



Basic traceability chains

JCTLM Working Group for Traceability: Education and Promotion (WG-TEP)

Area 2: Mini-presentations to explain scientific concepts



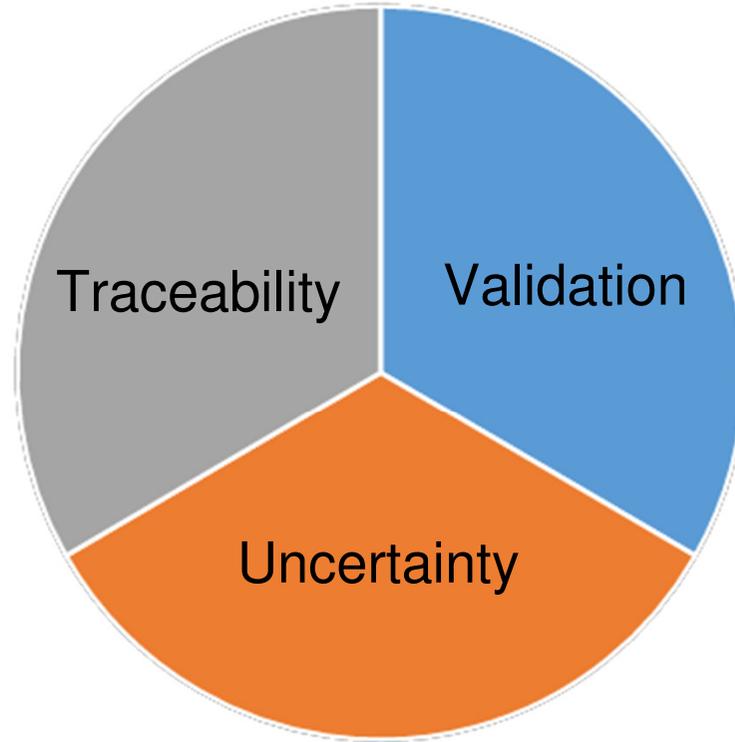
Benefits of Clinical Laboratory Test Traceability and Harmonization

- **Improved clinical guidelines:** When clinical practice guidelines that inform diagnosis and treatment are based on specific values for laboratory test results, the broad success of those guidelines depends on harmonized test results. Significant differences in values from lab to lab or over time limit the applicability of guidelines.
- **Better-quality healthcare:** Harmonized clinical laboratory tests help ensure reliable screening and diagnosis so that appropriate treatments are provided. Physicians can be confident in their diagnosis and treatment decisions only if they can rely on the values reported by the lab.
- **Fewer medical errors:** Harmonized laboratory tests allow more accurate decision making by physicians, reducing diagnostic and treatment errors that result from too much variation in test results.
- **Lower healthcare costs:** False-positive or false-negative results from non-standardized/harmonized clinical laboratory tests can lead to unnecessary follow-up diagnostic procedures and treatments, adding unnecessary costs to patient care



Components of quality of measurement results

Are the results traceable to a common reference?



Is the measurement system and method fit-for-purpose?

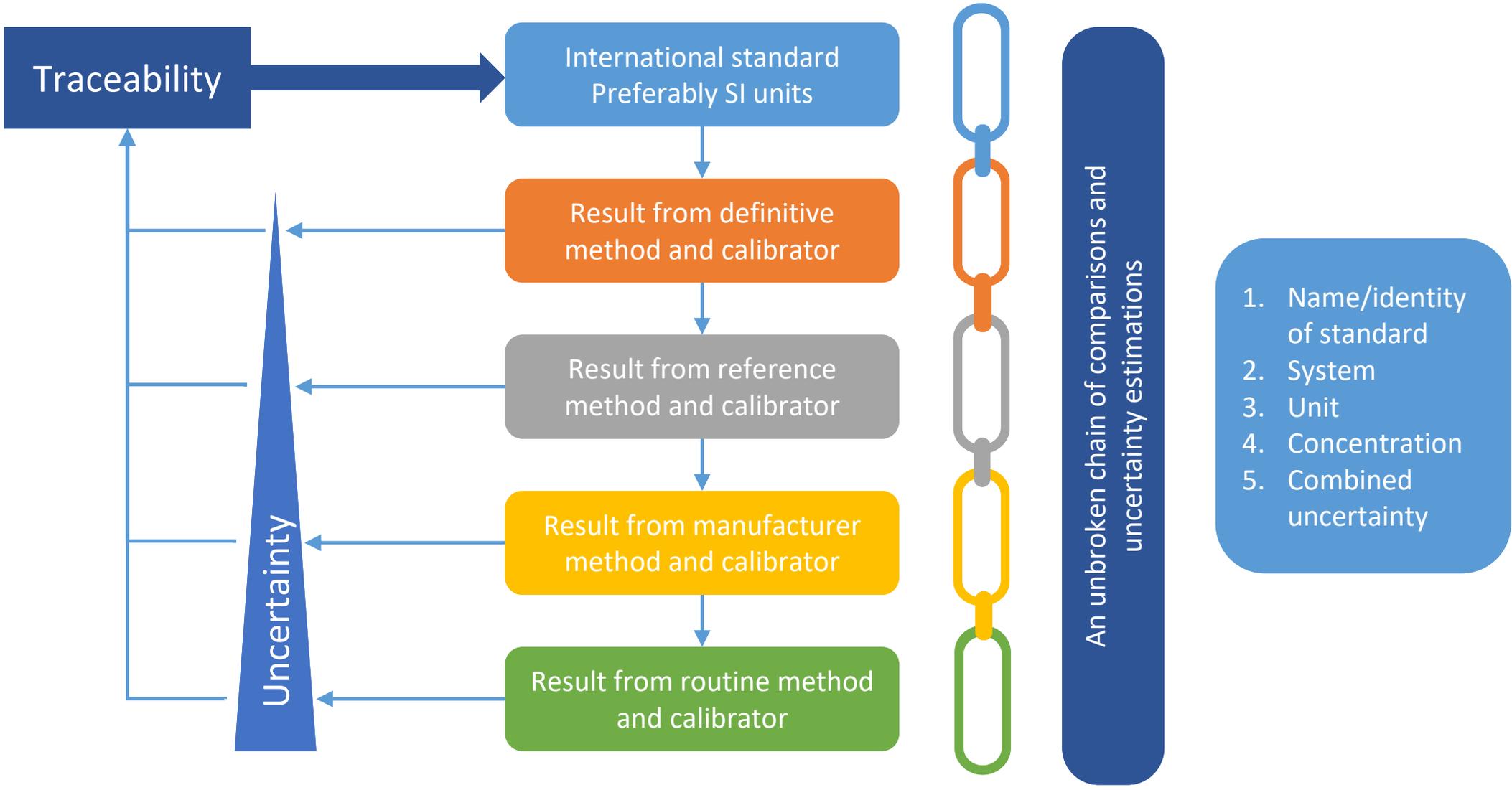
Are all relevant uncertainty components documented and fit-for-purpose?



Metrological Traceability

- VIM definition [VIM:3rd edition; JCGM 200:2012 (JCGM 200:2008 with minor corrections)]:
 - *is a 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 means – *Comparability*
 - The ability to compare the results of measurements between different laboratories
 - The use of a common reference
 - Metrological traceability is the property of a measurement result which allows measurements made under different conditions (e.g. at different times, by different people, in different locations, using different measurement procedures) to be compared in a meaningful way
 - Helpful resource: <https://www.nist.gov/traceability/traceability-table-contents>



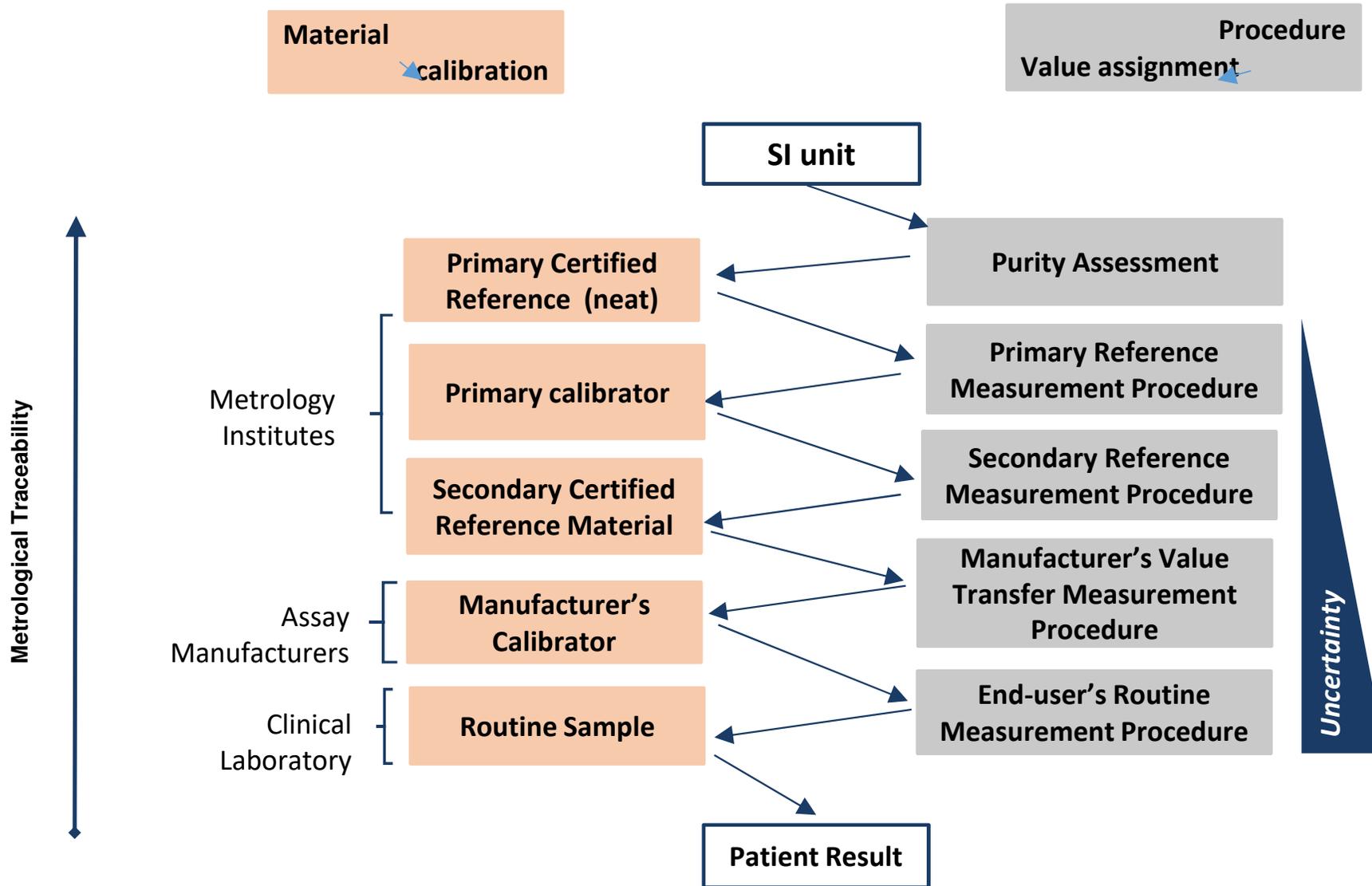


Metrologic traceability to what?

- **NOT** traceability to a
 - Producer of calibrators and controls
 - National or international metrology institute
 - Calibrator
 - Measurement system
 - Measurement method
- **IT IS** traceability of a measurement result
 - To a certified value of a common international or national reference standard or the definition of an SI unit
 - To the measurement results measured with nationally or internationally recognized reference methods
 - To reference intervals of a measurand in a population



Representative Measurement Traceability Chain



Adapted from: ISO 17511:2003(E)

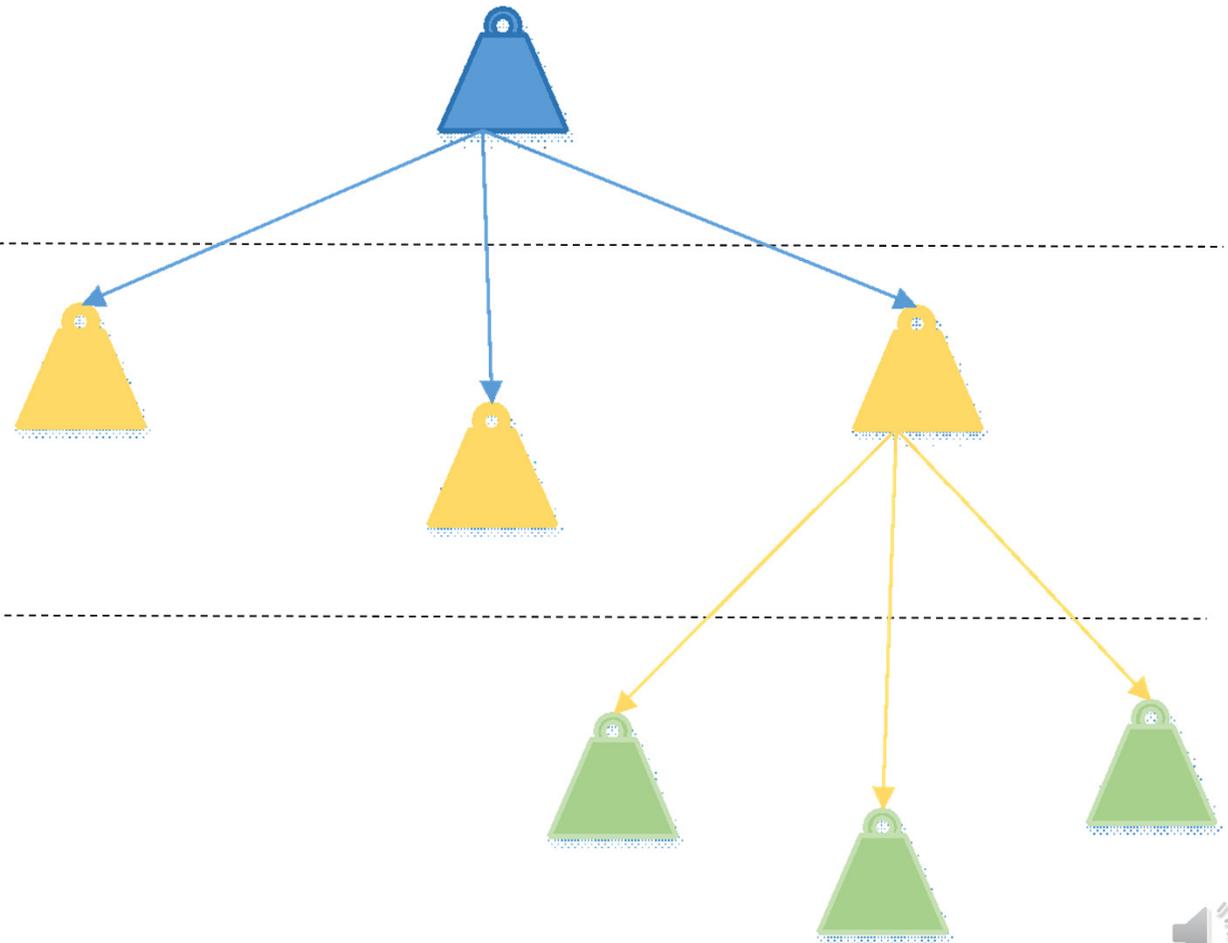


Hierarchical traceability of the kilogram

The international prototype of the kilogram “La Grande K”
BIPM in Sèvres, Paris

National metrological institutes.
Compared in 1889, 1948, and 1989
to provide traceability of
measurements of mass

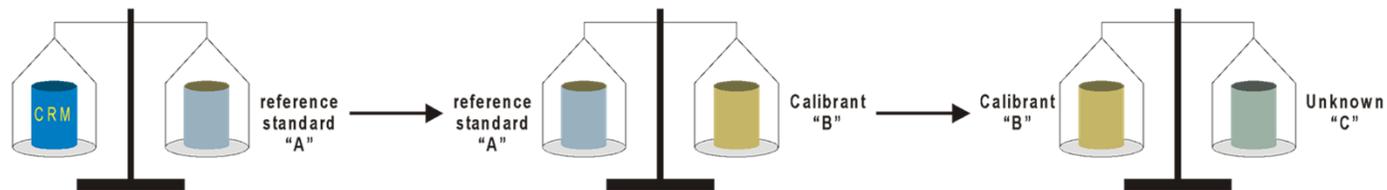
National users



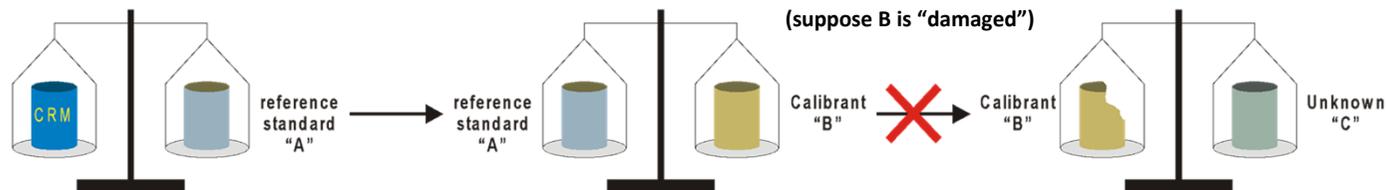
Traceability

- Traceability has been defined as:

a “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”



- Measurements of unknown “C” are traceable to a property value of CRM
 - Measurement uncertainty increases with each comparison
-



- Traceability depends on an “unbroken chain of calibrations”



Significance of traceability

- Links measurement results of a patient sample to a commonly accepted reference (certified reference material or reference measurement procedure)
- Measurement results comparable across different locations, methods and systems, and times.



Establishing traceability

- Specify the measurand
- Choose a suitable
 - Measurement procedure
 - Model equation
- Demonstrate by validation that
 - That all significant influence quantities have been taken into account in the model equation
 - The measurement conditions are adequate
- Establish traceability for each influence quantity
 - Choose appropriate reference standards
 - Calibrate using these standards
- Evaluate the uncertainty





Accurate results
for patient care

