



Traceability in Laboratory Medicine in brief

Authored by Elvar Theodorsson (elvar.theodorsson@liu.se, +46736209471) and reviewed by the JCTLM Traceability Education & Promotion Working group and by other beneficiaries of the JCTLM

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JCTLM Secretariat

Bureau International des Poids et Mesures

Pavillon de Breteuil

92312 Sèvres

Cedex France

Tel: +33 1 45 07 70 70

Fax: +33 1 45 34 20 21

Email: jctlm@bipm.org



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According to the International vocabulary of metrology, traceability **IS** “a *property of a measurement result* that can be related to a *reference* through a documented unbroken chain of calibrations, each contributing to the *measurement uncertainty*” (1).

In Laboratory Medicine, the *reference* must be amongst the following:

1. The *definition of a SI unit*
2. A certified value of a *reference material*
3. The result of a *reference measuring system*
4. The value assigned to an *international conventional reference material*
5. The values assigned to *international harmonization reference materials*

The VIM definition (1) of traceability alone is comprehensive in physics where measurements are direct. The *quality infrastructure of traceability* is self-evident and fulfilled, e.g., when measuring mass, length, time, or temperature. In contrast, the quality infrastructure – known as “pillars of traceability” in Laboratory Medicine must be detailed when claiming traceability since measurements in laboratory medicine are usually indirect and influenced by matrix effects (2-6).

If the quality infrastructure is not detailed in claims of traceability in laboratory medicine, “traceability,” like beauty, risks being in the eye of the beholder (7).

Quality infrastructure for traceability

The International Network on Quality Infrastructure (INetQI, <https://www.bipm.org/en/liaison-partners/inetqi>) has defined five *general components of the quality infrastructure for metrological traceability*:

1. Metrology
2. Standardization
3. Accreditation
4. Conformity assessment

5. Market surveillance

In *Laboratory Medicine*, measuring systems used by manufacturers and laboratories alike must be *fit for the intended use* through *validation/verification* and appropriate calibration.

The measuring principles used must have been proven *fit for the intended diagnostic use* during both technical- (8, 9) and diagnostic validation (10) to establish that a measuring system fulfills appropriate performance specifications (11-14).

The laboratory must have *documented quality management* through primary education, and continued education of its staff recorded quality systems, e.g., ISO-17025 or ISO-15189, with regular auditing by relevant authorities. The quality system must include optimal internal- and external quality control schemes.

The *external quality assessment* (EQA) should be trueness-based, using commutable-reference value materials.

There must also be documented procedures for monitoring and maintaining traceability of all traceable measurands over *time* (15, 16) since reference materials in Laboratory Medicine have varying and limited shelf-life, which influences the timelines of their traceability.

Traceability **IS NOT** “traceability” to:

1. the producers of the reference materials used for calibrating measuring systems
2. to the internal or external quality control samples used in the measurement
3. to the manufacturers of the reagents and measuring systems used.

Traceability can currently be claimed solely referring to ISO-17511:2020 (17) and ISO-21151:2020 (18). To what extent will regulators Field (19) or accreditation authorities demand one or more of the fundamentals of traceability for valid claims of traceability remains to be seen.

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