

1. Purpose

This policy and requirements are intended to explain how to accept the result of calibration equipment under the concept of measurement traceability. It is intended for all BLQS's staffs and assessors for their decision making on the acceptance of calibration equipment result during the assessment of medical and public health laboratories accreditation comply with ISO 15189: 2022 and ISO/IEC 17025: 2017.

2. Application

- 2.1 This policy and requirements are described how to achieve and demonstrate the acceptance of organization.
- 2.2 This policy and requirements are applicable to calibration of the equipment contributing to the ISO15189:2022.

3. References

- 3.1. ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories.
- 3.2. ISO 15189: 2022 Medical Laboratories – Requirements for quality and competence.
- 3.3. ILAC P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results.
- 3.4. TPS 41, UKAS Policy on Metrological Traceability (Edition 6, December 2022).
- 3.5. Why is it necessary to have my calibrator thermometer or hydrometer recalibrate ICL Calibration Laboratories, INC. www.icllabs.com
- 3.6. ISO Guide 30: 2015 Reference materials – Selected terms and definitions.
- 3.7. ISO 17034: 2016 General requirements for the competence of reference material producers.

4. Terminology and Abbreviation

4.1. Traceability (ISO Guide 30: 2015)

Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all has stated uncertainties.

4.2. **Calibration** (VIM: 1984)

The set of operations which establish, under specified conditions, the relationship between values indicated by measuring instrument or measuring system, and the corresponding standard or known values derived from the standard.

4.3. **Verification** (ISO 8402: 1994)

Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

4.4. **Reference standard** (VIM: 1993)

Standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived.

4.5. **Reference material** (ISO Guide 30: 2015)

Material or substance one or more of whose property values are sufficiently homogenous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

4.6. **Certified reference material** (ISO Guide 30: 2015)

Reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

4.7. **Basic equipment**

Basic equipment is the equipment that is not complicate to operate such as balance, temperature equipment, glassware, pH-meter etc. (but not include chromatography). That basic equipment that effects the validity of test result shall calibrate by external calibration or in-house calibration.

5. **Associated Documents**

- 5.1. ISO/IEC 17025: 2017 General requirements for the competence of testing and calibration laboratories.
- 5.2. ISO 15189: 2022 Medical Laboratories – Requirements for quality and competence.

6. Procedures

6.1. Acceptance criteria for the measurement result of calibration equipment that carried out by the external calibration services.

6.1.1. In case that the external calibration services are available for the calibrated equipment. The calibrated equipment of accredited laboratories shall be calibrated by the following:

- A calibration laboratory accredited to ISO/IEC 17025 by a mutually recognized accreditation body such as the Office of National Accreditation Council (ONAC), Thai Industrial Standards, Institute, and Ministry of Industry. A list of accredited calibration laboratories can be found at www.tisi.go.th.

Exception of this requirement must be done in case that the accredited laboratory has the ability to carry out in-house calibration of their basic equipment. The requirement of in-house calibration mentioned in item 5.2

- A recognized National Metrology Institute (NMI). A list of recognized National Metrology Institutes can be found at www.nimt.or.th.
- Reference standards shall traceable to SI units of measurement by reference to a primary standard or by reference to a natural constant, the value of which in terms of the relevant SI units is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (CIPM).

6.1.2. In case that the accredited calibration laboratories are not available. Those calibration laboratories shall have the evidence of traceability of standard reference or reference material to SI units by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards.

- 6.1.3. Calibration report or certificate shall contain or demonstrate appropriate statements of measurement results, measurement uncertainty, and traceability, in accordance with the requirements of ISO/IEC 17025 section 5.10.4 The statement of traceability shall indicate the traceability to national or international standards of measurement.
- 6.1.4. Where traceability of measurements to SI units is not possible. There are certain calibrations that currently cannot be strictly made in SI units. In these cases, calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as:
- The use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material;
 - The use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned.
 - Participation in a suitable programme of interlaboratory comparisons is required.
- 6.1.5 The frequency of calibration is determined by the real working conditions such as in high or low pH, at extreme temperature or pressure and at much different conditions. The interval of calibration has to match with such conditions that ensure the proper performance specificity. The frequency of calibration may be considered as followings.
- The frequency of calibration may be determined from the instruction or the manual of the manufacturer. If there is not available data, calibration shall be done at least once a year
 - The interval of calibration may be extended if there are three consecutive rounds of calibration that evidently show all corrected results.
 - Earlier calibration shall be commenced at once if there is sign of malfunction or the instrument is different from normal usages.

6.2 Requirement for acceptance the measurement result of in-house calibration equipment

6.2.1. All in-house calibrations must be supported the evidence by the following requirements: Controlled equipment that carried out by in-house calibration laboratory shall be the basic equipment such as balances, temperature equipment, glassware, pH-meter, etc. (but not include chromatography).

- The in-house laboratory shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from accredited calibration laboratory or an National Metrology Institute (NMI).
- The in-house laboratory shall monitor and maintain the record of monitoring the environmental conditions under which calibrations were made that have an influence on the measurement results such as temperature, humidity that effect the validity of calibration result.
- The in-house laboratory must maintain document procedure for in-house calibrations the procedures shall comply with the standard calibration methods. The in-house method laboratory shall maintain the evidence of calibration report, or calibration records, or other suitable methods, The evidence must be retained for an appropriate, prescribed time. In case that the in-house calibration method is the developed method. The laboratory shall ensure that the validation and its results are fulfilled and appropriate for the intended use.
- The in-house laboratory must have and apply procedures for estimation of measurement uncertainty. Measurement uncertainty shall be calculated for each type of equipment calibrations and records of these calculations shall be maintained.
- The in-house laboratory shall maintain training records for responsible personnel and these records must demonstrate the technical competence of the personnel performing the calibrations such as certificate of training or other document training.

- In-house calibration equipment shall have tag, labeled or other identified to indicate the status of calibration.

6.2.2. In-house laboratory shall establish the in-house calibration report/calibration record and shall have the statement of traceability and uncertainty.

6.3 Measurement uncertainty analysis is required for all calibrations, All calibration laboratories shall calculate measurement uncertainty in accordance with the ISO GUM “Guide to the Expression of Uncertainty in Measurement”. Laboratory shall report as the expanded uncertainty with a defined coverage factor, K (typically K=2) at 95% confidence level.

7. Data record and used document

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8. Supplementary notes

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9. History of Change

Revision No.	Details of Change	Prepared / Revised by	date Issued
00	Initial document	Mrs Chomchailai Sinthusarn	-
06	- Edited the reference to current ISO15189:2012, ILAC – P10:01/2013, UKAS TPS 41 Edition 4, ISO Guide 30: 2015	Ms. Panadda Virounbounyapat	30 June 2017
07	- Edited the reference to current ISO 17034: 2016 - Added ISO GUM “Guide to the Expression of Uncertainty in Measurement”	Ms. Panadda Virounbounyapat	13 November 2017
08	Revised reference from ISO/ IEC 17025: 2005 to ISO/ IEC 17025: 2017	Ms. Panadda Virounbounyapat	4 April 2019

Revision No.	Details of Change	Prepared / Revised by	date Issued
09	- Revised reference from ILAC Policy on Traceability of Measurement Results. ILAC – P10:01/2013 to ILAC P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results - Deleted reference UKAS TPS 52 UKAS Requirements for the Performance of In – house Calibrations. Edition 1, June 2005.	Ms. Panadda Virounbounyapat	19 January 2022
10	Edited the reference to the current version: - ISO 15189: 2022 - TPS 41, UKAS Policy on Metrological Traceability (Edition 6, December 2022)	Ms. Panadda Virounbounyapat	12 March 2024
11	– Deleted reference Section 3.3 Vocabulary concerned with quality management system of medical sciences laboratories; Bureau of Laboratory Quality Standards, Department of Medical Sciences. ISBN: 974-9627-24-5. 1st publication. Bangkok: Yutharin printing; 2003. – Page 3 of 7 updated website from www.bimp.org. to www.nimt.or.th. – Edited the name of issued by and reviewed by to be current	Ms. Wasittee Kaewkrajang	