

NIST 2017
International Forensic
Science Error Management
Symposium



ESTABLISHING
TRACEABILITY

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ASCLD-LAB Legacy: 1998, 2003

ASCLD-LAB ISO: 2008, 2013

(ANAB*: 2017, 2018...)





Objectives

1. Introduce Measurement Traceability
2. Discuss Requirements (as Related to Toxicology)
3. Offer Real World In-Laboratory Examples





1. Introduce Measurement Traceability

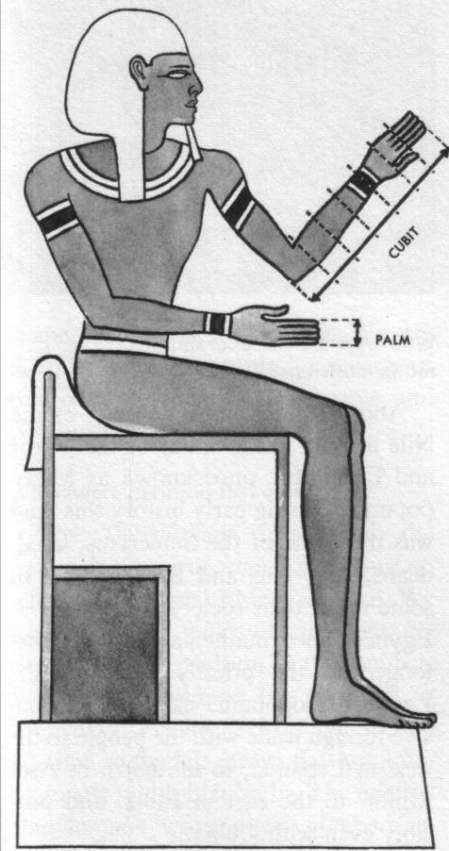
Why is measurement traceability important?

- Metrology: the scientific study of measurement. Plays a central role in *forensic* measurements
- Increased scrutiny not only from media and courts, but from other scientific bodies
- Producing high quality, reproducible scientific results should be central to *any* discipline



1. Introduce Measurement Traceability

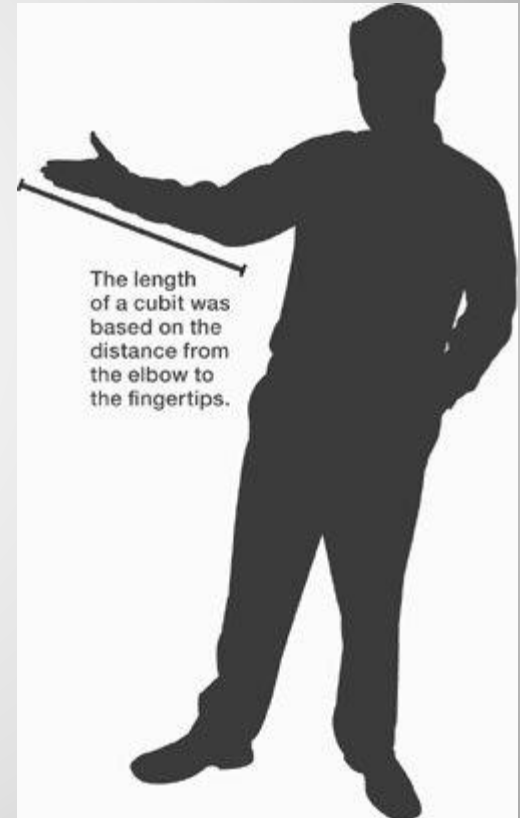
Why is measurement traceability important?



CUBIT:

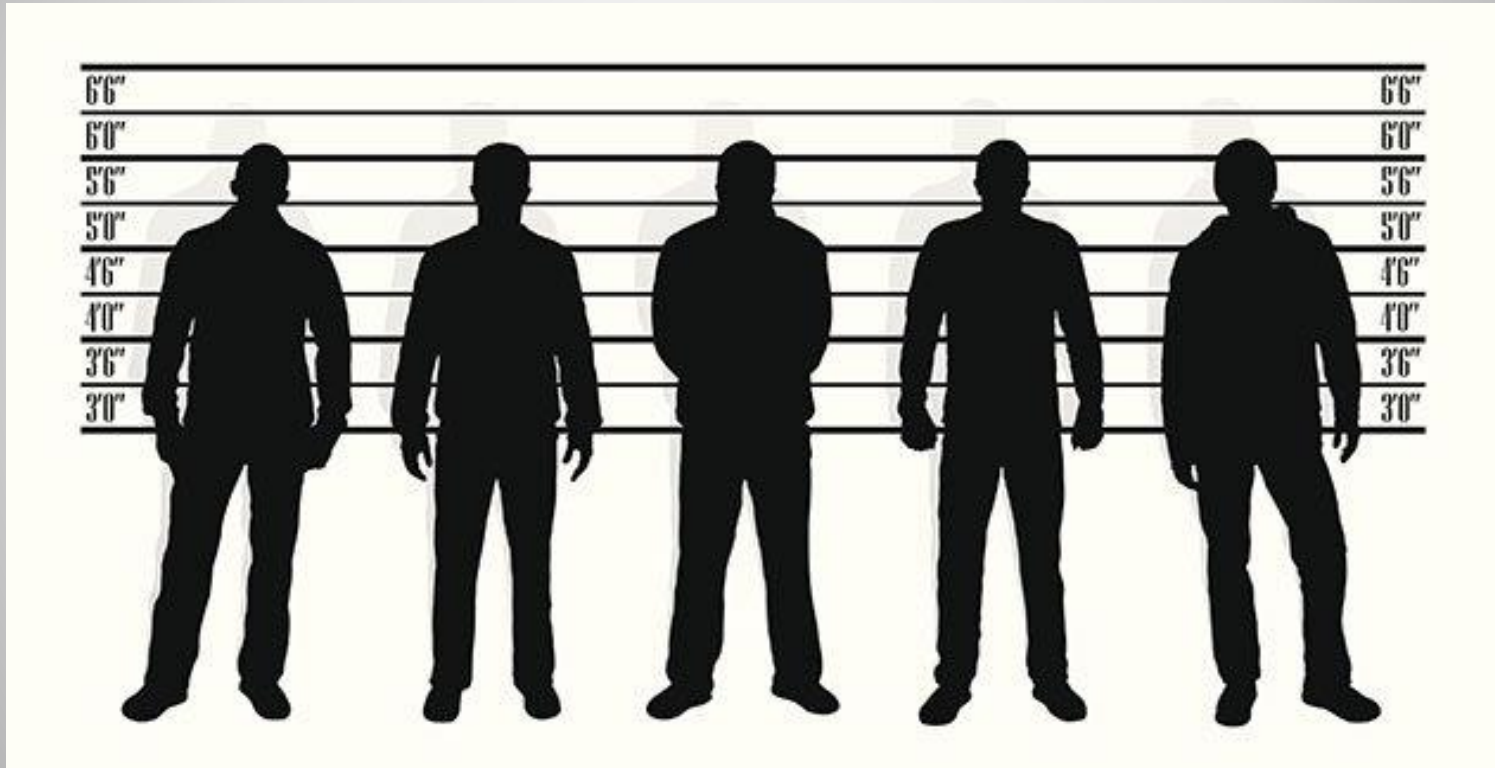
- ❑ An ancient unit used during the ancient Egyptian to Roman empires
- ❑ Based on the forearm length from the middle finger tip to the elbow bottom.
- ❑ Lengths 38 -51.8 cm (15.0 to 20.4 in)

±25% !



1. Introduce Measurement Traceability

Why is measurement traceability important?



1. Introduce Measurement Traceability

Why is measurement traceability important?



THE SMOOT

One smoot:

5' 7" (1.7 m), the height of Oliver R. Smoot, then an MIT undergrad who during his fraternity pledge in 1958 was used by his fraternity brothers to measure the length of the Harvard Bridge between Boston and Cambridge, Massachusetts.

Bridge Length:

364.4 smoots \pm one ear.

Presenter = 1.029 smoot





1. Introduce Measurement Traceability

Why is measurement traceability important?



Oliver R. Smoot

- ❑ MIT Bachelor of Science + Georgetown Juris Doctor
- ❑ 2000
House Science Committee's Subcommittee on
Technology “The Role of Technical Standards in Today's
Society and in the Future”
- ❑ 2001-2002
Chairman of the American National Standards Institute
(ANSI)
- ❑ 2003-2004
President of the International Organization for
Standardization (ISO)!

Even more at: <https://en.wikipedia.org/wiki/Smoot>





1. Introduce Measurement Traceability

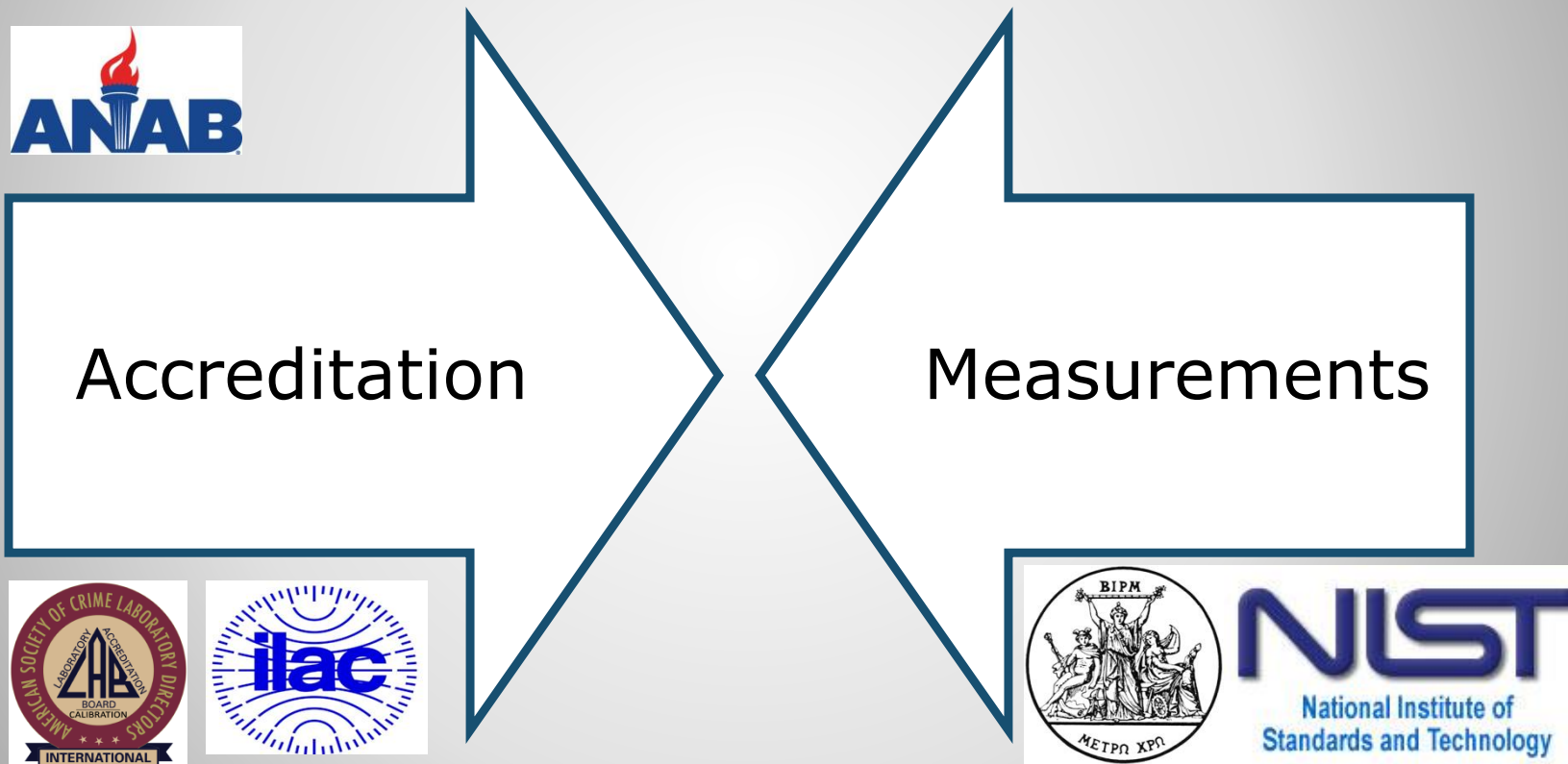
Why is measurement traceability important?

What do the customers need?

- Tests and calibrations performed by forensic laboratories to be reliable, accurate and comparable.
- To know that if the test or calibration was performed on a different day at the same laboratory, or at another accredited laboratory, the test or calibration result would be similar and comparable.
- The need for uniformity and consistency in measurements is not unique to forensic science but is also required in research, industry and commerce.**
- Measurement traceability inherently brings with it confidence and reliability.**




1. Introduce Measurement Traceability





1. Introduce Measurement Traceability

Provides accreditations to crime laboratories based on **ISO/IEC 17025**  and enhanced by:



- ASCLD/LAB-International Supplemental Requirements (2011, 2016)
- ANAB Accreditation Requirements for Forensic Science Testing Laboratories (2017)**
- ASCLD/LAB-International Breath Alcohol Calibration Supplemental Requirements (2007)
- ANAB Accreditation Requirements for Forensic Science Calibration Laboratories (2017)**
- Board Interpretations/Guidance Documents


*With ASCLD-LAB now under ANAB, your guidance documents may vary depending upon your accreditation cycle





1. Introduce Measurement Traceability

ISO 17025 is just another standard:

- ISO 3591: Sensory analysis -- Apparatus -- Wine-tasting glass 
- ISO 9407: Shoe sizes -- Mondopoint system of sizing and marking
- ISO/FDIS 13289: Recreational diving services -- Requirements for the conduct of snorkeling excursions
- ISO/CD 10788: Space systems -- Lunar dust simulant





1. Introduce Measurement Traceability

What is ISO/IEC 17025?

- ❑ An ISO standard that enumerates the *general requirements* for the *competence* of testing and calibration laboratories.
- ❑ It is the main ISO standard *used* by testing and calibration laboratories.
- ❑ In most major countries, ISO/IEC 17025 is the standard for which most labs must *hold accreditation in order to be deemed technically competent*.





1. Introduce Measurement Traceability

What is ISO/IEC 17025, continued?

- ❑ Laboratories use ISO/IEC 17025 to implement a *quality system* aimed at improving their ability to *consistently produce valid results*
- ❑ The standard is also the *basis for accreditation* from an *accreditation body*
- ❑ Since the standard is about competence, *accreditation is simply formal recognition of a demonstration of that competence*





1. Introduce Measurement Traceability

What is ISO/IEC 17025, continued?

- ❑ A prerequisite for a laboratory to become accredited is to have a documented quality management system.
- ❑ The usual contents of the quality manual follow the outline of the ISO/IEC 17025 standard.





1. Introduce Measurement Traceability

Provides accreditations to crime laboratories based on **ISO/IEC 17025** and enhanced by:

- ❑ ASCLD/LAB-International Supplemental Requirements (2011, 2016)

- ★ **ANAB Accreditation Requirements for Forensic Science Testing Laboratories (2017)**

- ❑ ASCLD/LAB-International Breath Alcohol Calibration Supplemental Requirements (2007)
- ❑ **ANAB Accreditation Requirements for Forensic Science Calibration Laboratories (2017)**
- ❑ Board Interpretations/Guidance Documents





1. Introduce Measurement Traceability

What are ANAB Accreditation Requirements for Forensic Science Testing Laboratories ?

- ❑ Additional interpretations or enhancements specific to crime laboratories
- ❑ These additional requirements can add to, but not take away from ISO/IEC 17025





1. Introduce Measurement Traceability

Provides accreditations to crime laboratories based on **ISO/IEC 17025** and enhanced by:

- ASCLD/LAB-International Supplemental Requirements (2011, 2016)
- ANAB Accreditation Requirements for Forensic Science Testing Laboratories (2017)**
- ASCLD/LAB-International Breath Alcohol Calibration Supplemental Requirements (2007)
-  **ANAB Accreditation Requirements for Forensic Science Calibration Laboratories (2017)**
- Board Interpretations/Guidance Documents





1. Introduce Measurement Traceability

What are Board Interpretations and Guidance Docs?

- ❑ **Additional interpretations of the existing documentation, often providing examples or answering questions.**
- ❑ **Intended to address commonly encountered gray areas, but can't cover everything.**

*again, with ASLCD-LAB now under ANAB, your guidance docs may vary





1. Introduce Measurement Traceability

**ISO/IEC
17025**

- Pipette only on Mondays

Fictional
Example!



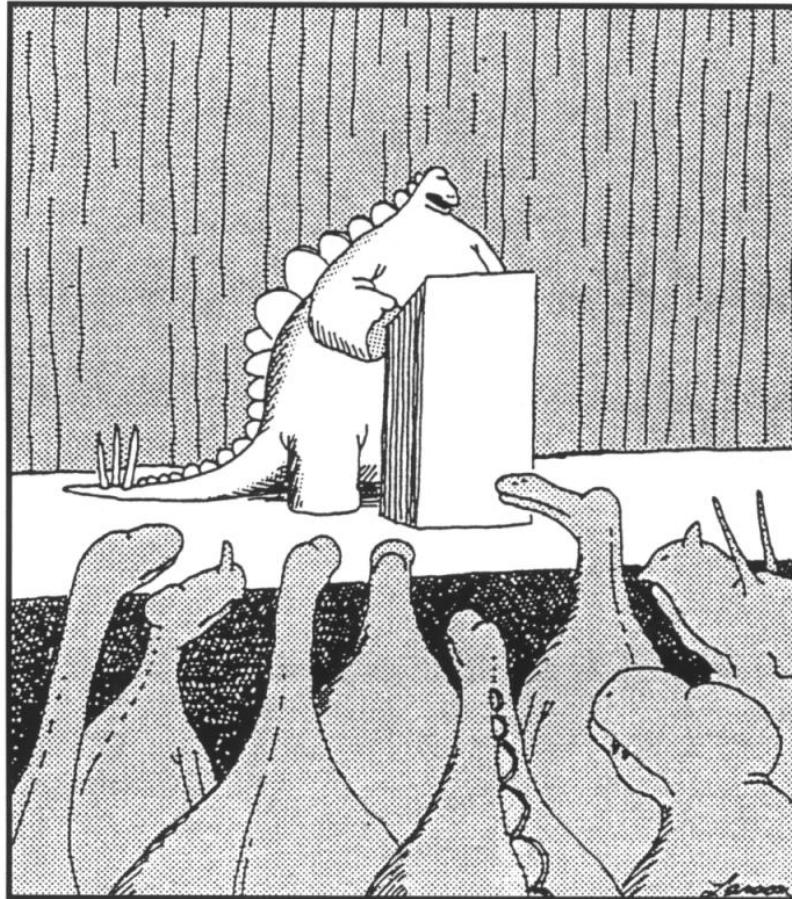


Objectives

1. Introduce Measurement Traceability
2. Discuss Requirements (as Related to Toxicology)
3. Offer Real World In-Laboratory Applications



2. Discuss Requirements (as Related to Toxicology)



"The picture's pretty bleak, gentlemen. ...
The world's climates are changing, the mammals
are taking over, and we all have a brain
about the size of a walnut."





2. Discuss Requirements (as Related to Toxicology)

Definitions:

- Metrology:** the science of measurement and its application
- Measurand:** the unknown quantity that will be measured
- Measurement:** process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity
 - Usually physical, chemical or biological
 - Implies comparison of quantities or counting of entities



2. Discuss Requirements (as Related to Toxicology)



- ❑ **Measurand:**
The # of jelly beans

- ❑ **Measurement:**
Guess?
Actually Count




2. Discuss Requirements (as Related to Toxicology)



- Measurand:**
**Concentration of
Blood alcohol**
- Measurement:**
**Guess?
Actually Measure**






2. Discuss Requirements (as Related to Toxicology)

Definitions:

- ❑ **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






2. Discuss Requirements (as Related to Toxicology)

When is measurement traceability required by ASCLD-LAB/ANAB?

- For all measurements where measurement uncertainty is estimated
- Where the measurement result has a significant impact on the final test result






2. Discuss Requirements (as Related to Toxicology)

When is measurement uncertainty required by ANAB? (continued)

When quantitative values are reported for:

1. the quantity (weight or volume) of controlled substance evidence or the quantity of a controlled substance when reported as a weight or volume fraction (purity) of the whole
 2. the concentration (weight or volume fraction) of a drug in a toxicology sample, including values reported for blood alcohol
- Additionally, for a measurement other than those listed above when required to meet the needs of a customer





2. Discuss Requirements (as Related to Toxicology)

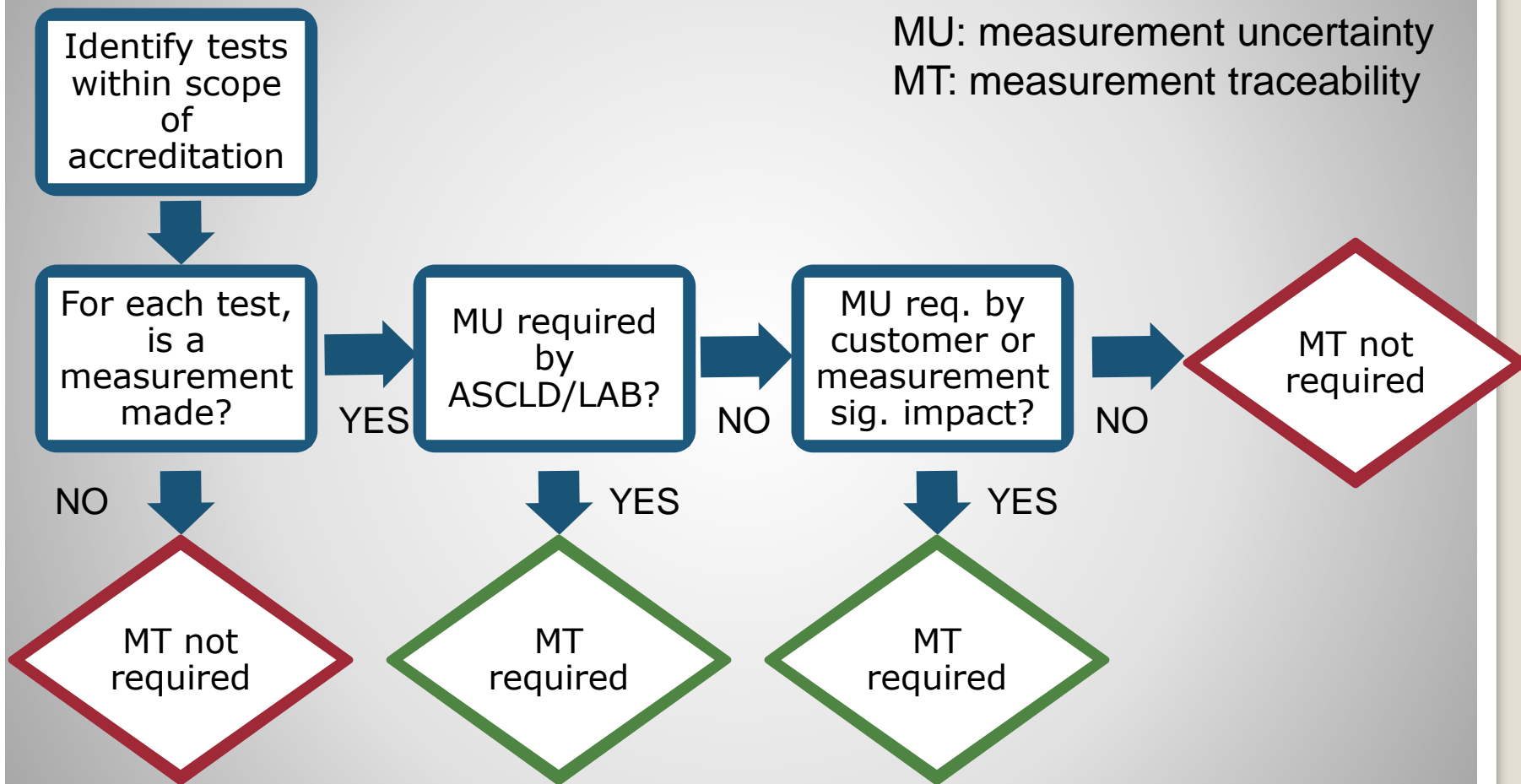
When is measurement traceability required by ASCLD/LAB?

Where the measurement result has a significant impact on the final test result (?)

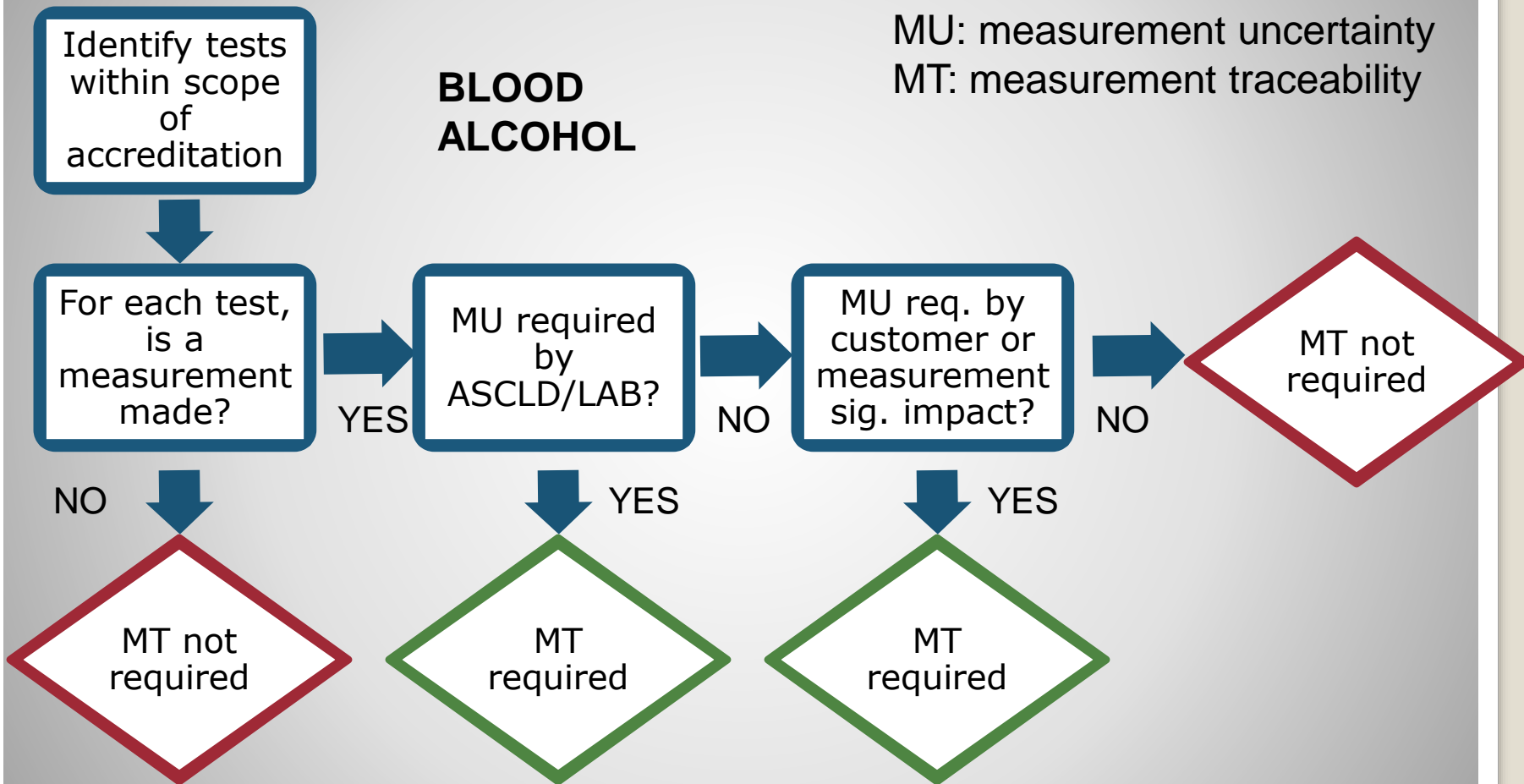
- It is up to each testing laboratory to identify the *measurements* that are being made in the laboratory.
- The laboratory must define significant impact.



2. Discuss Requirements (as Related to Toxicology)



2. Discuss Requirements (as Related to Toxicology)



2. Discuss Requirements (as Related to Toxicology)

HOW DO WE ESTABLISH TRACEABILITY?



MT
required

2. Discuss Requirements (as Related to Toxicology)

Unbroken Chain of Comparisons

Documented Measurement Uncertainty

Documented Measurement Procedure

Technical Competence


Realization of SI Units

Documented Calibration Intervals

Measurement Assurance

MT
required





2. Discuss Requirements (as Related to Toxicology)

Unbroken Chain of Comparisons

- Be able to trace back to a stated reference
- Usually a national or international standard

Documented Measurement Uncertainty

- Calculated according to defined procedure
- Must encompass the procedure's overall MU

Documented Measurement Procedure

- Generally accepted procedure must be used
- Steps and results of that procedure documented

Technical Competence

- Must maintain evidence of technical competence
- Training records, PT's, accreditations

Realization of SI Units

- Final results should end using SI units

Documented Calibration Intervals

- Calibrations repeated at established/appropriate intervals to preserve metrological traceability

Measurement Assurance

- Ensure the validity of the measurement process
- Ensure calibration and reference materials



2. Discuss Requirements (as Related to Toxicology)

Unbroken Chain
of Comparisons

BIPM (SI) (Bureau international des poids et mesures)

National Metrology Institute (NMI) - NIST

Accredited Calibration Service Supplier

Accredited Calibration Service Supplier

Forensic Laboratory Equipment

Forensic Laboratory Measurement

MT
required



2. Discuss Requirements (as Related to Toxicology)

Unbroken Chain
of Comparisons



BIPM (SI)- International prototype of the kilogram

National Metrology Institute (NMI) - NIST - Mass Reference Standards calibrated by the BIPM

Primary Calibration Laboratory - Mass Reference Standards calibrated by NIST


Accredited Calibration Service Supplier- Mass Reference Standards calibrated by the Primary Calibration Laboratory above

Forensic Laboratory Balance calibrated by the calibration service supplier above using the calibrated Mass Reference Standards.

Forensic Laboratory Measurement

MT
required





2. Discuss Requirements (as Related to Toxicology)

Documented Measurement Uncertainty


- Calculated according to defined procedure
 - Emphasis on *defined*
 - Just write it down!

- Must encompass the procedure's overall MU
 - Start to finish!

Documentation is key

MT
required





2. Discuss Requirements (as Related to Toxicology)


Documented Measurement Procedure

- Generally accepted* procedure must be used
- Steps and results of that procedure documented

Documentation is key

MT
required





2. Discuss Requirements (as Related to Toxicology)

Technical Competence


Realization of SI Units

- Must maintain evidence of technical competence
- Training records, competency tests, PT's, accreditations
- Use appropriate units

Documentation is key

MT
required






2. Discuss Requirements (as Related to Toxicology)

Documented Calibration Intervals

- Calibrations repeated at established/appropriate intervals to preserve metrological traceability
- What exactly is a **calibration**?

MT
required





2. Discuss Requirements (as Related to Toxicology)

Documented Calibration Intervals


Calibration:

- Follows a specified procedure for the calibration
- Uses a measurement standard that itself has been calibrated in a metrologically valid way and has a reference or known value with an associated uncertainty
- Compares the “indications” of the measurement standard on the equipment to the reference value
- Based on the measurements made during the calibration procedure, the calibration laboratory determines if the performance of the equipment being calibrated meets the required specifications



MT
required





2. Discuss Requirements (as Related to Toxicology)


Documented Calibration Intervals

Questions:

- GC/MS: Is “autotune” a calibration? What about a balance “CAL”?
- Can you perform your own calibrations?

MT
required





2. Discuss Requirements (as Related to Toxicology)

Documented Calibration Intervals

Questions:

- GC/MS: Is “autotune” a calibration? Balance “CAL”?

No. It is an “adjustment”, defined as “the process performed to improve the response of the item being calibrated to more closely align it with the known reference value.”


- Can you perform your own calibrations?

Possibly. But would have to have additional accreditation in the field of calibration. Most use “external provider”.



MT
required





2. Discuss Requirements (as Related to Toxicology)


Measurement Assurance

Ensure validity of:

- Calibration
- Reference materials and standards
- The measurement process

MT
required





2. Discuss Requirements (as Related to Toxicology)

Measurement Assurance


Ensure validity of Calibration:

- What instruments need to be calibrated?
- How often do they need calibration?
- Can the interval be changed?
- Do you need to check the calibration? How often?



MT
required





2. Discuss Requirements (as Related to Toxicology)


Measurement Assurance

Ensure validity of Calibration:

- What instruments need to be calibrated?
Determined by laboratory, backed by objective evidence.
- How often do they need calibration?
Interval determined by lab/manufacturer, documented
- Can the interval be changed?
Yes, backed by objective evidence
- Do you need to check the calibration? How often?
Determined by laboratory, backed by objective evidence

MT
required





2. Discuss Requirements (as Related to Toxicology)

Measurement Assurance


Ensure validity of Reference Materials:

- What is a reference standard?
- What reference standards are common in forensic lab?
- Are Drug Standards Reference Standards?



MT
required





2. Discuss Requirements (as Related to Toxicology)

Measurement Assurance

Ensure validity of Reference Standards and Materials:

- What is a reference standard?
Used routinely to calibrate or verify measuring instruments or measuring systems
- What reference standards are common in forensic labs?
Mass reference standards (weights) and gage (gauge) blocks are the most common
- Are “Drug Standards” Reference Standards?
No, a drug standard is a reference material.

MT
required



2. Discuss Requirements (as Related to Toxicology)


Measurement Assurance

Ensure validity of Reference Standards and Materials:

- What is a reference material?
It is sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process
- What reference materials are common in forensic labs?
Ethanol/Volatiles + Drug Reference Materials, generally used for identity
- What is a Certified Reference Material?
Accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures

MT
required





2. Discuss Requirements (as Related to Toxicology)


Measurement Assurance

Ensure validity of Measurement Process:

- Can I use the same CRM for calibration and control?
- Can a laboratory use old chemicals as a reference material?

MT
required





2. Discuss Requirements (as Related to Toxicology)


Measurement Assurance

Ensure validity of Measurement Process:

- Can I use the same CRM for calibration and control?
It is recommended that separate sources (i.e. Cerilliant & Lipomed for example) are used.
- Can a laboratory use old chemicals as a reference material?
Yes, so long as fit for purpose (cyanide example).

MT
required





2. Discuss Requirements (as Related to Toxicology)

Unbroken Chain of Comparisons

- Be able to trace back to a stated reference
- Usually a national or international standard

Documented Measurement Uncertainty

- Calculated according to defined procedure
- Must encompass the procedure's overall MU

Documented Measurement Procedure

- Generally accepted procedure must be used
- Steps and results of that procedure documented

Technical Competence

- Must maintain evidence of technical competence
- Training records, PT's, accreditations

Realization of SI Units

- Final results should end using SI units

Documented Calibration Intervals

- Calibrations repeated at established/appropriate intervals to preserve metrological traceability

Measurement Assurance

- Ensure the validity of the measurement process
- Ensure calibration and reference materials





Objectives

1. Introduce Measurement Traceability
2. Discuss Requirements (as Related to Toxicology)
3. Offer Real World In-Laboratory Examples



3. Offer Real World In-Laboratory Examples



3. Offer Real World In-Laboratory Examples (BAC)

Unbroken Chain of Comparisons

- NIST Traceable Standards, Pipette Calibrations

Documented Measurement Uncertainty

- Sources of Uncertainty, % Contribution

Documented Measurement Procedure

- Written SOP, Case File Documentation

Technical Competence

- Analyst Competencies and PT results

Realization of SI Units

- mg/dL, g%, g/100mL

Documented Calibration Intervals

- Twice annually, with pre-procedure checks

Measurement Assurance

- Control Chart Tracking, Maintain CRM/RM





Objectives

1. Introduce Measurement Traceability
2. Discuss Requirements (as Related to Toxicology)
3. Offer Real World In-Laboratory Examples





Objectives

1. Introduce Measurement Traceability
2. Discuss Requirements (as Found in the Field to Toxicology)
3. Offer Real World In-Laboratory Examples

4. Wait? What about MY Laboratory?



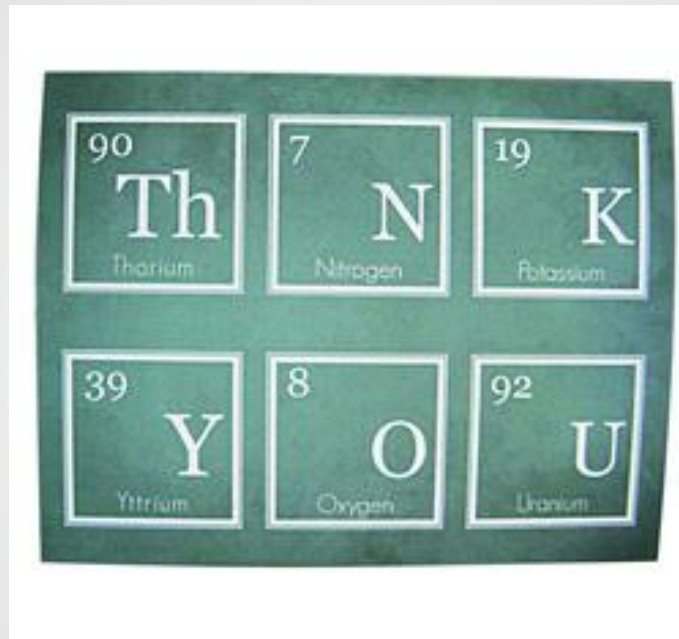


Objectives

4. Wait? What about MY Laboratory?

1. Can you implement traceability by yourself?
2. Would it help to establish buy-in and communicate underlying principles to stakeholders?
3. Can you identify “process champions” who will assist at the work unit or bench level?





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