1. Scope

1.1. This document is used for the purpose of performing technical and organizational conditions (TOC) assessments and factory production control (FPC) inspections at the manufacturing sites.

1.2. This document was prepared based on:

- policy of Polish Centre for Accreditation PCA DA-06 Policy on Traceability of Measurement Results, 5th edition, 20.01.2015 [1]

taking into account the applicable requirements of:

- Polish Standard PN EN ISO/IEC 17020:2006 Conformity assessment -- Requirements for the operation of various types of bodies performing inspection [3]
- Polish Standard PN EN 17025:2005 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) – a device, measuring system or its elements, designed to carry out independent measurements or in combination with one or more additional devices; measurement standards and reference materials are treated as measuring instruments1.

Note: measuring equipment – all measuring instruments, measuring references, reference materials, auxiliary equipment and instructions necessary to perform the measurement, used both in research and control as well as in calibration,

1.3.2. traceability (measurement), association with standards of measurement units, association with Etalons – property of a measurement result or standard measurement unit where it can be linked with specific references, usually national or international standards of measurement units, through an unbroken chain of comparisons, all of which have specified uncertainties2.

1.3.3. measurement uncertainty – concept recommended since 1993 by international standardization bodies for determining the measurement result called the equation (theory) of uncertainty and representing the parameter associated with values (a series) of measurement of a given physical quantity under constant conditions that can reasonably be attributed to the measured value and characterized by the dispersion in the range within which the value of the measured quantity can be positioned with a satisfactory probability. Measurement uncertainty results from the fact that it is always inaccurate, which is not only due to the imperfection of the apparatus and the senses of the observer, but it is an inherent feature of such an operation3.

Note: measurement uncertainty – a parameter associated with the result of measurement that characterizes the dispersion of values that could reasonably be attributed to the measured quantity,

1.3.4. adjustment of a measuring instrument – (in metrology) activity designed to bring the measuring instrument to a working state corresponding to its purpose4,

1.3.5. calibration – a set of operations that establish, under certain conditions, the relationship between the values of the measured quantity indicated by a measuring instrument or a measuring system, or values represented by standards of measurement units or a reference material and the corresponding quantity values realized by standards of measurement units. Result of calibration allows to assign the appropriate quantities

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1 Act of law dated 11 May 2001 – Law of measures (Dz. U 2013, poz. 1069),
2 „International Dictionary of Basic and General Terms in Metrology”, issued by Polish Central Office of Measures,
4 www.urzadmiar.krakow.pl,
of measurement value to the instrument’s indication or to determine the corrections of indications (measurement uncertainty)\(^5\).

1.3.6. **periodic checks** – act confirming that measurement and control equipment in use, between the designated calibrations, meets requirements set by the user in this regard\(^6\).

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

2. General provisions

2.1. The terms "shall" or "should" have been used to signify mandatory provisions be fulfilled. "It is recommended that" should be interpreted as an indication of recognized methods, procedures. The assessed organization can demonstrate compliance with these provisions in an equivalent manner, documented with a substantive analysis.

2.2. Traceability must be demonstrated when the measurement made using an particular instrument has significant impact on the performance of the products being the subject of TOC assessment / FPC inspection.

2.3. Traceability does not have to be demonstrated in case of instruments which do not have a significant impact on the results of tests/m measurements related to the performance of products mentioned above. The assessed organization applying such a device should document the substantive analysis, including the reason for making the assumption of no significant impact of a given measurement on the performance of the products subjected to TOC assessment / FPC inspection.

2.4. The requirements contained in these guidelines are intended for:

- manufacturers of products used for ensuring public safety or protecting health, life and property who are obliged to obtain a certificate of admittance,
- manufacturers of construction products covered by the obligation to carry out the conformity assessment process (mandatory national certification for a construction mark) or assessment and verification of constancy of performance in the meaning of the Regulation of the European Parliament and Council (EU) No 305/2011 of 9 March 2011,
- manufacturers, for whom CNBOP-PIB carries out the process of voluntary conformity assessment.

This applies respectively to TOC assessments or FPC inspections.

2.5. The goal of establishing and maintaining specific requirements for measuring instruments in a given organization is to ensure stable and reproducible manufacturing of products that meet the requirements of the applicable technical reference documents.

2.6. This document is used as criteria for TOC assessments and FPC inspections conducted by CNBOP-PIB at the manufacturer's or the place of production – in the case where the registered office of the manufacturer is different from that of the manufacturing plant.

3. Supervision over measuring instruments

3.1. The manufacturer should have adequate facilities and equipment, allowing to carry out all activities necessary to ensure the appropriate level of the manufactured product, and the used measuring instruments should provide traceability and the required accuracy.

3.2. The manufacturer shall precisely specify the rules for access to measuring instruments and the terms of use (competences and responsibilities of staff). The current instructions for use and maintenance of instruments should be readily available to personnel using the instruments.

3.3. The manufacturer shall ensure the maintenance of means and instruments as indicated in Section 3.1, in readiness for the intended use.

3.4. Measuring instruments should be clearly marked so that the status of calibration or check can be identified and it should contain the symbol (No) corresponding to a list of measuring instruments.

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\(^5\) [www.urzadmior.krakow.pl](http://www.urzadmior.krakow.pl),  
\(^6\) Own work.
3.5. The manufacturer shall establish and implement system documentation describing the rules of use, storage and maintenance of measuring instruments and carry out activities within the scope of their application.

3.6. The manufacturer, in cases where it is necessary, should provide calibration of the instruments before using them and then, according to a set schedule (plan) carry out periodic checks. Calibration (external) should be performed in accredited laboratories [4] associated with state, international standards of measurement units or national metrology institutes. In cases where the connection with international or national measurement standards of accredited calibration laboratories is impossible or unreasonable in a specific case, it is possible to use agreed calibrations, measurement standards (or measurement procedures), clearly described and accepted by all interested parties with measurement results in calibrations and / or research.

3.7. The entire calibration plan should be arranged and carried out in such a manner that, in cases where appropriate, it provides a link of measurements made by the manufacturer with national, international standards of measurement units or national metrology institutes, if they are achievable. Confirmation of calibration is proved by a calibration certificate and it should be issued by accredited calibration laboratories having accreditation symbol and containing necessary values of uncertainty and the expansion coefficient k[1].

3.8. Reference standards, which are in the possession of the manufacturer and are used for checking, should be used only for checking, not for any other purpose. They should be calibrated by a competent body that can provide a link to the national or international standards of measurement units.

3.9. In justified cases, the instruments in use should be subject to checks between the terms of the subsequent calibration. Such checks can be carried out for instance for:
   a) measurement of mass (weight) – using calibration weight,
   b) length measurement (calipers) – using gauge blocks,
   c) length measurement (retractable measuring tape) – using a rigid ruler of standard 1 m,
   d) pressure measurement (pressure gauge) – using a standard pressure gauge of a higher class as compared to the checked pressure gauge.

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

3.11. In justified cases the stored equipment, in order to detect deterioration in its condition, should be assessed at appropriate intervals.

3.12. If, in the context of production, the manufacturer uses electronically controlled equipment, he should provide the following:
   a) capacity/usefulness of computer software used to measure specified requirements for its intended use. This should be done before application;
   b) software testing to confirm its usefulness;
   c) establishing and implementing procedures to protect the integrity of data;
   d) maintenance of computers and automated equipment in a manner that ensures their proper operation;
   e) establishing and implementing procedures for data security.

3.13. Measuring instruments must be protected against adjustments which could invalidate the results of the measurements.

3.14. Measuring instruments must be protected from damage and deterioration during handling, storage and use. The manufacturer shall establish, implement and ensure compliance with documented procedures for dealing with defective (nonconforming) instruments. Such instruments should be removed from usage.

3.15. The manufacturer shall examine the impact of the detected defects on the results of previously conducted measurements to determine their impact on the quality of the products previously manufactured. Defective equipment should be stored in a way that prevents its use. It is recommended to clearly mark it in an unequivocal manner regarding its unsuitability for use. The manufacturer shall keep records of the activities carried out in relation to the measuring instruments (for instance identification, calibration, checking and maintenance). Retention time of these records should be defined.

3.16. The manufacturer shall specify (if applicable) the method of supervision over required environmental conditions that apply to the measurements and checks.
4. Summary

Implementation and compliance with the provisions of this document by the manufacturers, referred to in 3.1 may have a positive impact on ensuring traceability of measuring instruments used in the manufacturing process and it will improve the performance of the TOC assessments or FPC inspections carried out by CNBOP-PIB.

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