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PROCEDURE

OF EA "BAS" FOR METROLOGICAL TRACEABILITY POLICY OF MEASUREMENT RESULTS AND ITS IMPLEMENTATION

List of amendments

List of amendments

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1.	23.02.2016	Version 3	Update in compliance with requirements of ILAC P10:01/ 2013	01.03.2016
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6.	01.05.2022	Version 4	Update in compliance with BAS QI 24 (ver.1, 2021)	01.05.2022r.

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I. Purpose and scope

- 1.1 The present document sets out the policy of the Executive Agency "Bulgarian Accreditation Service" (EA BAS) for metrological traceability of the measurement results.
- 1.2 The present document is applied by Conformity Assessment Bodies (CABs), that perform measurements related to the activities, for which they are accredited:
 - laboratories for testing and calibration according to BDS EN ISO/IEC 17025 [1];
 - medical laboratories according to BDS EN ISO 15189 [2];
 - inspection bodies according to BDS EN ISO/IEC 17020 [3];
 - product certification bodies according to BDS EN ISO/IEC 17065 [4]
- 1.3 The present document is applicable for organizers of *proficiency testing providers* fulfilling the requirements of BDS EN ISO / IEC 17043 (item 4.4.1 and item 4.4.5) [5] and producers of certified reference materials (CRM) according to *BDS EN ISO 17034* [6].
- 1.4 The policy of EA BAS for metrological traceability of the measurement results is to establish the necessary conditions and sources for ensuring metrological traceability of the measurement results/ provided by the above CAB, in compliance with the policies of the international organizations EA and ILAC [8].

II. Basic provisions

Metrological traceability requires an unbroken chain of calibrations to designated reference element (reference) to the ultimate system for measuring the result, while result of any calibration is a measurement within given uncertainty and depends on the outcome of the previous calibration [8].

Reference element in metrological chain could be:

- definition of measurement unit through its practical realization,
- or measurement procedure, including measurement unit of a nonordinal value,
- or standard. [7,8]

Metrological traceability relates to the reference values of standard and measurement results.

NOTE 2 A reference can be a measurement unit, a measurement procedure, a reference material, or a combination of such.

NOTE 1: Metrological traceability of a measurement result must not be related to an organization, which provides these results (e.g. „traceability to certain National Metrology Institute“). This leads to a misinterpretation of the nature of the metrological traceability [7,8]

NOTE 2: In the text of this document we will further use the abbreviated term "metrological traceability" instead of the full "metrological traceability of the measurement result. [7]

EA BAS defines its metrological traceability policy taking into account the following:

- stated requirements for metrological traceability of the measurement results, provided by CAB, described in standards as listed in item 1.2 and item 1.3 of present document;
- policy papers and guides for provision of metrological traceability of the international organizations ILAC [8] and BIPM, as well as regional organizations, EA [8],[18], EURAMET, EURACHEM.
- in some fields as chemistry, medicine, biological sciences, implementation of requirements to ensure metrological traceability of the measurement results is still in the development stage, despite the efforts of some international organizations [8].
- In certain fields availability of reliable, traceable certified reference materials for

ensuring metrological traceability are in the process of study, research [8].

III. Metrological traceability of measurement results – terms and definitions

3.1 The abbreviated term "traceability" sometimes is used for different purposes.

In order to avoid the risk of error and confusion, the full term "metrological traceability" is preferred. [7]

3.2 In the present document of EA BAS basic terms and definitions are used as provided in the ISO/IEC Guide 99 International vocabulary of metrology - Basic and general concepts and associated terms (VIM), 2007, implemented in Bulgarian language as SD ISO/IEC Guide 99:2014 „International vocabulary of metrology- Basic and general concepts and associated terms“ [7]:

3.2.1 Metrological traceability (2.41, VIM)

Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

NOTE 1: For this definition a 'reference' can be a "definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard".

NOTE 2: The metrological traceability requires the establishment of hierarchy of calibrations.

NOTE 3: The reference description has to include the time during which it has been used for establishing the hierarchy of the calibrations, including all other relevant to the reference metrological information, e.g. as date on which first calibration from the hierarchy of calibration was performed.

NOTE 4: for measurements with more than one input value in measurement, each reading of input value has to be metrological traceable and included in the hierarchy of calibration and could form a branched structure or network.

The effort made in establishing metrological traceability for each input value reading should be a comparable with its relative contribution to the measurement results.

NOTE 5: Metrological traceability of measurement result does not provide that the measurement uncertainty is appropriate for particular purpose or lack of human errors.

NOTE 6: The comparison between two references may be considered as calibration, when it is used to verify and when necessary, to correct the reading of the value and the uncertainty of measurement, pertaining to one of the references.

3.2.2 Chain of metrological traceability (2.42, VIM)

Sequence of references and calibrations that is used to connect the result of measurement with the reference element.

NOTE 1: The metrological traceability chain is defined by hierarchy of calibrations.

NOTE 2: The metrological traceability chain is used for establishing the metrological traceability of the measurement result.

NOTE 3: The comparison between two references may be considered as calibration, when it is used to verify and when necessary, to correct the reading of the value and the uncertainty of measurement, pertaining to one of the references.

3.2.3 The metrological traceability to a measurement unit

Metrological traceability is a traceability, at which the reference element is the definition of the measurement unit by its practical realization.

NOTE 1: The expression "Traceability to SI" means "metrological traceability" to a measurement unit of the International System of Units, SI.

The use of the term reference material or „comparative" material is equivalent [7]

3.2.4 The use of the terms a Reference Material (RM) or „comparative" material is equivalent, as well as Certified Reference Material (CRM) *is equivalent of Certified „comparative" material*. Definitions of these terms is provided in the publications [7], [21].

3.3 Internal Laboratory calibration/ internal company calibration

Calibration performed by CAB for internal needs and activities is not a part of accreditation scope. It is object of assessment of EA BAS.

NOTE 1: Details of the EA BAS policy in this type of calibration are provided in section V of this

document.

3.4. For the implementation of the chain of metrological traceability and achieve acceptable valid measurement result the following elements are important:

- **Measurement Uncertainty**

At each stage of the metrological chain, the uncertainty must be calculated or estimated and expression of the measurement uncertainty on the basis of commonly adopted methods [10], [11], [12] and the results are reported in such a manner that whole chain uncertainty could be calculated or estimated;

- **Documentation**

Each stage of the metrological chain has to comply with documented procedure, usually, well-known procedures and each result has to be recorded;

- **Competence**

CAB, which perform one or more actions at each stage of this chain, must present evidence of their technical competence (e.g. through their accreditation and/or the international recognition of corresponding calibration and measurement capabilities confirmed by accreditation body in compliance with its policy);

- **Reference element – unit from the International System of Units, SI**

The metrological chain of traceability has to end up to initial reference, performing SI measurement units, when possible.

- **Calibration intervals (subsequent calibration)**

Calibration of measuring instruments has to be carried out at appropriate time periods. Periods of recalibration of measuring instruments depend on many factors (e.g. required uncertainty, stability of the instrument, frequency of use, method of use), described in details in a joint paper of International Organizations ILAC and OIML (ILAC G 24/ OIML D10) [16].

- **Method of measurement**

According to Note to cl. 7.2.1.1 of BDS EN ISO/IEC 17025:2018 [1] for the calibration laboratories term „**method**“ is equivalent to „**measurement procedure**“. According to cl. 2.6 of SD ISO/IEC Guide 99:2014 „International vocabulary of metrology- Basic and general concepts and associated terms“ [7]:

measurement procedure (procedure of measurement) is detailed description of measurement in accordance with one or more measurement principals and the given measuring method, on the basis of model of measurement, including all calculations for estimation of measuring result.

Note 1: Measurement procedure usually is enough detailed, that the operator can conduct the measurement.

Note 2: Measurement procedure can include declaration of the target uncertainty.

Note 3: Measurement procedure sometimes can be called standard operating procedure, in English „standard operating procedure“, with abbreviation "SOP".

The results of the internal laboratory calibration must be presented by the laboratory in accordance with the calibration requirements (if there are any) of relevant testing standard and ILAC-P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration [11] and EA-4/02-M:2022 Evaluation of the Uncertainty of Measurement in Calibration [12].

IV. Policy of metrological traceability of measurement results

4.1 CABs, has to calibrate all measurement instruments, which are used for calibration, for testing and/or other processes, having an impact on the validity and accuracy of the results, which are required to be metrological traceable, has to be calibrated [1], [2], [3], [4], [5], [6], [8].

4.2 CABs, in all cases, has to provide evidence for analysis and criteria against which the measurement instruments in the measurement process are appropriate and provide valid and metrologically traceable results.

4.3 Sources of traceability recognized by EA "BAS" are [8]:

- 1) Bulgarian Institute of Metrology (BIM), National Metrology Institutes (NMIs), including the

institutions with delegated rights, which are covered by CIPM MRA and published in Appendix C, BIPM KCDB [9];

NOTE: International Bureau of Weights and Measures, BIPM provides information about calibration of standards and certificates issued by countries and areas of measurement.

- 2) Accredited by EA "BAS" (like part of Multilateral agreement EA MLA in calibration) calibration laboratories performing calibration, which is appropriate for the intended use (accredited calibration and measurement capabilities are applicable for the intended use) [8].

Accredited calibration laboratories with calibration and measurement scope, accredited by other National Accreditation Body, signed the Multilateral Agreement of EA (EA MLA), ILAC (ILAC-MRA) or of Regional agreement, recognized by ILAC in the field of calibration field [8].

- 3a) *National Metrology Institutes (NMIs), which services are appropriate for the intended use, but not covered by CIPM MRA. In this cases EA "BAS" like national accreditation body sets policy to guaranty, that this service comply with the relevant criteria for metrological traceability of ISO/IEC 17025.*

or

- 3b) *Laboratories, which services are appropriate for the intended use, but not covered by ILAC or regional agreements, recognized by ILAC. In this cases EA "BAS" like national accreditation body sets policy to guaranty, that this service comply with the relevant criteria for metrological traceability of ISO/IEC 17025.*

Accredited organizations, demonstrated metrological traceability of results of their measurements by using calibration services, offered in compliance with 1) or 2) above, using services, that have been object of relevant PR assessment or accreditation. In other situations, where 3a) or 3b) are applied, this approach have to be applicable only where 1) or 2) are not possible for the calibration. (ILAC-P10:07/2020, cl.2)

4.3.1 In case of metrological traceability provided by Certified Reference Materials (CRM), EA BAS policy follows the policy of *ILAC-P10:07/2020* [8]:

- Assigned to CRM values, produced by NMI, members of BIPM KCDB or produced by accredited producers of Reference Materials (RM) in compliance with *BDS EN ISO 17034* [6], provide valid metrological traceability of measurement result;
- Assigned to CRM values, recorded in the database of JCTLM-BIPM [13], used by medical laboratories are considered with established and valid metrological traceability;

4.3.1.1 The content of the CRM certificate has to include not limiting to following:

- Stated measurement traceability of the certified value of CRM (e.g. traceability to measurement units of the International System of units SI or to values, obtained through a reference method);
- Stated uncertainty of measurement in compliance with the requirements of ISO Guide 98-3(GUM) [10];
- Information for the competence of the manufacturer in compliance with *BDS EN ISO 17034* [6], including information for the accreditation status;

or

- Information for the accredited calibration laboratory or NMI (see item 4.3), calibrated CRM in cases when the values of CRM are defined through calibration;

4.3.1.2 The content of the CRM certificate has to comply with requirements of ISO Guide 31 [14]

When Reference Materials (RM) and Certified Reference Materials (CRM) produced by other Reference Material Producers (RMPs), they can be recognized like critical consumatives. CAB have to prove, that any RM or CRM is applicable for the intended use, according to the

documents, pointed in cl. 1.2 and τ.1.3 of this procedure. Competence of Reference Material Producers (RMPs), must comply with BDS EN ISO 17034 [6].

4.3.2 EA BAS requires the certificate for calibration of measurement instrument to include: data and evidences of metrological traceability of used for calibration reference elements (standards, CRM, reference procedures, indicating the source of metrological traceability (see item 4.3) a statement of the result of calibration and associated measurement uncertainty.

The stated measurement uncertainty has to be calculated and declared in accepted methods described in international documents of BIPM [10], EA [12], ILAC [11] and in accordance with requirements of the relevant standards (accreditation criteria, see item 1.2.).

4.3.2.1 EA BAS recognized logo CIPM MRA on certificates for calibration set by NMI. Its presence means that the calibration service provided is covered by the CIPM MRA, while at the same time it is noted that the placement of the logo is not obligatory. EA BSA considers that the reliable source for calibration is covered by CIPM MRA, BIPM KCDB [8].

4.3.2.2 EA BAS requires accredited by EA BSA laboratories for calibration to meet the requirements for use of symbols of accreditation body under the procedure BAS QR 5 [15].

4.3.2.3 EA BAS requires calibration laboratories to declare their calibration and measurement capability (Calibration and Measurement Capability-CMC) following instructions of ILAC [11], EA[12] и BIPM [17].

4.3.2.5 When there is doubt about the validity of the certificate or other information regarding the possibility of performing a particular calibration, EA BAS can provide a response to the received signal and inquiry.

V. Internal Laboratory Calibration

5.1 EA BSA considers that the CAB may choose to perform internal laboratory calibration of their measurement instruments, to provide metrological traceability of the results, of the corresponding accredited activities as well as their maintenance, *keeping the requirements of cl.IV. cl. 4.3 (ILAC-P10:07/2020, cl.2)*. In this type of calibration, CAB uses its own standards, measurement instruments and personnel. *In this cases all elements of cl.3.4 have to be available.*

5.1.1 Measurement instruments used in internal laboratory calibration, which have been proven to have negligible impact* on the accuracy or validity of the result of the testing, research, are allowed to be checked following appropriate procedure in order to establish that their metrological properties and functional characteristics meet the documented requirements described in technical documents.

Note: * Assessment of the negligible impact on accuracy can be made based on measurement uncertainty. When in standard or generally valid technical document the criterion of "negligible impact" is defined, the CAB may use it. In case of absence of such information, the following guidance could be used for this: "negligible impact" is defined as "unchanging value of the expanded uncertainty by more than 5%". Responsibility for this assessment is of CAB, but in all cases, it has to be based on analysis and proves, that are subject of evaluation.

5.2 EA BAS recognizes that in certain areas performing the test, measurement, calibration, research, could be conducted after calibration immediately before use of measuring system or a measuring instrument.

Often in these cases, the calibration procedure is described in the test standard or standard for a given process and it is part of the overall test procedure or process.

In this case, the internal calibration can be considered as "calibration prior to use". To this kind of "calibration prior to use" measuring systems requiring frequent recalibration (e.g. daily,

weekly, monthly) are regarded.

5.2.1 EA BAS considers that the CAB in order to conduct measurement and provide metrological traceability has to perform competent internal laboratory calibration.

5.2.2 CAB has to indicate internal laboratory calibration that is performed and to provide evidences that it is performed competently in compliance with requirements.

5.3. CAB has to comply with requirements to assure the metrological traceability when conducting competent internal laboratory calibration, to ensure the accredited scope of testing or calibration, or other process such as:

- provide appropriate conditions for performing the calibration;
- provide trained and authorized personnel to perform calibration and the necessary verifications of the measuring system or the measuring instrument when they are applicable and appropriate;
- provide the necessary appropriate standards and/or certified reference material (CRM), reference technical instruments where they are required by the procedure;
- documented procedure for each type of calibration including description of the process and method of calculating the calibration measurement uncertainty in accordance with requirements of international documents [10,11,12].
- resources for recording and for calculating data;
- appropriate level of methods for *validity of the results*;
- records for calculations of calibration result, including records and the measurement uncertainty, for impact of the calibration result on the final measurement result.

Records showing the overall process of internal calibration has to be traceable and the requirements for them to be specified in the procedure.

NOTE 1: When in the standardized method of testing or calibration or of another process the calibration procedure is included, sufficiently described in details and information is clear, then CAB has to refer to it and implement it. *In this cases like enough evidence CAB can give detail records for the verification of the method.*

NOTE 2: When in the standardized method of testing or calibration or other process, calibration procedure is not sufficiently described in details and is not clear (often the procedure for calculating the uncertainty the procedure for calculating the uncertainty in CABs calibration is not described or metrological properties of measuring tools and other details that make difficult its implementation), then CAB may refer to the method, but it is required to have additional description in details of this part of the method of the implementation of calibration, which is not detailed and clear enough, taking into account all conditions under which that calibration is performed, including the level of competence of the personnel performing the calibration. *In this cases like needed evidence CAB can give detail records for the validation of the method.*

In informative Annex 1 some basic elements of the calibration procedure that can be used in assessing the documentation of calibration, complying with the requirements of the standards set out in section 1.2 of present document are described.

5.4 CAB has to declare to EA "BAS" activities performed during internal calibration and provide information that at least contains, but is not limited to the following:

- calibration method/ procedure,
- measurement uncertainty budget,
- complete information for ensuring metrological traceability.

This information is provided to EA BAS for assessment of this activity by competent personnel using assessment methods given in BAS QR 2.

5.5. Possibilities for internal laboratory calibration are not published and are not included in the accredited scope of CABs, *nevertheless, CAB must to give records for this. For possibilities for internal laboratory calibration CAB can use requirements of BAS QI 24 [22].*

5.6 EA "BAS" keeps the records of the evaluation of internal laboratory calibration performed by the CAB.

VI. Maintenance of metrological traceability

6.1 CAB has to use calibrated measuring instruments with valid calibration status when they have impact to the accuracy and validity of the results from the measurement, calibration, testing, sampling.

6.1.1 To maintain metrological traceability of results from calibration, measurement, testing, sampling and other activities CAB has to define the measurement instruments that has to be periodically calibrated.

6.1.2 CAB has to maintain updated its programs for calibration of measuring instruments, of standards (reference standards) as well as certified reference materials (only for those used for calibration) and for that purpose define recalibration perions in compliance with instructions of Guide ILAC G24 [16].

6.1.3 The program for calibration has to be controled and operated, to assure metrological traceability of calibrations, testing, measurements, research, performed by the CAB, to units of the International System of Units, SI.

6.1.4 Standards (reference standards) of llaboratories for calibration has ~~only~~ to be used for calibration and not for any other purposes, unless the proves are provided that the metrological properties of standards (reference standards) are not violated, which is subject to evaluation by EA BAS.

7. Ensuring metrological traceability – additional options and specific issues

7.1 There are cases when NMI could calibrate measuring instruments, appropriate for the intended need, but the calibration is not covered by CIPM MRA (*ILAC-P10:07/2020, cl. 3a*) [8]), then EA BAS requires the following additional evidences, without limiting to this:

- Copies of calibration procedures and records for their validation;
- Copies of procedures for assessing of measurement uncertainty, including the budget of measurement uncertainty;
- Documentation - proves of metrological traceability of measurements;
- Documentation and records to assure the quality of the calibration results, including results of participation in interlaboratory comparisons with other NMI, which has recognized calibration and measurement capabilities (CMC) covered by the CIPM MRA and published in Appendix C, BIPM KCDB;
- Evidences for competence of the personnel and authorization;
- Documentation of calibration conditions and premises;
- On site audit/audits of calibration laboratory, including measuring audit.

7.1.1 EA BAS assessed the proves and capabilities of the organization in order to assure that the criteria for metrological traceability in accordance with present document are respected.

7.2 *In some cases when CAB can perform calibration of measuring instruments, sufficient for the needed use of CAB (ILAC-P10:07/2020, τ.3b) [8]), but there is not available evidences to proves for ensuring metrological traceability to units SI, then EA BAS considers that the CAB could use the following reference elements:*

- certified reference materials (usually matrix) delivered by a competent provider,
- comparison with documented validated methods (preferably reference), and / or
- consensus standards that are described in detail and approved by all stakeholders, or
- a combination of above (*ILAC-P10:07/2020, τ.3b*) [8]).

NOTE 1 EA“BAS” defines as a competent provider of CRM, that who meets the requirements of *BDS EN ISO 17034* [6] (*ILAC-P10:07/2020, τ.7a*) [8]).

NOTE 2: When no appropriate CRM exists, the CAB can choose a RM or to develop a RM, appropriate for the purposes of measurement, calibration and to obtain reliable results, by presenting:

- records for characterization of RM, with applied scheme for characterization, participating laboratories, competence of the organizer of the scheme for the characterization and/or

certification - National Metrology Institute, an organization accredited to *BDS EN ISO 17034* and others (*ILAC-P10:07/2020, cl.4,5,6*) [8]),

- experimental proves of calibration and measurement capabilities of the laboratory that performed the characterization and giving of the *assigned* values of the characteristics of the material or substance,
- results of participation in interlaboratory comparisons (ILC) schemes or proficiency testing (PT), respectively organized by competent providers, international organizations [5] (*ILAC-P10:07/2020, cl.7b, rem.5*) [8]),
- systematic records of quality control through the application of generally accepted statistical methods.

Responsibility for characterization and establishing metrological properties of the material is of CABs as the presented proves are assessed by EA BAS.

Additional possibilities for maintaining of metrological traceability according to cl.7.1 and 7.2 are applicable only where described in 1) or 2) of cl. IV. cl. 4.3, are not possible for this calibration (ILAC-P10:07/2020, cl.2).

NOTE 3: In specific and justified cases, the CAB could use material / sample involved in the proficiency testing scheme [5]. This option is subject to evaluation by EA BAS.

7.3 In cases when metrological problems of metrological traceability are identified, in informative Appendix A of ILAC-P10:07/2020 [8] are given instructions to request additional evidences supporting the decision on the validity of the results.

These include but are not limited to (*related to clauses of EN ISO/IEC 17025:2018*):

- Records of validation of the method for calibration (cl.7.2.2.4);
- Procedures for assessing uncertainty (cl.7.6);
- Documents, records of metrological traceability (cl.6.5);
- Documents, records for validity of the results of calibration by using appropriate methods (cl.7.7);
- Documents, records for competence of personnel (cl.6.2);
- Documents, records of measuring equipment (cl.6.4);
- Documents, records of ambient conditions (cl.6.3);
- Records of audits (cl.8.8).

Indicated option is only for cases when no other eligible sources of metrological traceability are available. EA BAS accepts these guidelines. EA BAS assess the proves presented by the CAB.

7.4 In the cases described in paragraphs 7.1 and 7.2 CABs provide additional evidences to ensure confidence in the results obtained from measurements through participation in appropriate programs of interlaboratory comparisons or schemes for proficiency testing, (*ILAC-P10:07/2020, cl.7b, Note:5.*) [8]), subject to assessment by EA BAS in compliance with requirements of BDS EN ISO / IEC 17043 [5] and BAS QR 18 [19].

7.5. If necessary, EA BAS could use the expertise of specially established working groups of technically competent persons, representing interested parties on a particular issue to the Technical Accreditation Committees (TACs).

7.6 EA BAS has the right, in certain specific cases in some fields where the provision of metrological traceability is not yet fully understood and adequately studied in the world to deviate from the policy thus defined and require other evidence and facts to assure confidence in measurement results on the basis of documents of the BIPM, ILAC, EA, EURACHEM and other international organizations operating on issues of metrological traceability (*ILAC-P10:07/2020, cl.7b, Note:4.*) [8].

8. Additional information and instructions

8.1 EA BAS maintains information about the best calibration and measurement capabilities of accredited calibration laboratories, as well as for sources for their measurement traceability

referring to the published official data on them.

8.2. The information that is necessary for CAB and interested parties for traceability of national metrological institutes, members of the Multilateral Agreement of the International Committee for Weights and Measures -CIPM (CIPM MRA), is published in Appendix C of the CIPM MRA. (Www.bipm.org).

8.3. If necessary, the CAB has to submit the originals of certificates for calibration or other evidences, proving the authenticity of the documents. During the onsite assessments, CAB has to present to the assessors originals of the calibration certificates.

8.4 EA BAS consider that:

- Certificates for calibration issued by an accredited laboratory, without reference to accreditation, are not recognized as enough evidence for metrological traceability.
- Issued documents for measurement or calibration, referred to certificate of conformity with ISO 9001 (because the organization issuing it has been certified under ISO 9001) that have a mark (logo) of the organization that carried out the certification to ISO 9001 are not proves of metrological traceability in terms of present procedure.

9. Transitional provisions

9.1. The present policy, defined in present document „ Procedure of EA “BAS” for metrological traceability policy of measurement results and its implementation “, version 4, cancels „Procedure of traceability policy of EA BAS and its implementation” BAS QR 27 version 3, dated 01.03.2016 r., enters into force commencing 01.05.2022 and has to be implemented immediately for all accreditation applicants, applying after that date as well as by accredited CAB.

10. Reference

1. БДС EN ISO/IEC 17025:2018 General requirements for the competence of testing and calibration laboratories.
2. БДС EN ISO 15189:2012 Medical laboratories -- Requirements for quality and competence.
3. БДС EN ISO/IEC 17020:2012 Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
4. БДС EN ISO/IEC 17065:2012 Conformity assessment -- Requirements for bodies certifying products, processes and services
5. БДС EN ISO/IEC 17043:2023 Conformity assessment - General requirements for the competence of proficiency testing providers
6. БДС EN ISO 17034:2017 General requirements for the competence of reference material producers
7. ISO Guide 99 International vocabulary of metrology- Basic and general concepts and associated terms (VIM), 2007, applied in Bulgarian language as СД ISO/IEC Ръководство 99:2014 Международен речник по метрология. Основни и общи понятия и свързани термини
8. ILAC-P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results
9. Mutual recognition of national measurement standards and of calibration and measurement certificates issued by national metrology institutes, International Committee for Weights and Measures, 1999, (CIPM-MRA), <http://www.bipm.org>
10. ISO/IEC Guide 98-3:2008 Uncertainty of measurement - Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)
11. ILAC-P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration
12. EA-4/02-M:2022 Evaluation of the Uncertainty of Measurement in Calibration
13. JCTLM data base : Laboratory medicine and *in vitro* diagnostics www.bipm.org
14. ISO Guide 31:2015 Reference materials Contents of certificates, labels and accompanying documentation (Remark to translation: replaced by ISO 33401:2024 "Reference materials — Contents of certificates, labels and accompanying documentation")
15. BAS QR 5 Rules for use of EA BAS accreditation logo
16. ILAC-G24/OIML D 10: Guidelines for the determination of recalibration intervals of measuring equipment used in testing laboratories

17. BIPM, Calibration and Measurement Capabilities – CMCs, KCDB, www.bipm.org
18. Joint BIPM, OIML, ILAC and ISO declaration on metrological traceability, 2011
19. BAS QR 18 „Procedure for performing interlaboratory comparisons and schemes for proficiency testing”
20. BAS QI 10 Instruction for assessment of calibration laboratories for compliance with technical requirements of BDS EN ISO/IEC 17025
21. ISO Guide 30:2015 Reference materials — Selected terms and definitions
22. BAS QI 24 *Instruction for formulation of scope of accreditation of laboratories performing calibration*

This document translation has been prepared for the needs of activities related to the accreditation, based on the official document of EA BAS.

In case of discrepancies and differences between the Bulgarian document and its translation, the original document in Bulgarian shall be considered as leading.

ANNEX A (informative)

Component of the content of calibration procedure

For each calibration must be described the way for its implementation, taking into account the available technical documentation (applicable standards, international guidelines, generally recognized specifications, recommendations of the manufacturer of the measurement tool and other publications of respected authoritative international organizations that contain requirements for ways to perform calibration and how the results of its implementation, including the uncertainty of measurement in calibration).

In developing the calibration procedure CAB has to take into account whether the described method is sufficient and clear for the completion of calibration, including compliance with requirements for presentation of the results with the associated uncertainty [10] [11] [12].

The technical procedure for the calibration of measuring tool or a group of measuring devices should include the following elements, without being limited to the following:

- name and identification of the procedure;
- scope;
- description of the measurement tool or group of measuring devices for which the procedure applies, including their basic metrological characteristics; measured values in the calibration and indications,
- calibration conditions, including inside and outside the laboratory premises;
- references used, CRM, RM, calibrators with descriptions of their metrological properties; setup required, depending on environmental conditions, including indication of the prior time, who is required for stabilization of the measurement tool;
- requirements for measures, that to be taken during operation, transport and storage of technical measurement tools, CRM, RM and other additional equipment, including safety ones;

Note: In cases where necessary, the CAB describe or refer to the method / the procedure for the preparation of calibrators. It is usually implemented in some areas, such as chemistry, physical chemistry, biology, medicine and other similar fields.

- requirements for use, transport, storage and preparation of the technical means, including those to be calibrated;
- criteria to secure metrological traceability and its proves of securing;
- Use of additional and other equipment, consumables, including their technical characteristics (especially when they affect the process of measurement);
- requirements for the competence of the personnel performing the calibration and maintenance of his competence;
- preparation of calibration objects and the technical means used in calibration and verification of their operation;
- model / function for measurement during calibration;
- sequence of calibration activities and instructions for their implementation and the necessary records to prove it;
- procedure for calculating the uncertainty of measurement during calibration, including budget for uncertainty [10,11,12], and on other appropriate manuals for the specific area;
- criteria for acceptance / rejection of the results of calibration;
- a way of registration and recording the results of the calibration;
- criteria for the assessment of period of re calibration, way of its definition and recording of their implementation;
- information on the confirmed options for measurement and for calibration and records thereof[12]