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PROCEDURE

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

List of amendments

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List of amendments

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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 interlaboratory comparisons fulfilling the requirements of BDS EN ISO / IEC 17043 (item 4.4.1 and item 4.4.5) [5] and producers of certified reference (comparative) materials (CRM) according to ISO Guide 34 [6].
- 1.4 The policy of EA BAS for metrological traceability of the measurement results is to establish the necessary conditions and sources to secure metrological traceability of the measurement results provided by the above CAB, in compliance with the policies of the international organizations EA and ILAC her [8].

II. Basic provisions

Metrological traceability requires an unbroken chain of calibrations from designated reference elements (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 implementation,
- or measurement procedure, including a unit of measurement of a nonordinal value,
- or reference. [7,8]

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

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], EA and other regional organizations of accredited conformity assessment bodies, members of ILAC and EA [8], [18].
- in certain 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 securing 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)

Feature of a measurement result, which may be related to "reference element" (reference), by means of continuous chain of calibrations, each of them contributing to the measurement uncertainty.

NOTE 1: According to the definition the reference may be:

- definition of the measurement unit through its practical implementation or
- measurement procedure, including a unit of measurement of a non ordinal value or
- reference.

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, implemented in practice.

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 terms a 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). 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 not subject of accreditation 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 announced 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].

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]:

- 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 references and certificates issued by countries and areas of measurement.

- Accredited by EA "BAS" (member of Multilateral agreement EA MLA in calibration) calibration laboratories with calibration, which is appropriate for the intended use (accredited calibration capabilities and measurement are applicable for the intended use [8]).
- Accredited calibration laboratories with calibration and measurement scope, accredited by other National Accreditation Body – member of the Multilateral Agreement of EA (EA MLA) or ILAC (ILAC-MRA) or of Regional agreement, recognized by ILAC in the calibration field [8].

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

- Assigned to CRM values, produced by NMI, members of BIPM KCDB or produced by accredited producers of Reference Materials (RM) in compliance with ISO Guide 34 [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 (license) has to include not limiting to following:

- Stated 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 ISO Guide 34[6];

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 (license) has to comply with requirements of ISO Guide 31 [14]

4.3.1.3 In the cases, when Reference Materials (RM) and CRM are produced by other producers of RMPs, they may be considered as critical consumables. CAB has to prove that each Rm or CRM is appropriate for its intended use in compliance with the documents of items 1.2 and 1.3 of the procedure.

4.3.2 EA BAS requires the certificate (license) for calibration of measurement tool to include: data and proves of metrological traceability of used for calibration reference elements (reference, 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 expressed 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 (license) 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] EA BAS recognized logo CIPM MRA on certificates (license) 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 laboratories for calibration by EA BSA to meet the requirements on the use of symbols of accreditation body under the procedure BAS QR 5 [15].

4.3.2.3 EA BAS requires calibration laboratories to state their opportunity for calibration and measurement (Calibration and Measurement Capability-SMC) 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 carrying out 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 tools to provide metrological traceability of the results of the corresponding accredited activities as well as their maintenance. In this type of calibration, CAB uses its own references, measurement tools equipment and personnel.

5.1.1 Measurement tools 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 the absence of such information, the following indication could be used for this assessment: "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 which are subject to evaluation.

5.2 EA BAS recognizes that in certain areas performing the test, measurement, calibration, research could not be done without measuring system or a measuring tool to be calibrated immediately before.

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 relevant 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 proves that it is performed competently in compliance with requirements.

5.3. CAB has to comply with requirements to secure 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 tool when they are applicable and appropriate;
- provide the necessary appropriate references and / or certified reference material (CRM), reference technical means where they are required by the procedure;
- documented procedure for each type of calibration including description of the process and method of calculating the measurement uncertainty during calibration in accordance with requirements of international documents [10,11,12].
- means for recording and for calculating data;
- appropriate level of methods for quality control;
- records for calculations of calibration result, including records and the uncertainty of measurement, 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 and calibration or of another process the calibration procedure is complete, sufficiently described in details and information is clear, then CAB has to refer to it and implement it.

NOTE 2: When in the standardized method of testing and 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 calibrators and other details that hamper its implementation), then CAB may refer to the method, but it is required to have further 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 informative Annex 1 some basic elements of the contents of the calibration procedure that may 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,
- uncertainty budget,
- complete information for securing metrological traceability.

This information is provided to EA BAS for evaluation 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 in the accredited scope of CABs.

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 means with valid calibration status when they affect the accuracy and validity of the results from the measurement, calibration, testing, sampling (samples).

6.1.1 To secure metrological traceability of results from calibration, measurement, testing, sampling and others CAB has to define the means of measurement that has to be periodically calibrated.

6.1.2 CAB has to maintain updated its programs for calibration of measuring means of reference (initial references) as well as certified reference materials (only for those calibrated) and for that purpose define time periods for recalibration in compliance with instructions of Guide ILAC G24:2007[16].

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

6.1.4 References (initial) of laboratories 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 reference (source reference) are not damaged, which is subject to evaluation by EA BAS.

VII. Securing Metrological Traceability – open issues

7.1 There are cases when NMI could calibrate measuring means, appropriate for the intended need, but the calibration is not covered by CIPM MRA, then EA BAS requires the following additional proves without limiting to them:

- Copies of calibration procedures and records for their validation;
- Copies of procedures for assessing the uncertainty of measurement, including the budget of measurement uncertainty;
- Documentation- proves of metrological traceability of measurements;
- Documentation and records to secure the quality of the calibration results, including results of participation in interlaboratory comparisons with other NMI, which has recognized possibilities for calibration and measurement (CCC) covered by the CIPM MRA and published in Appendix C, BIPM KCDB;
- Proves of personnel competence and his authorization;
- Documentation of environmental conditions and premises;
- Audit / audits of calibration laboratory on site, which may include measuring audit.

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

7.2 When CAB is unable to provide proves for securing 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 supplier,
- comparison with documented validated methods (preferably reference) and / or
- consensus references that are described in detail and approved by all stakeholders or
- a combination thereof.

NOTE 1 EA BAS defines as a competent provider of CRM, the one who meets the requirements set out in ISO Guide 34 [6].

NOTE 2: When no appropriate CRM exists, the CAB may 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 ISO Guide 34 and others.,
- experimental proves of capability of measuring and calibration of laboratory that performed the characterization and attribution of the values of the characteristics of the material or substance,
- results of participation in interlaboratory comparisons or schemes for proficiency testing (PT), respectively organized by competent providers, international organizations [5],
- 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.

NOTE 3: In specific and justified circumstances, the CAB could use material / sample involved in the scheme proficiency testing [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: 01/2013 [8] are given instructions to request additional proves that would support a decision on the validity of the results. These include but are not limited to:

- Records of validation of the method for calibration;
- Procedures for assessing uncertainty;
- Documents, records of metrological traceability;
- Documents, records for quality assurance of the results of calibration by introducing appropriate methods for quality control and its assurance by CAB
- Documents, records for competence of personnel
- Documents, records of ambient conditions
- Records of audits.

Indicated option is only for cases when there are no other eligible sources of metrological traceability.

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 proves to ensure confidence in the results obtained from measurements through participation in appropriate programs of interlaboratory comparisons or schemes for proficiency testing, 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 from interested parties on a particular issue to the Technical Accreditation Committees (TACs).

7.6 EA BAS has the right, in certain specific cases in areas 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 secure 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.

VIII. Additional information and instructions

8.1 EA BAS maintains information about the best option for measurement and calibration of accredited calibration laboratories, as well as for sources for their 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 institute member 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 (licenses) for calibration or other proves, confirming the authenticity of the document. In assessing on the site, CAB has to present to the assessors originals of the certificates (licenses) for calibration.

8.4 EA BAS consider that:

- Certificates (certificates) for calibration issued by an accredited laboratory, without reference to accreditation, are not proves of metrological traceability.
- Issued documents for measurement or calibration, which quoted a 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.

IX. Transitional provisions

8.1. The present policy, defined in present document „ Procedure of EA BAS for policy of metrological traceability and its implementation“, version 3, cancels „Procedure of traceability policyof EA BAS and its implementation“ BAS QR 27 version 2, revision 5 dated 01.01.2012 г., enters into force commencing 01.03.2016 and has to be implemented immediately for all accreditation applicants, applying after that date as well as by accredited CAB.

X. Reference

1. BDS EN ISO/IEC 17025:2006 General requirements for the competence of testing and calibration laboratories.
- 2.BDS EN ISO 15189:2012 Medical laboratories -- Requirements for quality and competence.
3. BDS EN ISO/IEC 17020:2012 Conformity assessment -- Requirements for the operation of various types of bodies performing inspection
4. BDS EN ISO/IEC 17065:2012 Conformity assessment -- Requirements for bodies certifying products, processes and services
5. BDS EN ISO/IEC 17043:2010 Conformity assessment -- General requirements for proficiency testing
6. ISO Guide 34:2009 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-P10:01/2013 ILAC Policy on 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-P14:01/2013 ILAC Policy for Uncertainty in Calibration
12. EA - 4/02-M:2013 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
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

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]