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Guide to Fulfillment of Metrological Traceability Requirements

Purpose

This document from the Diagnostic Accreditation Program (DAP) provides guidance for organizations on fulfilling the Laboratory Medicine Accreditation Standards.

If you have questions about items in the standards, please email them to laboratorymedicine@cpsbc.ca.

Terms and definitions

accuracy	The closeness of agreement between a measured quantity value and a true quantity value.	CLSI
certified reference material	A reference material, accompanied by a certificate, with a confirmed property value that is metrologically traceable and has a stated level of uncertainty.	CLSI
calibrator	A working solution of known concentration used for calibration purposes.	
calibration	Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties, and in a second step, used this information to establish a relation for obtaining a measurement result from an indication.	ISO
commutability	The closeness of agreement between the measured values for a calibrator and representative clinical samples obtained by two or more procedures for the same measurand.	CLSI
examination	A set of operations having the object of determining the value or characteristics of a property. Synonyms: analysis, assessment, investigation, measurement, study, test	ISO

measurand	Quantity intended to be measured. Synonym: analyte	ISO
metrological traceability	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.	BIPM
procedure	A documented, specified way to carry out an activity of a process. **Note:** For the purposes of accreditation, procedures must always be documented, implemented and maintained.	ISO
traceability	The ability to identify and trace the history, distribution, location, and application of products, parts, materials, and services. A traceability system records and follows the trail as products, parts, materials, and services come from suppliers and are processed and ultimately distributed as final products and services**.**	ISO
uncertainty of measurement/measurement uncertainty	A parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.	ISO
user (of laboratory services)	Physicians and others who order diagnostic examinations and/or receive diagnostic information and reports from laboratories.	DAP ISO

Introduction

The ability to produce equivalent measurement results for the same measurand from a variety of measurement procedures is dependent on traceability to a reference that expresses results to a measurement unit of the International System of Units (SI). Ensuring traceability allows laboratories to confirm the comparability of results, which enables the establishment of common reference intervals and clinical decision values.

For consistently interpretable clinical information, results from test kits used in the laboratories must be traceable to references of higher order. A reference of higher order is a reference standard calibrated by an accredited body that can provide traceability, a certified reference material produced by a National Metrology Institute. The acceptability of more than one procedure through comparisons between laboratory results and higher order standards allows the formation of a traceability chain without disrupting measuring systems already in place.

Objectives

The objectives of this document are to

- familiarize assessors with the concept of metrological traceability,
- identify where metrological traceability is relevant in laboratories, and
- describe the assessment of metrological traceability.

What is metrological traceability?

"Metrological Traceability is the property of the result of a measurement or the value of a standard that is related to national or international standards through an unbroken chain of comparisons all having stated uncertainties."[1] In other words, metrological traceability is the property that connects an examination result to a reference standard used in calibration to a measurement unit of the International System of Units (SI). Associating an examination result to a reference standard means that result can be compared to another result linked to the same reference standard even "in a different place at a different time." This can extend throughout the laboratory system where results can be compared because all results are derived from comparison to the same reference standard in the system. Equipment and reference standards must be calibrated by a National Metrology Institute (NMI) or an accredited calibration laboratory whose service is covered by the CIPM Mutual Recognition Arrangement (CIPM MRA).

Although metrological traceability plays a critical role in achieving harmonized laboratory results, it is not sufficient in producing reliable results. There are other factors such as quality assurance and quality control measures that need to be in place to ensure the measurement process is stable and in control. Qualified staff, proper maintenance of equipment and reagents, use of document controlled measurement procedures, and monitoring quality control results all play an important role in creating a stable measurement process.

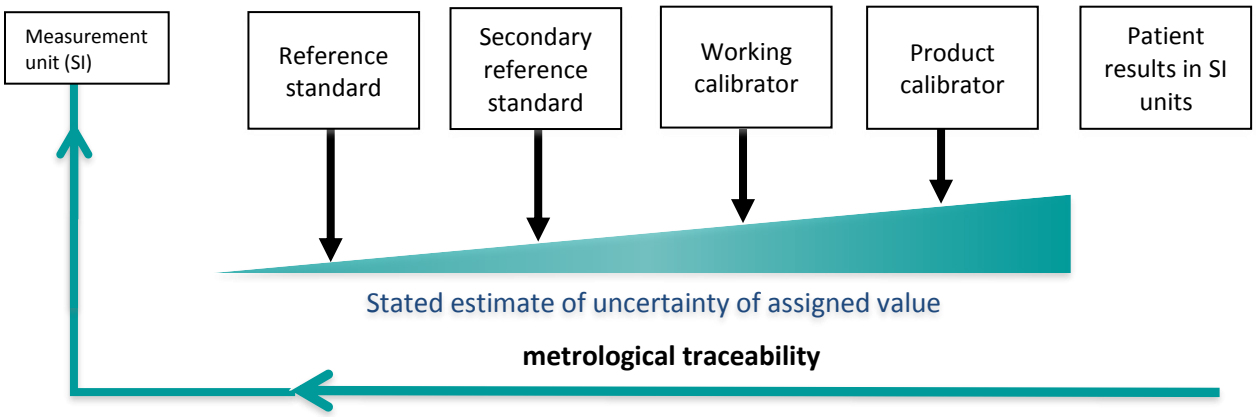
Relationship of metrological traceability and uncertainty of measurement

Uncertainty of measurement is defined as a parameter associated with the result of a measurement that characterises the dispersion of the values that could reasonably be attributed to the measurand. The term "parameter" may be considered a standard deviation, range or interval with a certain level of confidence. An estimate of the uncertainty of measurement provides an interval or range of values within which the true value is believed to lie with an approximate confidence level of 95%. The uncertainty can be attributed to random variation from one measurement to the next over the measurement timescale and sources of bias from repeated measurements. Therefore, uncertainty of measurement includes the allowance of both random and, to some degree, systematic errors, and the "true value" of the measured result must fall within the range of values.

Uncertainty of measurement is an essential component of metrological traceability. All routine measurement results for a given measurand must have a measurable relationship to an internationally recognized or certified reference standard. This relationship is established through a hierarchy of calibrators, typically from a higher order international reference standard via secondary reference standards to laboratory routine method calibrators. At each stage, the value and estimated uncertainty of measurement of the calibrators must be known. The example below illustrates the relationship between metrological traceability and uncertainty of measurement.

[1] ISO, International Vocabulary of Basic and General Terms in Metrology. Geneva: International Organization for Standardization, 1993

Relationship of metrological traceability and uncertainty of measurement



DAP metrological traceability requirements

There is only one DAP criterion that directly addresses metrological traceability:

ERS3.1.6	**M**	Calibration procedures record the metrological traceability of the calibration standard and the traceable calibration of the item of equipment.
Evidence:		Demonstrate metrological traceability to an SI unit and provide evidence of the calibrators' traceability to reference standards recognized by an NMI.
Where:		Regional: Chemistry and hematology protocols
Interpretation:		The laboratory must use higher order reference standards available for calibrators. Laboratories must review manufacturer's information to ensure that those reference materials are appropriate for the measurand and the instruments used.

What must a laboratory do to ensure metrological traceability?

Use higher order reference standards available for calibrators. All reference standards must be calibrated by a NMI or an accredited calibration laboratory and covered by the CIPM MRA that includes the range and uncertainty. Refer to the Bureau International des Poids et Measures key comparison database (BIPM KCDB) Appendix C: Calibration and Measurement Capabilities (CMCs): https://kcdb.bipm.org/appendixC/.

Assessing metrological traceability

To evaluate ERS3.1.6, assessors should examine the procedures and information for reference materials and calibrator preparation to ensure laboratories have used the correct material. This includes reviewing the manufacturer's information or documentation that the reference standards are approved by an NMI.

References

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3. International Organization for Standardization. In vitro diagnostic medical devices – measurement of quantities in biological samples – metrological traceability of values assigned to calibrators and control materials. Geneva: International Organization for Standardization; 2003. 23 p. ISO 17511.
4. Clinical and Laboratory Standards Institute. Expression of measurements uncertainty in laboratory medicine. Wayne, PA: Clinical and Laboratory Standards Institute; 2012. CLSI document EP29-A
5. White, Graham; Hitchhiker's Guide to Measurement Uncertainty (MU) in Clinical Laboratories, published April 2012. https://www.westgard.com/hitchhike-mu.htm