 **Director of "National Accreditation Body” SNCO**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_A. Obosyan**(name, surname)

«30» June 2023

Order No\_6-KH

**MANAGEMENT SYSTEM**

**ACCREDITATION OF TESTING LABORATORIES**

**ANNEX PR-7/ATL-01**

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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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Contents

[1. Scope 4](#_Toc152541338)

[2. Normative References 4](#_Toc152541339)

[3. Reference documents and abbreviations 4](#_Toc152541340)

[4. General Requirements of Testing Laboratories 6](#_Toc152541341)

[4.2 Accreditation application and attached documents 9](#_Toc152541342)

[4.3 Documents review 9](#_Toc152541343)

[4.4 On-Site Assessment 11](#_Toc152541344)

[4.5 Sampling 14](#_Toc152541346)

[4.6 Testing report (protocol) 14](#_Toc152541347)

[4.7 Presenting opinions and interpretations 15](#_Toc152541348)

[5 Assessments and reaccreditation 16](#_Toc152541349)

[*6. Reaccreditation* 17](#_Toc152541350)

[7 Extending, reducing, updating scope of accreditation, suspending and withdrawing of accreditation 18](#_Toc152541353)

[8 Complaints and appeals 21](#_Toc152541358)

[9. Obligations of TL and ARMNAB 21](#_Toc152541359)

[10. Annexes 21](#_Toc152541360)

# Scope

The present procedure describes the modalities to be respected by the “National Accreditation Body” SNCO (hereinafter “ARMNAB”) personnel for arranging and carrying out assessments for accreditation, reaccreditation, surveillance, extension, reduction, extraordinary assessment, as well as updating, recovering of accreditation of testing laboratories.

This document is an annex to the main document PR-7, which covers the requirements and procedure for accreditation of a given type of conformity assessment body that are not defined in PR-7.

# 2. Normative References

The referenced documents with no-date shall be applicable only by the latest edition. The documents referenced in this document are presented in the document "AC-4.6 General Accreditation Criteria and List of Documents" developed by ARMNAB.

EA and ILAC documents are posted on the following websites:

EA: <http://www.european-accreditation.org/>, ILAC: <http://www.ilac.org>/.

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# 3. Reference documents and abbreviations

3.1 In this procedure, the following terms and definitions, including those stipulated by “Law on Accreditation”, GOST ISO/IEC 17000, GOST ISO/IEC 17011 and PR-7, apply:

**Laboratory**: a legally recognized entity or a part of one (e.g. department, location area etc.) with unequivocal identification. In the present document, unless otherwise indicated, the term “laboratory” means a laboratory which carries out tests/samplings.

**Testing laboratory:** a laboratory which carries out chemical, microbiological, mechanical, electronic tests etc. or sampling related to a successive test.

**Testing:** determining one or more characteristics of an object of conformity assessment in accordance with a procedure. A test is defined by the testing materials/matrices/products, the quantities/parameters, the testing methods used and the category. For the purpose of the present document, unless otherwise indicated, the term “test” is taken to mean also “sampling related to a subsequent test”.

**Test method:** the specific technical procedure for carrying out a test.

**Calibration:** operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication.

**Internal calibration**: calibration the results of which significantly influence the CMC (Calibration and Measurement Capabilities) of the Calibration Laboratory but which does not fall within its scope of accreditation (and as such cannot be offered as an accredited calibration service) and which is carried out using personnel and equipment of the Calibration Laboratory.

*NOTE 1: Internal calibration should not be confused with self-calibration, for example there are analytical balances that have a built-in calibration load that self-calibrates by pressing the appropriate CAL button.*

*NOTE 2: Internal calibration can be carried out, for example, with certified reference material (CRM) or with suitable weights providing the accuracy class for scales according to OILM R 111-1.*

**Scope of accreditation**: Specific conformity assessment activities for which accreditation is sought or has been granted.

**Fixed scope of accreditation:** description of the scope of accreditation giving full details of the test in terms of testing materials/matrices/products, quantities/parameters to determine, the testing methods and procedures of examination used and the category of the test.

*NOTE: ARMNAB accredits only the fixed scope of accreditation. Accreditation with a flexible scope of accreditation is not carried out.*

**Extension of accreditation:** addition of conformity assessment activities to the scope of accreditation.

**Updating of scope of accreditation:** the process of making changes in the accreditation documents by ARMNAB at the request of the CAB.

**3.2 Abbreviations**

- RA: Republic of Armenia,

- EAEU: Eurasian Economic Union,

- EAEC: Eurasian Economic Commission,

- ARMNAB: "National Accreditation Body" SNCO,

- CAB: Conformity Assessment Body,

- AC: Accreditation Committee,

- TL: testing laboratory,

- EA: European Accreditation Cooperation,

- ILAC: International Laboratory Accreditation Cooperation.

# 4. General Requirements of Testing Laboratories

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**4.1** Accreditation requirements are set out in PR-7 Procedure, as well as below:

1) Presence of a Management System and compliance with the Management System requirements defined in the documents;

2) Presence of normative legal acts, standardization documents, testing and measurement methods and rules, including the sampling rules and other documents specified under the scope of accreditation;

3) Laboratory staff that perform tests and measurements and have:

* higher or secondary vocational education or additional professional trainings in the relevant field of accreditation;
* trainings on performance of tests (certificates in conformity with the requirements of GOST ISO/IEC 17025 Standard and other documents).
* competence, i.e. to carry out certain types of tests/sampling, to use certain types of equipment, to make a decision based on test results about compliance with specifications or a standard, to approve test reports, to give opinions and interpretations, if applicable, in accordance with EA-4/23.

The laboratory testing and measurement employee-trainee should perform tests and measurements under supervision of an experienced supervisor.

4) Internal organizational requirements for laboratory activities, which shall provide:

a) rights and responsibilities of the structural subdivision performing tests and measurements of a legal entity or private entrepreneur (of its staff), to exclude the conflict of interest, in case of cooperation with other subdivisions of legal or physical (its staff) entities;

b) presence of documents signed by the laboratory staff, which shall define functional responsibilities, including the distribution of rights, responsibilities and liabilities among the laboratory staff.

5) presence of mechanisms to ensure impartiality.

6) presence of rules on quality management of testing and measurement results, including the rules for review and planning of quality control of testing and measurement results, which may provide for performance of PT and ILC, use of tested standard samples and/or internal quality control by use of standard samples, and performance of double tests.

7) presence of rules to ensure and control the environmental conditions for laboratory operation (air temperature, humidity, lighting, noise level and other external conditions affecting the results of tests and measurements).

8) presence of rules on development, validation (verification) and use of non-standard methods, standard methods and modified standard methods (if such methods are applied or planned to be applied);

9) presence of rules (procedure) on how to deal with testing and measurement objects, which shall provide for:

a) rules for shipping, recept, use, maintenance, storage and/or disposal of testing and measurement objects;

b) rules for identification of testing and measurement objects;

c) rules for documentation of work with testing and measurement objects, including when testing and measurement results have deviations from normal or standard conditions.

10) existence of rules/procedures for calibration of measuring instruments.

11) rules for estimation of measurement uncertainty (in case of independent calibration of laboratory measurement instruments).

12) Existence of comformity statements and decision-making procedures and rules;

13) The testing laboratory shall have the facilities and equipment provided under legal contracts to perform product tests and parameter (indicators) measurementscontained under the scope of accreditation.

14) When the laboratory carries out testing in regulatory sector, where testing/sampling methods are defined in Technical Regulations, the laboratory shall apply the relevant methods (standards and other legal acts) referred to in the Regulations.

15) Is not permitted to use the facilities and / or equipment of another accredited testing laboratory, except for the cases when the laboratory carries out activities outside its permanent location, in temporary or mobile locations or in the territory of the applicant (for example, tests carried out within the framework of TR TC 018/2011 regulation).

# 4.2 Accreditation application and attached documents

The TL submitting an application and attached documents for accreditation (in accordance with Annex ATL-01-01 – ATL-01-10), forms are posted on the official website of ARMNAB: www.armnab.am.

The procedure for acceptance of the accreditation application and attached documents, analysis of resources and registration of the application is defined in PR-7, which is posted on the website www.armnab.am.

During the accreditation of laboratories with different specializations, operating under the same legal entity, the ARMNAB shall accept the application in the following cases:

- When the same product/sample is tested in all technical subdivisions of the laboratory applying for accreditation, the applicant shall submit one accreditation application and be issued one accreditation certificate that covers all technical subdivisions;

- When different types of products/samples are tested in each technical subdivision of the laboratory, each technical subdivision may submit a separate accreditation application and be issued a separate accreditation certificate, or submit one accreditation application provided that all technical subdivisions are included in the application.

# 4.3 Documents review

4.3.1 After the appropriate payment has been made by the TL and the assessment team has been approved, the examination of the accreditation application and attached documents begins in accordance with PR-7.

4.3.2 In order to accredit the laboratory, the ARMNAB must analyze the documentation of the implemented management system in accordance with the accreditation requirements. The document review report form is given in ATL-01-DR.

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

The assessment plan 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 method;
* 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;
* 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;

The TL 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.

4.3.4 The surveillance program for the accreditation cycle shall be prepared by the assessment team leader, taking into account the technical assessors’/experts’ recommendations, taking into account the risks mentioned in point 4.3.3 related to the activity in the scope of accreditation and the criteria for selecting representative samples and the following:

- the number of complaints and appeals,

- the results of previous assessments,

- staff changes, etc.

# 4.4 On-Site Assessment

**4.4.1** The purpose of the assessment is to certify the compliance of the TL activity with this procedure, the documents of the ARMNAB, EA, ILAC documents and other applicable general and sectoral normative, standardization documents, the documents of the TL management system (quality manual, MS documents, procedures, instructions, personnel qualifications, etc.).

4.4.2 On-site assessment period (days/person) is determined according to the number of procedures defined by the management system, product groups, technical regulations and procedures, number of places subject to assessment, voluntary/mandatory sector, number of personnel and other factors, for example, found during the documents review, number of nonconformities etc.

* + 1. The assessment methods of a TL used by an ARMNAB is comprised:

**- on-site assessment)** – visiting of the head office and any operational units or branches where conformity assessment activities are carried out. During the on-site assessment, the management system and the testing/sampling process are evaluated. As a result of the on-site assessment, a report is drawn up in accordance with Annexes ATL-01-R and ATL-01-AR,

- **Remote assessment** - assessment of the physical location or virtual site of a TL using electronic means.

Remote assessment is performed in exceptional cases, such as Force Majeure Impacts, Epidemic Diseases, Impossibility of Assessor/Technical Expert on-site visit, and other justified cases.

- **Witnessing** - observation by the accreditation body of a conformity assessment body carrying out conformity assessment activities within its scope of accreditation;

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

File (Case) review is a complete assessment of all aspects of testing for the selected representative test.

**- Document review** – checking of the CAB’s documentation.

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

- **Review of performance in proficiency testing and other interlaboratory comparisons** - assessment testing results performed by TLs with another TLs or PT providers;

- **Validation audits** - assessment results of validation performed by TL;

- **Measurement audits** – assessment tasting results performed by TL;

- **Interviewing** – conversation with the TL's personnel.

4.4.4 If the laboratory introduces a self-developed method (non-standard method) in the accreditation application, this method shall be presented to the ARMNAB so that the assessors/experts will prepare for on-site assessment. If the laboratory fails to present the testing procedures to the ARMNAB, the term of on-site assessment shall be extended to allow for on-site study of these documents by assessors/experts.

4.4.5 The measuring instruments used in the TL must be calibrated. The TL shall define, in line with the specifics of the testing/sampling to be performed, the acceptable requirements relating to deviations, uncertainties etc both for internal calibrations and calibrations outsourced to external centers.

Regarding such equipment as incubators, heaters, climate chambers, the thermometer/logger data in the equipment shall be calibrated. The homogeneity control of temperatures in the equipment is a preliminary evaluation for establishing whether the instrument keeps the temperature within the limits of the method.

For complex equipment such as spectrometry, GC, HPLC mass spectrometry, the calibration is done using suitable reference materials (see ISO/IEC 17025 § 6.5).

4.4.6 While performing internal calibration, the laboratory shall meet the requirements of PL-06 document. The technical assessor/expert shall assess the competence of the laboratory to perform internal calibration.

4.4.7 During the on-site assessment the tester shall be witnessed for his/her performance, starting from sampling of test specimens/products to the end of testing, and, as a result, a report shall be prepared in accordance with Annex ATL-01-TWR. The witnessing of testing of test specimens/products is carried out for the pupose of checking the accuracy of test results and staff conpetence.

The sample selected by assessors/experts for each testing method specified under the scope of accreditation shall be representative for each method (and for lab personnel), ensuring that the laboratory is competent to perform as specified under the scope of accreditation.

4.4.8 If more than one technical subdivision/place of performance is indicated in the accreditation application, the assessment shall be carried out in the head office and all technical subdivisions/places of performance of the entity.

# 4.4.9 Testing Activities through Subcontracting

The accredited testing laboratory shall independently perform the testing activities specified under the scope of accreditation. The ARMNAB shall not accredit the testing activities carried out through subcontracting, except when the laboratory has adequate resources and competence, but due to unforeseen reasons (for example, employee illness, temporary equipment failure, etc.) cannot perform tests partially or completely..

# 4.5 Sampling

Sampling can be accredited only in case it is connected with the testing subject to accreditation.:

The following situations can occur:

1) sampling methods are separate standardized methods which are different from the one defined in the testing method (e.g. AST ISO 18593, GOST EN 1482-1, etc.):

In that case the laboratory shall fulfil the requirements of point 7.3 of the GOST ISO/IEC 17025 standard and shall submit the report in line with the requirements of point 7.8.5 of the standard.

2) the method includes both sampling and testing,

In that case the laboratory can:

- indicate the entire method in the accreditation scope (sampling and decision),

- mention only the part of the analytical decision, excluding the section related to sampling.

# 4.6 Testing report (protocol)

The laboratory shall define different protocol forms for internal and external clients. The protocol form for internal clients may be more simplified.

If the laboratory does not carry out sampling, the testing protocol shall include information on the sampler and, if necessary, the conditions of using the test results, such as due to the failure to estimate the sampling uncertainty.

When sampling involves performing measurements (e.g., volume, flow speed, surface, etc.) the laboratory shall express the results through a traceable measurement unit.

Therefore, if sampling is not accredited or is not performed by the client, the laboratory shall express the result without taking into consideration the measures taken during the sampling stage (e.g., mg and not mg/m3, UFC and not UFC/m2 and so on) and correctly identify the received sample (reference material) (e.g., ampule, filter, etc. and not mention the working space).

If sampling is not performed by the laboratory, the testing protocol shall clearly indicate that sampling was performed by the client.

# 4.7 Presenting opinions and interpretations

The laboratory cannot apply only for accreditation opinions and interpretations. While forming the accreditation scope it is necessary to follow the example stipulated in Annex B of the EA-4/23 document.

An opinion and interpretation are a process outcome through which the applicability of the testing or calibration result can be extended. It shall be formulated by a person/persons with respective technical qualifications (see point 6.2 of the standard, EA-4/23), and the subsequent conclusions shall be made based on the achieved result, using the person’s knowledge and professional judgement in the given testing sphere. The expressed opinion and interpretation shall be technically grounded and shall be supported by evidence (see point 7.5 of the standard).

If during the formation of opinions and interpretations information provided by the applicant is used, the laboratory shall keep the respective records and clearly specify in the testing protocol that the opinions and interpretations are based on the information provided by the applicant.

Opinions and interpretations shall be an indispensable part of the testing protocol/report and shall be mentioned in the section titled “Opinions and Interpretations”. They shall not be included in any other document or annex.

Opinions and interpretations shall be based only on the results obtained from the sample testing, but other pieces of information from calculations, literature or bibliographical data may also be necessary.

Accreditation of opinions and interpretations is granted only based on results obtained from accredited tests.

It is not possible to express opinions and interpretations through results obtained only from external laboratories.

Orally expressed opinions and interpretations, even if they were recorded (see ISO/IEC 17025 point 7.8.7.3 of the standard) cannot be regarded as accredited.

4.8 The assessment process, as well as the detection and classification of non-conformities, is defined in the PR-7 procedure.

**4.9 Decision Making on Accreditation**

The process of making a decision on accreditation and issuing an accreditation certificate and scope(s) is defined in the PR-7 procedure.

# Assessments and reaccreditation

***5.1 Surveillance***

The surveillance procedure is set out in PR-7, taking into account the requirements below.

5.2 At least 10 working days prior to the scheduled periodic assessment, the TL shall submit the following documents to the ARMNAB:

- list of amended documents and the documents (printed and/or electronic versions), according to Annex C format.

- Information on the number of tests performed within the scope of accreditation and participation in proficiency tests/interlaboratory comparisons (PT/ILC), as from the previous assessment, according to the format provided in Annex B.

5.3 When drawing up the surveillance assessment plan, the team leader conducts a risk analysis, taking into account the results of previous assessments, so that during the accreditation cycle the entire management system of the TL and the accreditation scope are assessed.

The representative sample is selected according to clause 4.3.3 of this document, taking into account the changes in the personnel of the TL, the number of sites (branches) of activity implementation, the number of reports issued, the mandatory sector, being a risky product, appeals and complaints, etc.

***Note 1: When planning assessments in an accreditation cycle, persons who have not been assessed with witnessing technique during previous assessments are selected.***

***Note 2: If the TL carries out its activities at different addresses (branches), surveillance is carried out at the head office and all branches. All branches must be assessed in the accreditation cycle.***

5.4 The surveillance period (days/person) is determined according to the characteristics of the test method, product groups, technical regulations and procedures, the number of places to be evaluated, the voluntary/mandatory sector and other factors, for example, nonconformities found during previous assessments, complaints received, expansion, reduction, suspension of accreditation, the distance of activity of TL, etc.

***5.5 Extraordinary assessments***

The extraordinary assessment procedure is set out in PR-7.

***5.6 Decision making***

Based on the results of surveillance/extraordinary assessment, the AC adopts a decision to maintain, reduce, extend, restore, suspend, withdrawn accreditation.

***5.7 Change in accreditation standards, including transition to a new accreditation standard***

If an accreditation standard is updated or amended, the TL is required to demonstrate that it has the appropriate procedures and competence to perform the activities defined by the new/amended standard.

The assessment procedure for changes in accreditation criteria is set out in PR-7.

***6. Reaccreditation***

**6.1** The procedure for reaccreditation is set out in PR-7, taking into account the following requirements:

- in case of inclusion of a new test method, ARMNAB can carry out the documentary examination during the on-site assessment of the TL,

- the period of re-evaluation (day/person) is determined according to the characteristics of the method, such as the number of test methods to be re-evaluated, product groups, technical regulations and procedures, the number of sites to be evaluated, voluntary/mandatory sector, results of previous evaluations, complaints received, the distance of activity of TL, etc.

# 6.2 Decision on reaccreditation

# The process for making a decision on reaccreditation and issuing an accreditation certificate and scope(s) is defined in the PR-7 procedure.

# 7 Extending, reducing, updating scope of accreditation, suspending and withdrawing of accreditation

7.1.1 For the purpose of expanding the scope of accreditation, the TL submits the accreditation extension application and the attached documents to ARMNAB, the formats of which are posted on the ARMNAB website. In case of absence or incompleteness of necessary data and documents, ARMNAB may request additional documents.

7.1.2 The testing laboratory shall extend the scope of accreditation if:

a) a new product, group of products is added;

b) new characteristics are added;

c) a new testing/sampling method/opinions and interpretations is added;

d) a new technical subdivision/location is added.

7.1.3 The planning and assessment of the process of extending the scope of accreditation of the laboratory shall be carried out in the same way as the accreditation process in accordance with PR-7 and PR-7.10-7.11.

7.1.4 TL shall have the right to refer to its accreditation only after accreditation of the extended/renewed scope.

7.1.5 The process of extending the scope of accreditation may combined with surveillance of the TL. In this case, the laboratory shall submit the application at least 4 months prior to the subject assessment.

7.1.6 The extended scope of accreditation shall be valid through the end of the term of TL accreditation.

7.1.7 During the period of suspension of accreditation or in case of non-fulfillment of the obligations defined by the accreditation agreement, the TL cannot submit an application for extension of accreditation, as well as for reaccreditation.

7.1.8 In case of extending the scope of accreditation, the accreditation certificate shall be reformulated. An annex on extending the scope of accreditation or revising the scope of accreditation shall be enclosed with the accreditation certificate, which shall be recorded in the Registry of Accredited CABs and the Registry of Accredited Testing Laboratories, according to Annex A.

**7.2 Updating of the scope of accreditation**

**7.2.1** For the updating of the scope of accreditation, the application and the attached documents TL submits to the ARMNAB.

Updating of the scope is carried out at a request of the CAB:

a) review of a test method by a standardization body (or relevant authorized body), public administration body or laboratory, which does not involve on-site assessment,

b) use of accredited test methods for testing other products;

c) changing the name of a legal entity,

d) reduction of the number of accredited activity sites (rejection of accreditation of one or several sites in the case of testing the same product);

e) change of the code of the common product nomenclature of the external economic activity of the Eurasian Economic Union.

7.2.2 No on-site assessment is performed during the updating process. The updating process is defined in procedures PR-03 and PR-7.

# 7.3 Reduction of the scope of accreditation

**7.3.1** The process of reduction of the scope of accreditation takes place in according to PR-7.10-7.11 and PR-7 procedures:

- 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).

**7.3.2** 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 and the Registry of Accredited Testing Laboratories, according to Annex A.

# 7.4 Suspension and Withdrawing of accreditation

7.4.1 The grounds and procedure for suspension and withdrawing of accreditation are defined in PR-7 procedure.

# 7.5 Recovery of accreditation

**7.5.1** 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.

**7.5.2** The procedure for recovery of accreditation is defined in procedure PR-7.

# 8 Complaints and appeals

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)).

# 9. Obligations of TL and ARMNAB

9.1 The obligations of CAB and ARMNAB are defined in the Accreditation Agreement concluded between CAB and ARMNAB, as well as in section 5 of this document.

9.2 All information related to the relationship between ARMNAB and an accredited TL, or an TL and an applicant, must be confidential, therefore ARMNAB provides information about an TL to a third party if:

• publication of information is provided by accreditation standards, rules,

• defined by law or authorized bodies,

• the request with its justification is sent to ARMNAB by another accreditation body that is a signatory party to the EATM, EA, ILAC accreditation organizations,

• the provision of information is carried out with the express and unanimous consent of all involved parties.

# 10. Annexes

Annex A – Template of the Registry of Accredited Testing Laboratories

Annex B – Information on testing reports (protocols) provided by the testing laboratory, Participation in PT and/or ILC, on Plan performance

Annex C - Updated List of Documents and Documents

Annexes ATL-01-01 - ATL-01-11 – Application form and attached documents for testing laboratories

Annex ATL-01-01-DR – Document Review Report form, according to GOST ISO/IEC 17025-2019 Standard

Annex ATL-01-02-DR – Additional Document Review Report form, according to GOST ISO/IEC 17025-2019 Standard

Annex ATL-01-R – On-Site Assessment Report form, according to GOST ISO/IEC 17025-2019 Standard

Annex ATL-01-AR – Additional On-Site Assessment Report form, according to GOST ISO/IEC 17025-2019 Standard

Annex ATL-01-TWR –Testing Laboratory Witnessing Report form

**DOCUMENT AMENDMENTS LIST**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Edition:** | **Amendment:**  | **Amended points / words** | **Amended (previous) version** | **Signature of the amending person** |
| **No** | **Date of approval** | **No** | **Date of approval** |
| 1 | 17.11.2015 | 1 | 30.03.2016 | Remove Annex ATL-01-07  | Information on laboratory equipment with chemical agents and bacteriological media  |  |
| 2 | 13.01.2017 | **Annexes**ATL-01-02–of Eurasian Economic Union; ACB-01-09 – Remove the 3rd column; ACB-01-11- add the words “in the subject sector” in the 7th column.  | Customs UnionName of the document-  |  |
| 3 | 20.03.2017 | Annex ATL-01-03Add a new column“Notes and comments”.Annex ATL-01-09 LIST of applied standards and technical regulations;LIST of applied legal acts and procedures (including the standard operational procedures (SOP)) | -LIST of applied standards, technical regulations, procedures and legal acts  |  |
| 4 | 02.08.2018 | Annex ATL-01-01, documents attached to application - add a new Clause 14.  | - |  |
| 5 | 15.11.2018 | Annex ATL-01-10 – provide with the new 3rd edition.  | - |  |
| 2 | 17.05.2019 |  |  | Text of the procedure  | New edition |  |
| 1 | 17.05.2019 | Annexes ATL-01-01, ATL-01-02, ATL-01-03, ATL-01-05 ATL-01-11, ATL-01-DR, ATL-01-R, ATL-01-AR | New edition |
| 2 | 15.08.2019 | Annexes ATL-01-01, ATL-01-03, ATL-01-05  | New edition |
| 3 | 08.10.2019 |  |  | Text of the procedure, Annex B | New edition |  |
| 1 | 08.10.2019 | Annexes ATL-01-01, ATL-01-03, ATL-01-05, ATL-01-DR, ATL-01-R, ATL-01-ARNew annex ATL-01-TWR | New edition |
| 2 | 13.01.2020թ. | New annex - ATL-01-02 | New edition |
| 3 | 25.05.2020թ. | Appendix ATL-01-11In the 3rd column, add "Working hours specified in the contracts of the main and part-time employees" | - |  |
| 4 | 16.03.2020 |  |  | Text of the procedure | New edition |  |
| 1 | 01.07.2020 | Remove "Additional Requirements" table from ATL-01-03, ATL-01-DR appendices | "Additional Requirements |  |
| 5 | 29.12.2020 |  |  | Text of the procedure | New edition |  |
| 1 | 11.03.2021թ. | Annex ATL-01-02 | 6-րդ սյունակի անվանման մեջ փոփոխություն |  |
| 2 | 07.10.2021թ. | Annex C | New edition |  |
| 6 | 10.01.2022 |  |  | Text of the procedure | New edition |  |
| 7 | 04.07.2023 |  |  | Text of the procedure | New edition |  |
| Annex ATL-01-01 | 6 edit. |  |
| Annex ATL-01-04  | 4 edit. |  |
| Annex ATL-01-10  | 5 edit |  |

**FAMILIARIZATION LIST**

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