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This webinar is being recorded and will be available in it's entirely on the Perry Johnson Laboratory Accreditation Website. <u>www.pjlabs.com</u>

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Duration of webinar is set for one hour.

You can type any questions directly into your webinar box; We will review them at the conclusion of today's session;









Overall this policy has remained unchanged. References have been updated to align with ISO/IEC 17025:2017

PL-2-PJLA Policy Measurement Traceability

3.13- Removed the reference to calibration lab and stated provider only since it would include all types of providers not just calibration laboratories.

3.14- Traceability requirement for Reference Material Producers added to policy



Metrological Traceability (VIM clause 2.41): 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**.





Traceability is characterized by a number of essential elements

- An unbroken chain of comparisons,
- Measurement uncertainty,
- Documentation
- Competence
- Reference to the SI units,
- Calibration intervals,

All of these items are subject to accreditation assessment.



In-house Calibration: A calibration performed by an organization of its own equipment for use in its accredited calibration or testing activities. By definition, an in-house calibration is a calibration the organization is not accredited to perform. An organization must establish traceability for the results of in-house calibrations with the same degree of rigor required of accredited calibrations.

PJLA needs to know if these in-house calibrations are taken place so they can be assessed appropriately;



A simple example for an unbroken chain of comparisons is as follows





PJLA Policy on Measurement Traceability "PL-2" Estimations of measurement uncertainty must be calculated (or provided) for each part of the chain so that the overall uncertainty of measurement can be calculated.

A chain of traceability exist when all of the measurements are known or can be known for each link or comparison along with the associated uncertainty of measurement

Each link has an associated uncertainty. Each uncertainty with each associated link will increase the further you get away from the origin (NIST)



A broken link may be an instance for example that the measurement uncertainty was not estimated for that calibration and thus traceability stops at that point.



6.5.1 The laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.



6.5.2 The laboratory shall ensure that measurement results **are traceable to the International System of Units (SI) t**hrough:

- a) calibration provided by a competent laboratory; or
- b) certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or.
- c) direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

The **SI base units** are the standard units of measurement defined by the International System of Units (SI) for the seven base quantities of what is now known as the International System of Quantities: they are notably a basic set from which all other SI units can be derived;



SI Base Units

Base Quantity	Name	Symbol
Length	meter	m
Mass	kilogram	kg
Time	second	S
Electric Current	ampere	Α
Thermodynamic Temperature	kelvin	K
Luminous Intensity	candela	Cd
Amount of Substance	mole	mol



Kilogram Change

These values — the speed of light, the behavior of atoms, the nature of electromagnetism — are fundamental features of nature that do not change whether the observer is on Earth or Mars whether it's the year 1875 or 2018.

But the kilogram prototype, known as "Le Grand K," was made by humans and is subject to all our limitations

Recently an exquisitely accurate weighing machine known as a watt balance, which measures an object's mass by calculating the force needed to lift it.

A published a result that met this standard.

Planck's constant is equal to $6.626069934 \times 10^{-34} \text{ kg} \cdot \text{m}^2/\text{s}$, they said. And their uncertainty was just 13 parts per billion.



(3.4) Calibration certificates issued by the accredited organization for calibrations performed must provide evidence that measurement results are traceable when this is necessary for the interpretation of results If the organization chooses to reference this traceability on calibration certificates, it must reference traceability **to the SI** when possible.

(3.5) This can be accomplished through inclusion of a statement similar to the following on the certificate or report. "*The calibration results published in this certificate were obtained using equipment capable of producing results that are traceable through NIST to the International System of Units (SI)*" This statement is intended only as an example and other statements which express the same intent would be

acceptable. (ISO/IEC 17025:2017 Section 7.8.4.2 c)

--- Not appropriate to state to NIST



An NMI whose calibration is covered by the CIPM MRA. Calibration services covered by the CIPM MRA can be found in Appendix C of the BIPM KCDB (www.kcdb.bipm.org) with the range and uncertainty listed; BIPM KCDB =The International Bureau of Weights and Measures key comparison database

National Institute of Standards and Technology

The **CIPM** Mutual Recognition Arrangement (**CIPM MRA**) is the framework through which National Metrology Institutes demonstrate the international equivalence of their measurement standards and the calibration and measurement certificates they *issue*;



An accredited provider for which the calibration is covered by the scope of accreditation and the accreditation body is covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC (ex: APAC, EA, IAAC etc.).



Results are traceable because that laboratory has been accessed and it's ability to produce traceable results has been established. This means that an investigation has taken place to determine that the chain of traceability is unbroken





In the United States, pursuant to the Constitution Article 1 Section 8, and an act of the US Congress in 1901, the National Institute of

Science and Technology (previously was called the National Bureau of Standards) was created to establish authoritative national standards. For this and mainly for measures used in legal metrology, NIST recognizes State laboratories as capable of providing traceability through its Weights and Measures program. Not all States have laboratories that are part of the program, and not all States have the same scopes of measurements recognized under their Certificate of Metrological Traceability



https://www.nist.gov/pml/weights-and-measures/laboratory-metrology









It is possible to provide traceable measurements through:

- An NMI whose calibration is suitable for the intended need, but it is not covered by the CIPM MRA.
- A calibration laboratory whose service is suitable for the intended need but not covered by the ILAC Arrangement or by Regional Arrangements recognized by ILAC.

In these cases, the accreditation body shall establish a policy to ensure that those services meet the relevant criteria for metrological traceability in ISO/IEC 17025:2017.

PJLA has documented this process which is outlined in PL-2



Use of non-accredited external calibration providers and NMI's not recognized by the CIPM MRA will be approved on a case-bycase basis. If such situations arise, applicant or accredited organizations shall **complete the LF-123** Traceability Form located on the PJLA website. Organizations shall make this

document and **relevant information available** during assessments. Assessor approval will be required, and records of the approval and associated documentation will be provided with the assessment material filed at PJLA headquarters.

The LF 123 specifies in order for the lab to claim traceability for the results of its calibration or tests it must satisfy the following 6 elements of traceability



- 1) provide a clearly defined quantity that has been measured –off report
- 2) provide a complete description of the measurement system or working standard used to perform the measurement – are they traceable
- 3) provide a stated measurement result or value, with a documented uncertainty
- provide a complete specification of the stated reference at the time the measurement system or working standard that was compared to it (UUT) – on report identity of unit of test
- 5) provide an internal measurement assurance program for establishing the status of the measurement system or working standard at all times pertinent to the claim of traceability (IMAP)



- 6) provide an internal measurement assurance program for establishing the status of the stated reference at the time that the measurement system or working standard was compared to it. (organization seeking calibration)
- In other words, the integrity of the calibration needs to be maintained. An IMAP should be established by the laboratory seeking traceable calibration services as a means of maintaining that traceability
- All documents and records associated with the organizations verification shall be made available for review by PJLA staff or assessors upon request. PJLA reserves the right to reject a claim of traceability if in the opinion of PJLA all necessary requirements for establishing traceability have not been satisfied





Along with the report produced by the unaccredited provider other objective evidence needed would include;

• Measurement and Test Equipment (M&TE) used to perform the calibration is in fact traceable and is within it's current calibration cycle. (Current Report of Calibration).

Again, is this performed by an accredited laboratory or a National Metrology Institute (NIST) and the certificate should be reviewed.



• Evidence that the M&TE is evaluated between calibrations (check standards, control charts, repeatability studies) and does the laboratory participate in proficiency testing (PL-1) and if so are the results acceptable.

The laboratory should have an Internal Measurement Assurance Program (IMAP)

• Evaluation of the organizations measurement uncertainty (uncertainty budget)

By definition: the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty



If an organization is utilizing accredited sources as a means of assuring measurement traceability, then also assure:

Actual calibration report provided.

• Is it an accredited type report? Does it contain the accreditation body logo? Is before and after results included with stated uncertainty; Was your device in tolerance?

Review of the laboratory "Scope of Accreditation"

• Just because the lab is accredited, does not necessarily mean that the particular calibration performed is covered under that scope of accreditation



TRACEABILITY REQUIREMENTS: TESTING ORGANIZATIONS (INCLUDING CLINICAL TESTING ORGANIZATIONS (15189)

For testing organizations, PJLA's policies regarding measurement traceability must be maintained, unless it has been established that the uncertainty of the calibration is not a significant contributor to the total uncertainty of the test result(s).

In the event that traceability to the SI is not possible, the testing organization shall demonstrate traceability to certified reference materials applicable and accepted reference standards, methods or consensus standards



TRACEABILITY REQUIREMENTS: TESTING ORGANIZATIONS (INCLUDING CLINICAL TESTING ORGANIZATIONS (15189

If calibration is not a dominant factor in the testing result(s) and the associated uncertainties the laboratory is to have evidence to substantiate or confirm the fact that traceability (of the equipment calibration results) does not need to be demonstrated;

Don't just tell me. SHOWME.



TRACEABILITY REQUIREMENTS: REFERENCE MATERIAL PRODUCERS (RMPS)/(CRMS)

The values assigned to CRMs produced by NMIs are included in the BIPM KCDB or produced by an accredited RMP under its accredited scope of accreditation to *ISO17034:2016*, are considered to have established valid traceability.

BIPM KCDB = The International Bureau of Weights and Measures key comparison database

ISO 17034 = General requirements for the competence of reference material producers







This time is allocated for answering questions. You should have a space provided for submitting questions.

Please keep questions related to the topic covered in this webinar;





Save the Date

Next PJLA Webinar



Friday, Jul 23rd 2021

Requirements Specified in PJLA Policy on Uncertainty PL-3

