauses 6.2.3-6.2.9.14.10 of this procedure, applying the assessment techniques specified in clause 6.2.9.3.

**7.4.1.9** Based on the results of the surveillance, the AC makes a decision on maintaining, extending, reducing, recovering, suspending, withdrawing of accreditation.

**7.4.1.10** The surveillance/extraordinary assessment process diagram and timelines are set out in Annex PR-7-05.

# 7.4.2 Extraordinary assessment, announced visits

**7.4.2.1** During the accreditation/reaccreditation cycle, ARMNAB may conduct extraordinary assessments, announced visits in the following cases:

1) complaints, received from the state and non-state bodies, individuals or legal persons;

2) of reasonable suspicions of ARMNAB;

3) according to the application of the CAB, changes in the conditions of accreditation (cases are stipulated in the accreditation contract),

4) recovery accreditation after the suspension.

**7.4.2.2** An unannounced visit is described in clause 6.2.9.3 (j).

**7.4.2.3** In case of changes in accreditation conditions, including changes in accreditation criteria, the process is carried out in accordance with this procedure. In case of changes in the accreditation criteria, the process can be combined with the surveillance of the CAB. In this case, the CAB submits the application at least 4 months before the surveillance.

**7.4.2.4** In order to carry out the extraordinary assessment, the team leader draws up the assessment plan and provides it to the CAB within 3 working days.

**7.4.2.5** The assessment team examines the documents within 3 working days and carries out the assessment within the timeframe envisaged by the assessment plan.

**7.4.2.6** Extraordinary assessment is carried out in accordance with clauses 6.2.3-6.2.9.14.10 of this procedure, applying the assessment techniques mentioned in clause 6.2.9.3.

**7.4.2.7** Based on the results of the extraordinary assessments, the AC makes a decision on maintaining, extending, reducing, suspending, recovering, withdrawing of accreditation.

# 8. Reaccreditation

**8.1** The reaccreditation is carried out as the initial accreditation, taking into account the results of the assessments made during the accreditation cycle.

**8.2** In case of reaccreditation, the CAB submits the application at least 6 months before the end of the accreditation period. If the reaccreditation process has not been completed, the accreditation certificate of the CAB continues to be valid until the adoption of the relevant decision on accreditation by the AC, but the period from the date of issuance of the accreditation certificate to the adoption of the relevant decision should not exceed 5 years. If the specified period is exceeded, the operation of the accreditation certificate is terminated and a reaccreditation process is carried out. Information on the extension of the validity of the accreditation certificate, as well as the termination, is included in the relevant register.

**8.3** During reaccreditation, the team leader and assessment team members are changed (if possible).

**8.4** The decision on reaccreditation is made in accordance with clause 6.3 of this procedure. Based on the positive decision, is issued a new accreditation certificate, scope of accreditation, with maintaining the unique registration number.

# 9. Extension, reduction, suspension, recovery and withdrawing of accreditation

# 9.1 Extension of accreditation

**9.1.1** The process of extension of the scope of accreditation is performed at a request of the accredited CAB. The review of the application, making the decision and the documentation submition are carried out in accordance with this procedure and PR-7.10-7.11 procedure.

The purpose of the process of extension of the scope of accreditation is to:

- assess whether the technical competencies of the applying CAB enabe obtaining reliable results in the new fields of the activity, in accordance with the application for extension of the scope of accreditation;

- assess whether the implemented management system sufficiently takes into account the new fields of the activity.

**9.1.2** Accreditation experts (assessors) and technical assessors shall include in their reports only the points of the standard related to the extension of accreditation.

**9.1.3** In case of extension of accreditation, reformulation of accreditation certificate shall be carried out (according to PR-7.8). The annex on extension of the scope of accreditation or that on the scope of accreditation having been changed shall be attached to the accreditation certificate whereon a respective indication shall be made in the registry of accredited CABs.

**9.1.4** The process of extension of accreditation may run in parallel with the surveillance of the CAB. In such case, the ARMNAB shall submit the application at least 4 months prior to the mentioned assessment.

**9.1.5** The validity of extension of the accreditation shall be defined prior to expiry of the accreditation period of the CAB.

**9.1.6** The decision on extension of accreditation is made by the AC.

# 9.2 Reduction of the scope of accreditation

**9.2.1** The process of reduction of the scope of accreditation takes place in according to PR-7.10-7.11 procedure:

- at a request of the accredited CAB;

- as a result of a failure to fulfil, in the prescribed time, the conditions established at the time of the suspension of accreditation in a part of the scope;

- as a result of surveillance/extraordinary assessment, unannounced visit, witnessing (see Annex C of this procedure),

- as a result of after accreditation, until the next surveillance, no application/letter was submitted by the CAB for witnessing, as a result of which the NAB did not carry out witnessing given certification scheme/type of management system/object (see 6.2.3), except when the CAB did not receive applications during that period.

**9.2.2** In the process of reduction of the scope of accreditation, the assessment team conducts a documents review (15 working days) in order to assess whether the reason of the reduction of the scope of accreditation does not negatively impact the CAB’s competencies in relation to the remaining part of the scope. The reduction of the scope of accreditation is equivalent to withdrawal of accreditation in the specified part of the scope.

**9.2.3** The information on the reduction of accreditation as a result of surveillance/extraordinary assessment/announced visit/witnessing, is recorded in the report and submitted to the AC for making a relevant decision.

**9.2.4** In case of reduction of accreditation, reformulation of accreditation certificate shall be carried out according to procedure PR-7.8. The annex on reduction of the field of accreditation or that on the field of accreditation having been changed shall be attached to the accreditation certificate whereon a respective indication shall be made in the register of accredited CABs.

# 9.3 Suspension and Withdrawing of accreditation

**9.3.1** Accreditation may be suspended for all or part of the scope of accreditation.

**9.3.1.1** Suspension for all or part of the scope of accreditation can result from:

1) on the basis of CAB application;

2) a failure to resolve on time the nonconformities stated during the surveillance, witnessing, extraordinary assessment, unannounced visit processes, indicating that the accredited CAB does not meet the accreditation requirements;

3) violation of accreditation criteria, including accreditation requirements of the Republic of Armenia under the accreditation legislation, Eurasian Economic Union documents and breach of obligations under international treaties of the Republic of Armenia;

4) a failure to meet the obligations stipulated by the Contracts concluded with the ARMNAB.

**9.3.1.2** During the period of suspension of accreditation, the CAB does not have the right to apply for extension of accreditation and reaccreditation.

**9.3.1.3** Accreditation in the full scope or in a part of the scope is suspended for a period of 4 months.

**9.3.1.4** In the cases defined by subparagraphs 2, 3 and 4 of clause 9.3.1.1 of this procedure, the period of suspension of accreditation is set for no more than 4 months from the day following the adoption of the relevant decision by the AC, based on the information provided by the CAB from the deadlines for implementing the measures to eliminate the grounds for suspension.

**9.3.2** Withdrawing of accreditation takes place in the case of:

1) on the basis of CAB application;

2) in case of non-elimination of the grounds for suspension of accreditation within the period defined by point 9.3.1.3 and 9.3.1.4 of this procedure;

3) in case of refusal to conduct assessments;

4) in case of failure to provide information to the ARMNAB regarding compliance assessment activities or providing false information;

5) in case of using the accreditation mark and/or making a text reference regarding accreditation while engaged in conformity assessment activities out of the field of accreditation;

6) in case of termination of the accreditation contract concluded between the ARMNAB and CAB.

**9.3.2.1** In case of adoption of a decision on suspension or reduction of accreditation as a result of nonconformities recorded during the assessments, the CAB may submit an application for accreditation or extension at least 6 months after the adoption of the corresponding decision, in case of elimination of nonconformities.

**9.3.2.2** After the adoption of the decision on the withdrawing of accreditation by the AC, within 3 working days, the status of the CAB is changed in the relevant register (terminated) and the CAB shall, within 10 working days, return the original copy of the accreditation certificate together with its annexes to the NAB, irrespective of the possibility of appeal.

# 9.4 Recovery of accreditation

**9.4.1** After suspension of accreditation, accreditation is recovered through an extraordinary or surveillance assessment by one or a combination of the following processes:

• examination of documents,

• on-site assessment,

• witnessing.

**9.4.2** If the suspension of accreditation was made on the basis of CAB application, the accreditation shall be recovered in accordance with the application submitted at least 5 working days before the expiration of the suspension period, otherwise the accreditation is withdrawing.

**9.4.3** In the cases defined by sub-points 2, 3 and 4 of clause 9.3.1.1 of this procedure, the proofs of elimination of the grounds for suspension of accreditation are submitted to ARMNAB. ARMNAB implements the assessment processes mentioned in point 9.4.1 through the assessment team.

**9.4.4** The decision on recovery of accreditation is made by the AC.

# 9.5 Updating of the scope of accreditation

**9.5.1** Updating of the scope is carried out at a request of the CAB (PR-03):

1) for the reason of a necessity to add or change the symbol, the name or the edition status of the normative document referred to in the scope of valid accreditation;

2) for changes and/or corrections of the forms of the accreditation scope and attached documents;

3) for inclusion in the relevant register of accredited CABs.

# 9.6 Change in accreditation standards, including transition to a new accreditation/certification standard

If an accreditation/conformity assessment standard/normative document is updated or changed, ARMNAB develops a policy on establishing a transition period for the new standard, based on Policy P-01 and posted on www.armnab.am. In the event of a change in the accreditation standard/criteria, the CAB submits an application for accreditation by marking the line "☐ transition to a new version of the standard", after which the assessment process is carried out in accordance with clauses 5.1-6.3 of this procedure. In the event of a change in the accreditation standard/critera, the on-site assessment process may be combined with the surveillance. In that case, the CAB submits the application at least 4 months before the assessment.

During the change of the conformity assessment standard/normative document, the CAB is obliged to demonstrate that it has a developed procedure and competence to carry out the activities defined by the new/amended standard. The assessment of changes to the standard/normative document is carried out through extraordinary assessment or surveillance.

# 9.7 Complaints and appeals

**9.7.1** The procedure for receiving, registering, evaluating, making decisions on appeals is established in K-04, for complaints – in PR-7.12 and posted on the ARMNAB website ([www.armnab.am](http://www.armnab.am)).

# 10. Obligations of CAB and ARMNAB

The obligations of CAB and ARMNAB are defined in the Accreditation Agreement concluded between CAB and ARMNAB.

# 11. Annexes

Annex A – Declaration on impartiality and confidentiality

Annex B – Selection of objects to be assessed

Annex C – Description of the classification of nonconformities

Annex PR-7-01 – Preliminary visit contract form

Annex PR-7-02 – Pre-Accreditation contract form

Annex PR-7-03 - Accreditation contract form

Annex PR-7-04 - Accreditation/reaccreditation/accreditation extension process flow chart and timelines

Appendix PR-7-05 - Surveillance/Extraordinary assessment process flow chart and timelines

Annex PR-7-06 - Assessment plan form

Annex PR-7-07 - Surveillance program form

Annex PR-7-08 – Application and attached documents set form

Annex PR-7-09 – Corrective actions program form

Annex PR-7-10 – Resource review form

Annex PR-7-11 - Opening meeting protocol form

Annex PR-7-12 - Closing meeting protocol form

Annex PR-7-13 – Assessment sheet form for assessing the risks associated with the CAB’s accreditation (extension)

Annex PR-7-14 - Remote assessment risk analysis and related decision making form

Annex PR-7-CA – Report on Corrections/Corrective Actions Implemented by the CAB

Annex PR-7-NCR - Nonconformity sheet form

Annex PR-7-PR - Preliminary visit report form

# Annex A

# 

**DECLARATION ON IMPARTIALITY AND CONFIDENTIALITY**

1. By the present declaration the Personnel involved in the accreditation process shall safeguard the impartiality and the confidentiality of the activities carried out during the provision of accreditation services.
   1. The Personnel involved in the accreditation process shall have adequate arrangements to safeguard the confidentiality of the information obtained in the process of the provision of the services and shall not disclose it to other persons, except where the RA law requires such information to be disclosed or by the decision in force made by the court.
   2. Confidential information in the present declaration shall be referred to any information, that the Client or the conformity assessment body provides to the Personnel involved in the accreditation process in a written, oral, electronic or any other form, which refers to the process of the services provision by the Personnel involved in the accreditation process, as well as to factual and analytic data, conclusions and materials, including but not limited to the notes, documentation and correspondence, except the information which cannot be considered confidential according to the regulations of RA.
2. The information requested by the competent state authorized body in the scope of the competence of the Personnel involved in the accreditation process can be provided only if the Perfomer has informed in advance to the Client in written form about the request. The notification about the request shall contain a reference to the clause of the law by virtue of which the Personnel involved in the accreditation process shall provide the information, as well as all the necessary characteristics of the information requested.
3. The Personnel involved in the accreditation process shall follow the rules established by ARMNAB, that refer to the impartiality and the independence from the persons participating in the procedure or the third persons and other interests. Personnel involved in the accreditation process are obliged to inform ARMNAB about the existence of the following relationships with the accredited/accredited conformity assessment body within the last three years, which may affect impartiality:

- joint contracts,

- general management,

- general real estate,

- friendly and kinship ties with the management and staff of the accredited/accreditation-seeking conformity assessment body, as well as providing advice to the accredited/accreditation-seeking conformity assessment body.

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 (initials, signature)

# Annex B

# Selection of objects to be essessed

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of activity and stages** | | **Initial accreditation** | **Extending of accreditation** | **Reaccreditation** | **Surveillance** |
| **1** | **2** | **3** | **4** | **5** | **6** |
| Assessment, including witnessing | Scope of accreditation | Scope of accreditation:  100% - for 1-6 directions of activity;  - more than 6 directions of activity, one representative sample[[1]](#footnote-1) in each direction) (method)\*  \* **Note**.  One of the criteria for selecting of representative methods are:  - principle of the test/inspection method/measurement principle and the properties of the tested object, complexity of the test/calibrations method (technical equipment, labor input);  - risks of consequences in the adoption of the CAB of an incorrect decision based on the results of tests/calibrations/inspections (the number of works carried out in the scope of accreditation), etc. | Scope of accreditation:  100% - for 1-10 directions of activity;  60% - for 11-100 directions of activity. | Taking into account the results of the previous assessment with a view to surveillance and analyzing the information submitted by the CAB in such a way that during the accreditation cycle all the activities of the CAB according to the object and test codes and the type of testing/calibration/inspection/ and all areas (directions) of the accredited CAB’s activities were covered by the assessment for the accreditation cycle. | Taking into account the results of the previous assessment with a view to surveillance and analyzing the information submitted by the CAB in such a way that during the accreditation cycle all the activities of the CAB according to the object and test codes and the type of testing/calibration/inspec-tion/proficiency testing and all areas (directions) of the accredited CAB’s activities were covered by the assessment for the ac-creditation cycle |
| Assessment | Management system | 100% of the elements of the management system using the technique of document review and interviewing | 100% of the elements of the management system using the technique of document review and interviewing, which are amended and/or added related to extending of accreditation | 100% of the elements of the management system using the technique of document review and interviewing | Selection of elements of the management system, taking into account the results of the previous assessments, as well as changes in the management system that have occurred in the CAB so that all elements of the management system undergo a assessment for the accreditation cycle |
| Assessment | Pesonnel | CAB’s personnel performing activities for the selected representative methods/program/scheme of testing/calibration/inspection/sertification according to the scope of accreditation by the witnessing method, the rest with application of the interview method and record review. | CAB’s personnel performing activities for the selected representative methods/program/scheme of testing/calibration/inspection/sertification according to the extending of scope of accreditation by the witnessing method, the rest with application of the interview method and record review. | Selectively from the number of personnel performing the activity for selected representative methods/program/scheme of testing/calibration/inspection/sertification planned for reassessment by the witnessing method (taking into account the changes in the CAB’s staff, as well as the results of previous assessments), the rest using method of interview and record review.  **Note**.  When planning the assess-ments in the next accreditation cycle, it is necessary to select personnel for the assessment by the witnessing method, which was not witnessed in the previous cycle. | Selectively from the number of personnel performing the activity for selected representative methods/program/scheme of testing/calibration/inspection/sertification planned for reassessment by the witnessing method (taking into account the changes in the CAB’s staff, as well as the results of previous assessments), the rest using method of interview and record review.  **Note.**  When planning the assess-ments in the next accreditation cycle, it is necessary to select personnel for the assessment by the witnessing method, which was not witnessed in the previous cycle. |
| Assessment | Locations | Office premises of the CAB, in which key activities are carried out and 100% of the production facilities of the CAB, where activities are carried out directly according to the scope of accreditation | 100% of the production facilities of the CAB, where activities are carried out directly according to the scope of accreditation | Office premises of the CAB, of locations and activities for selected representative methods in accordance with the scope of accreditation, taking into account the analysis of the information provided by the CAB | Office premises of the CAB, of locations and activities for selected representative methods in accordance with the surveillance and reassessment program for accreditation cycle, taking into account the results of the previous assessments and analysis of the information provided by the CAB in such a way that during the accreditation period all the sites of the CAB’s activities in the scope of accreditation were assessed at least once. |

**Annex C**

**A description of the classification of nonconformities (NC)**

|  |  |  |  |
| --- | --- | --- | --- |
| **The type of NC** | **Classification criteria** | **Actions of ARMNAB** | **Actions of CAB** |
| **1** | **2** | **3** | **4** |
| **Considerable** | Identified inconsistencies ­.  1) refer to the conformity assessment activity of the CAB, which directly affects the results of the CAB's activity (provided test protocol, certificate of conformity, registered declaration, etc.),  For example, **in the case of TL (testing lab.).**  - Regarding the compliance of the TL with the requirements of the EAEU and the technical regulations of the RA (hereinafter referred to as the TR):   * testing report, the operation of which does not apply to that type of product, * testing report, in which the document defining the specified test method is not included in the mandatory list of standards defining the rules and methods of testing and measurement, including sampling, attached to the TR, which necessary for the application and fulfillment of the requirements of technical regulations,   - provision of a test report without conducting tests,  - provision of test protocols in the absence of calibration/internal calibration of the measuring instrument, failure or absence of the measuring instrument, use of expired standard samples, personnel without appropriate competence/qualification, calibration of test/environmental conditions and other technical requirements, | Compilation of the non-conformity sheet and report, approval of the deadline for the implementation of correction/corrective actions by the CAB, additional assessment based on the deadlines set by the PR-7 procedure.  **For accredited CABs.**  - if during the assessment, at least one sub-item of item 1 of column 2 and/or more than 2 NCs defined by item 4 are found during the assessments, the Accreditation Committee (hereinafter AC) makes a decision to ­reduce the scope of accreditation;  - in case of NCs defined by points 1-4 of column 2, ­based on the results of the additional assessment after corrective actions, or in case of failure to provide information on corrective actions, the AC makes a decision on maintaining, reducing, suspending or withdrawing the accreditation, | Analysis of causes of NCs and development of correction and corrective actions­, agreement with ARMNAB and implementation |
|  | **in the case of product certification body.**  - Issuance/registration of a product conformity assessment document on compliance with TR requirements, the action of which does not apply to that type of product,  - wrong choice of product conformity assessment scheme (certification, declaration registration, state registration),  - the procedures provided by the certification scheme were not fully implemented,  - the tests for the certified product with the safety requirements defined by the TR were not fully performed,  - lack of sufficient grounds for issuing/registering conformity assessment documents or procedural violations.  2) in the conformity assessment documents (certificate of conformity, declaration, etc.) provided/registered by the CAB, information about the product is not complete to ensure its unambiguous identification (for example, type, brand, model, article number, etc.);  3) NCs in the management system ­(for example, absence of grounds for certification, non-implementation of internal audit, etc.),  4) Violation of the obligations of the CAB (for example, the field of accreditation has not been modernized and an activity was carried out within its scope and a corresponding document was provided, violation of the requirements of the accreditation symbol, etc.),  5) using an accreditation symbol and a text reference to accreditation in the conformity assessment document when carrying out conformity assessment activities outside of accreditation scope.­ | - In case of detection of inconsistencies defined by point 5 of the 2nd column ­(no less than 3 during the accreditation cycle), the AC makes a decision to withdrawing the accreditation.  **For CABs seeking for accreditation.**  In cases where the identified NCs cannot be eliminated through the development and implementation of corrective actions, or the information on corrective actions is not provided to the ARMNAB, then the accreditation of the CAB is rejected. |  |
| **Trivial** | Deviation (minor error) in the implementation of accreditation requirements, which does not affect the results of the activity of the CAB (for example, the management system document was developed, but there are defects in the content, the internal audit was not completed, the registers are filled with defects, the standard sample is out of date, but tests/calibrations have not been performed, equipment that does not significantly affect the measurement results or uncertainty is used but not mentioned in the equipment records, incorrect application of the accreditation text reference and/or the accreditation symbol (e.g. the accreditation symbol is applied in large quantities or applied without their logo, etc.). | Compilation of the nonconformity sheets and report, correction by the CAB during the on-site assessment and/or implementation of corrective actions, deadline confirmation, additional assessment based on the deadlines set by the PR-7 procedure.  **For accredited CABs.**  - On the basis of the results of the additional assessment ­after corrective actions done by CAB, the AC makes a decision on maintaining, reducing, suspending or withdrawing the accreditation.  **For CABs seeking for Accreditation.**  In cases where it is not possible to eliminate the identified non-conformity through the development and implementation of corrective actions, or the information on corrective actions is not provided to the ARMNAB, then the accreditation of the CAB is rejected. | Analysis of causes of non-conformities, correction and development of corrective actions, agreement with ARMNAB and implementation. |

**DOCUMENT AMENDMENTS LIST**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Edition:** | | **Amendment:** | | **Amended points / words** | **Amended (previous) version** | **Signature of the amending person** |
| **N/N** | **Date of approval** | **N/N** | **Date of approval** |
| 1 | 28.11.2015 | 1 | 17.07.2017 | 5.5.1 point | Add new sentence |  |
| 2 | 01.03.2021 |  |  | Text and added new Annexes:  Annex B, C;  Annex PR-7-10;  Annex PR-7-11;  Annex PR-7-12;  Annex PR-7-13 | - |  |
| 1 | 18.06.2021 | Еxclude cl. 6.4.1.10, 6.4.2.8 |  |  |
| 2 | 13.12.2021 | Annex PR-7-13-2-nd ed. | 1-st ed, 01.03.2021 |  |
| 3 | 21.01.2022 | 5.8.1.2-5.8.1.4, 5.8.3.4, 6.2, 6.2.1, 8.2.1, 8.3.1.1, annex PR-7-07 | - |  |
| 4 | 11.03.2022 | Аnnex PR-7-10 (3-rd ed) |  |  |
| 3 | 10.08.2023 |  |  | Text and Annexes |  |  |
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1. ) **representative sample** — sampling made according to the rules, so that it reflects the spec-ificity of the total population by composition, and by the individual characteristics of representative ob-jects included in the sampling. [↑](#footnote-ref-1)