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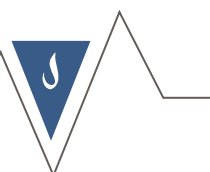
CNBOP-PIB REQUIREMENTS FOR ENSURING MEASUREMENT TRACEABILITY

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1. Scope of use

1.1. This document is used to assess the technical and organizational conditions of the product manufacturing site (TOC) and the inspection of factory production control (FPC).

1.2. This document is based on:

- policy of the Polish Center for Accreditation PCA DA-06 *Policy on ensuring measurement traceability, issue 7 of 20.04.2020* [1]

taking into account the applicable requirements of:

- PN-EN ISO 9001:2015-10 *Quality management systems. Requirements.* [2]
- PN-EN ISO/IEC 17020:2015 *Conformity assessment. Requirements for the operation of various types of bodies performing inspection.* [3]
- PN-EN 17025:2018-02 *General requirements for the competence of testing and calibration laboratories* [4]

1.3. Definitions of terms used in this document:

1.3.1. **measuring instrument** (*control and measuring equipment*) – device, measuring system or its components, designed to perform measurements alone or in combination with one or more additional devices; measurement templates and reference materials are treated as measuring instruments;¹

Comment: control and measuring equipment – all measuring instruments, measurement templates, reference materials, auxiliary instruments and instructions necessary to perform the measurement, used in both testing and control as well as in calibration.

1.3.2. **(measurement) traceability, relationship with units of measurement templates, relationship with etalons** – a property of the measurement result at which the result can be associated with specific references (generally with state standards or international measurement units) through a documented uninterrupted calibration chain, each of which contributes to measurement uncertainty;²

1.3.3. **measurement uncertainty** – non-negative parameter characterizing the dispersion of the magnitude value, assigned to the measurand (magnitude to be measured), calculated on the basis of the obtained information;²

Comment: it can be such a parameter as, for instance, standard deviation called measurement uncertainty (or its multiple thereof) or half of the width of the range having a certain probability of extension.

1.3.4. **adjustment of the measuring device (system)** – (in metrology) a set of activities performed on the instrument / measuring system ensuring that the values of the quantities to be measured correspond to the correct indications;²

Comment: adjustment should not be confused with calibration, which is its pre-condition.

1.3.5. **calibration** – an action that, under certain conditions, in the first step determines the relationship between the size values mapped by the measurement standard along with their measurement uncertainties, and the corresponding indications along with their uncertainties, and in the second step uses this information to determine the relationship that allows obtaining the measurement result based on the indication;²

1.3.6. **periodic checking** – activity performed by the manufacturing plant confirming that the control and measuring equipment in use meets the user-defined requirements in the applicable scope;³

Comment: periodic checks should be carried out using a higher-order calibrated instrument not used to inspect the product at any stage of production.

1.3.7. **National Metrology Institutes (NMI)** – in Poland the Central Office of Measures (GUM) performs the function of NMI.

¹ Act of 11 May 2001 – Law on measurement (Polish Journal of Laws: Dz. U. 2020 poz. 140).

² PKN-ISO/IEC Guide 99:2010 International vocabulary of metrology. Basic and general concepts and associated terms (VIM).

³ Own elaboration.



2. General provisions

- 2.1. The terms “shall” or “should” have been used to indicate mandatory provisions to be met. “Recommended” should be interpreted as an indication of recognized methods and procedures. The evaluated organization may demonstrate compliance with these provisions in an equivalent manner documented by substantive analysis.
- 2.2. Measurement traceability must be demonstrated when the measurement made with a given device has a significant impact ([significance](#)) on the performance of products subject to TOC assessment / FPC inspection.
- 2.3. Measurement traceability need not be demonstrated for instruments that do not have a significant effect on the test / measurement results in relation to the performance of the products mentioned above. The assessed organization using such a device should document a substantive analysis, justifying the assumption that there is no significant impact ([significance](#)) of a given measurement on the performance of products subject to TOC assessment / FPC inspection.
- 2.4. The requirements in these guidelines are intended for:
 - manufacturers of products serving to ensure public safety or to protect health and life and property, which are required to obtain a certificate of admittance;
 - manufacturers of construction products covered by the obligation to carry out the process of [national assessment and verification of constancy of performance of construction products](#) (obligatory national certification for a construction mark) or assessment and verification of constancy of performance of [construction products](#) in accordance with the Regulation (EU) No. 305/2011 of the European Parliament and of the Council of 9 March 2011;
 - manufacturers of products for which CNBOP-PIB carries out certification process of conformity [a voluntary conformity assessment process](#);
 - [voluntary conformity assessment of a product \(in order to obtain certificate of conformity recognized by United Arab Emirates\)](#).

The above applies to TOC assessments or FPC inspections, respectively.

- 2.5. The purpose of establishing and maintaining appropriate requirements for the control and measuring equipment used in an organization is to ensure stable and repeatable production of products that meet the requirements of applicable technical reference documents.
- 2.6. This document is used as the criteria for TOC assessment and FPC inspection carried out by CNBOP-PIB at the manufacturer or at the place of production – if the manufacturer’s seat is different from the manufacturing plant.

3. Supervising control and measuring equipment

- 3.1. The manufacturer should have adequate means and equipment to carry out all activities to ensure the appropriate level ([i.e. a level not less than that identified in the accredited test results used by the Certification Body](#)) of the manufactured product, and the used measuring equipment should ensure measurement traceability and the required accuracy.
- 3.2. The manufacturer should precisely define the rules for access to control and measuring equipment and the conditions for using it (competence and responsibility of personnel). Current instructions on the use and maintenance of equipment should be easily accessible to personnel who is using the equipment.
- 3.3. The manufacturer shall ensure that the means and equipment referred to in point 3.1 are maintained in readiness for the intended use.
- 3.4. Control and measuring equipment should be marked in such a way as to identify the status of calibration or checking [within at least the date of the next calibration / checking](#) and contains an [identification](#) symbol from the list of control and measuring equipment.
- 3.5. The manufacturer should develop and implement system documentation describing the principles of use, storage and maintenance of control and measuring equipment and carry out activities in the field of its application.
- 3.6. The manufacturer, in cases where it is necessary, should ensure the calibration of equipment before putting it into service and then, in accordance with the agreed schedule (plan), [carry out its periodic calibration / checking](#). (External) calibration



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should be performed in accredited laboratories [4] associated with national or international standards of measurement units or national metrological units.

3.7. In cases where a link to international or national measurement standards of accredited calibration laboratories is impossible to obtain or irrational in a particular case, it is possible to use agreed calibrations, measurement standards (or measurement procedures), clearly described and accepted by all parties interested in the results of measurements in calibrations and / or tests.

3.8. The entire program of equipment calibration should be arranged and implemented in such a way as to ensure, where applicable, that the measurements made by the manufacturer are linked to national, international standards units of measurement or national metrological units, if available.

3.9. **Control and measuring equipment should be calibrated:**

- in National Metrological Institutions or Designated Institutions maintaining state standards of units of measurement, whose calibration services are suitable for the intended use and covered by the CIPM MRA agreement. Calibration should be confirmed by a calibration certificate. In this case, it is not mandatory that the calibration certificate bears the CIPM MRA symbol (a reliable source is the BIPM KCDB database available on the Internet at <https://www.bipm.org/en/cipm-mra/>) [1];
- in accredited calibration laboratories, whose calibration services are suitable for the intended use and whose scope of accreditation includes appropriate calibration and the accreditation body is a signatory to EA MLA and/or ILAC MRA agreements or regional agreements recognized by ILAC. Calibration should be confirmed by a calibration certificate. In this case, it is mandatory that the calibration certificate bears the accreditation symbol of the accreditation body that is a signatory to the EA MLA and/or ILAC MRA agreements or regional agreements recognized by ILAC. The accreditation symbol may be replaced by an appropriate textual reference identifying, among others the accreditation number.

The calibration certificate for the control and measuring equipment should contain the necessary values of uncertainty and expansion factor k [1].

3.10. Reference standards which the manufacturer has and uses them for checking should be used only to perform checks. They should be calibrated by a competent unit that can provide a link to the national or international standard of the measurement unit.

3.11. In justified cases, equipment during use should be checked between the dates of subsequent calibrations. Such checks can be carried out for:

- a) mass measurement (weight) – using a calibration weight;
- b) length measurement (caliper) – using gauge blocks;
- c) length measurement (retractable tape measure) – with a stiff reference ruler 1 m long;
- d) pressure measurement (manometer) – using a reference manometer of a higher class than the tested manometer.

3.12. Reference materials (templates) should, if possible, be linked to national or international template reference materials. If a link to national or international standards is not possible, the manufacturer should provide satisfactory evidence of correlation or accuracy of measurement results.

3.13. In justified cases, stored equipment should be assessed at appropriate intervals to detect deterioration.

3.14. If the manufacturer uses electronically controlled equipment in connection with the production being carried out, he should provide the following:

- a) the capacity/suitability of computer software used to measure the specified requirements for its intended use. This should be done before use;
- b) testing of computer software to confirm its usefulness;
- c) establishing and implementing procedures to protect data integrity;
- d) maintenance of computers and automated equipment in a way that guarantees their proper functioning;
- e) establishing and implementing data security procedures.

3.15. Measuring equipment should be protected against adjustments that could invalidate the measurement results.



- 3.16. Measuring equipment should be protected against damage and deterioration during handling, storage and use. The manufacturer should establish, implement and ensure that the documented procedure for dealing with defective equipment is followed. Such equipment should be taken out of service. Faulty equipment must be stored in a manner that prevents its use. It is recommended that it is clearly marked so that it is unmistakable. The manufacturer should examine the impact of the detected defect on the results of previous measurements to determine their impact on the quality of previously manufactured products.
- 3.17. The manufacturer should make records of activities carried out in relation to control and measuring equipment (e.g. identification, calibration, checking and maintenance). The storage time of these records should be specified.
- 3.18. The manufacturer should specify (if applicable) how to monitor the required ambient conditions that apply to the carried out measurements and checks.

4. Conclusion

This document is one of the criterion documents when performing FPC inspections and TOC assessments. The application of these requirements by manufacturers is obligatory and has a positive impact on ensuring the measurement traceability of the control and measuring equipment used in the production process.

THE END