

Questions and answers for enhancing the understanding metrological traceability.

What legitimate claims of traceability can be made provided a laboratory has used a single non-certified calibrator?

A “single non-certified calibrator” may or may not represent a certified reference material. In case an explicit documentation of traceability to a certified value of a reference material or to a result of a reference measurement method are not available, the single calibrator is not traceable. Furthermore, the single calibrator may or may not fulfil necessary criteria of fitness for the intended use such as linearity or the absence of proportional bias. Finally, since no information on the uncertainty of a possible traceability chain for the “single non-certified calibrator” is available, the available information is not sufficient for claims of traceability.

The conclusion is therefore that no claim of metrological traceability can be based on a “single non-certified calibrator” if additional information regarding its traceability and calibration hierarchy uncertainty is not available.

What legitimate claims of traceability can be made provided a laboratory has used a single certified reference material for calibration?

A claim of metrological traceability can be based on a single concentration of a certified reference material provided it has been validated as fit for purpose for the measuring system and method used showing that a serial dilution of the certified reference material with a suitable matrix results in a linear calibration function devoid of proportional bias.

What legitimate claims of traceability can be made provided a laboratory has used a single certified reference material for internal quality control?

Traceability is established through a calibration hierarchy only. Internal and external quality control samples or schemes can be used for repeated control of validated methods but not for establishing traceability nor as basis for claims of traceability.

Should the uncertainty of the traceability be added to repeatability and reproducibility measurement uncertainties when making claims of measurement uncertainty?

Yes – the measurement uncertainty of measurements of patient samples should be estimated by adding the repeatability or reproducibility measurement uncertainty estimated from the internal quality control samples to the measurement uncertainty of the traceability hierarchy.

Can a legitimate claim of traceability of a measurement result be based on a result corrected by a single measurement of a certified reference material?

No – traceability is based on a documented unbroken chain of calibrations. A single measurement of a certified reference material does not fulfil this basic criterion. The simple fact that the persons responsible for the measuring system or method consider relying on a correction by a single certified reference material indicates a substantial lack of confidence in the essential calibration hierarchy of the measurement method. Furthermore, the use of a single certified reference material does not harmonize with the demand for “an unbroken chain” of calibrations.

Can “operationally defined measurands” be traceable?

Yes – “operationally defined measurands” which cannot be expressed in SI units can be metrologically traceable through internationally agreed *measurement procedures*, or the quantity value carried by *certified reference materials*, e.g. international conventional reference materials.

The metrological traceability's must be realized through an unbroken hierarchy of calibrations or comparisons. The unbroken traceability hierarchy ensures that the metrological traceability of a measurement result has been established to a stated metrological reference.

The essential foundation of international conventional reference materials is an international consensus that a certain manufacturer of reference materials, materials from this manufacturer or a certain measurement procedure should be the core reference material or reference measurement procedure at the top of the traceability hierarchy

Are immunochemical measurement results traceable to the same WHO international conventional reference material for Thyreotropin (TSH) implicitly equivalent?

No – they are not – because the antibodies used in the immunochemical methods may not necessarily bind to the same epitopes of the TSH or be subject to the same influence factors. In fact, the measurand TSH is essentially a surrogate quantity for the “analyte” TSH, and the quantities measured by the two immunochemical measuring systems for TSH are not necessarily equivalent even though they are both traceable to the same WHO international conventional reference material.

In Laboratory Medicine examples like this is a common reason why traceability to SI is preferable whenever possible.

Is the average value of measurement results of a proficiency testing sample implicitly traceable?

No – it is not. It is not a certified value of a reference material, nor the result of a reference measurement method, and not the definition of an SI unit. Furthermore, a measurement hierarchy is not involved.

What legitimate claims of traceability can be made provided a laboratory has used counting of single nucleotide sequences and a single certified reference material for calibration?

The single reference material used in this instance is not of primary importance. Accurate Counting of individual nucleic acid sequences is a higher order reference measurement method which can be properly calibrated using a single certified reference material for the purpose.