Traceability in Laboratory Medicine in brief

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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 and 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 f*it 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) in order to establish that a measuring system fulfills appropriate performance specifications (11-14).

The laboratory must have *documented quality management* through basic education and continued education of its staff, documented 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 regulators (19) or accreditation authorities will demand one of more of the fundaments of traceability for valid claims of traceability as well remains to be seen.

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