ASCLD/LAB UPDATE

American Society of Crime Laboratory Directors
Laboratory Accreditation Board

Update for the Texas Forensic Science Conference
June 4, 2012

Laurel Farrell
ASCLD/LAB Instructor

Objectives

- Update on the number of laboratories accredited by ASCLD/LAB
- Recent focus areas:
  - Sampling vs Sample Selection
  - Measurement Traceability
  - Measurement Uncertainty

ASCLD/LAB Accredited Laboratories

- 388 Accredited Laboratories
  - 23 Federal Laboratories
  - 192 State Laboratories
  - 132 Local Agency Laboratories
  - 17 International Laboratories
  - 24 Private Laboratories
- 200 accredited under the International Testing Program
- 6 accredited under the International Calibration Program
- 182 accredited under the Legacy Program

Texas ASCLD/LAB Accredited Laboratories

- 45 Accredited Laboratories
- 26 accredited under the International Testing Program
- 19 accredited under the Legacy Program

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ASCLD/LAB Accredited Laboratories

- **http://www.ascld-lab.org/**

ASCLD/LAB Accredited Laboratories

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- Accredited Laboratories
  - Listed alphabetically by state
  - Hyperlink to the Laboratory Accreditation Certificate and also the Scope of Accreditation for laboratories accredited under the International Program
- Accreditation Revoked
- Accreditation Suspended
- Laboratories on Probation
- Voluntary Withdrawal

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ASCLD/LAB – *International* Program Accreditation Requirements

- **Laboratory management system**
- **ASCLD/LAB-*International* Requirements**
  - Testing Supplemental - 2011
  - Calibration Supplemental - 2007
  - Policies and Board Interpretations
- **ISO/IEC 17025:2005**

General requirements for the competence of testing and calibration laboratories

ASCLD/LAB Training Courses

- All courses include a review of ISO/IEC 17025 and the ASCLD/LAB – *International* Supplemental requirements
- Each course then focuses on a specific application

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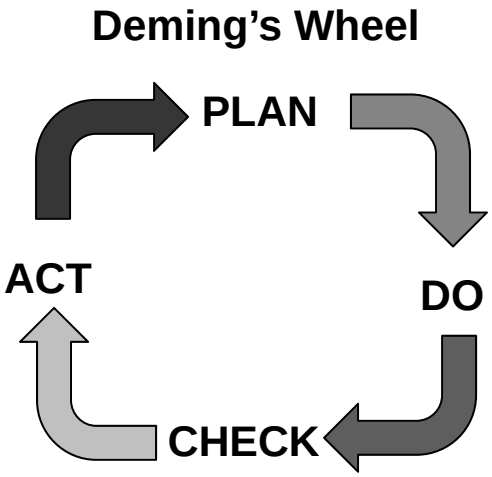
Objectives

- Update on the number of laboratories accredited by ASCLD/LAB
- **Recent focus areas:**
  - Sampling vs Sample Selection
  - Measurement Traceability
  - Measurement Uncertainty
  - Will look at select of the accreditation requirements but not all due to time constraints
  - Will look at ASCLD/LAB Policies in these areas

Continuous Improvement



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Focus Areas

- Continuous Improvement
  - Accreditation
    - Compliance
    - Competence
    - Effectiveness

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- Recent focus areas:
  - **Sampling vs Sample Selection**
  - Measurement Traceability
  - Measurement Uncertainty

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Sampling vs Sample Selection

- ASCLD/LAB Policy on Sampling, Sampling Plans and Sample Selection in the Drug Chemistry Discipline
  - Effective Date: March 1, 2012
- ASCLD/LAB Guidance Document on Sampling, Sampling Plans, and Sample Selection
  - Guidance Documents DO NOT contain accreditation requirements
  - Offer more information on a topic and examples
- Will take a look at the principles as they relate to Drug Chemistry
- Sampling and Sample Selection - applicability to other disciplines

Sampling vs Sample Selection

- Sample Selection - A practice of selecting items to test, or portions of items to test, based on training, experience and competence. In sample selection, there is no assumption about homogeneity.
  - *Source: ASCLD/LAB*
- Homogeneous - composed of parts or elements that are all of the same kind.
  - *Source: dictionary.com*
- The laboratory report will provide test results for the selected items that were tested.

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Sampling vs Sample Selection

- Example 1:
- Item #7 contains 100 plastic bags containing white powder
- Laboratory analyzes the content of six plastic bags
- One possible Report Statement:
  - 100 baggies of white powder with a total gross weight of 145.2 grams were received in item 7. Contents of four of the baggies were tested and found to contain cocaine. The net weight of the contents of the four tested baggies was 6.1 grams.
- The number of sub-items analyzed was based on training, experience and knowledge of state statute levels.
- There is no statement about the identification of the white powder in the remaining plastic bags.

Sampling vs Sample Selection

- Example 2:
- Item #10 contains 10 light green tablets with logo M15
- Laboratory analyzes one tablet
- One possible Report Statement:
  - Item 10A – one light green tablet, net weight 1.5 gram with logo M15 was found to contain oxycodone.
  - Item 10B – 9 light green tablets with logo M15 were not tested.

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Sampling vs Sample Selection

- Sampling - Taking a part of a substance, material or product for testing in order to reach a conclusion, make an inference about, and report on the whole. Sampling should only be used when there is a reasonable assumption of homogeneity of the whole.
  - *Source: ASCLD/LAB*

- The laboratory report will provide test results for all sub-items in an item of evidence.
  - Going back to Example 1:
  - The laboratory will issue a report for all 100 plastic bags in Item #7

Sampling vs Sample Selection

- Sampling Plan - For an item that consists of a multi-unit population (e.g., tablets, baggies, bindles), a sampling plan is a statistically valid approach to determine the number of sub-items that must be tested in order to make an inference about the whole population. *Source: ASCLD/LAB*

ASCLD/Lab Policy:

- 4.2.2 Two statistically valid approaches are Frequentist (e.g. Hypergeometric) and Bayesian. …Other statistically-valid sampling plans are also acceptable.
  - See the European Network of Forensic Science Institutes (ENFSI) publication "Guidelines on Representative Drug Sampling" for an in-depth discussion of these approaches.
  - http://www.enfsi.org/ (Choose "Documents;" then choose "External Publications;" and then choose "*Drugs Sampling Guideline UNODC-ENFSI*")

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Sampling vs Sample Selection

ASCLD/LAB Policy:

- 4.2.1 A statistically valid sampling plan makes use of probability, and results in a conclusion which has a confidence level that at least a certain percentage of the population is the drug in question (e.g., X% confidence that at least Y% of the baggies contain cocaine.) For an ASCLD/LAB accredited laboratory, the confidence level (X) must be at least 95%.

- A laboratory will determine the confidence level to be used.
  - Communication between laboratory and legal customers
  - Flexible:
    - Can vary by jurisdiction
    - Can vary by drug

Sampling vs Sample Selection

ASCLD/LAB Policy:

- 4.2.1 …For an ASCLD/LAB accredited laboratory, the confidence level (X) must be at least 95%.

- A few examples of possible choices that all meet the required minimum:
  - 95% confidence that at least 90% of the baggies contain cocaine.
  - 95% confidence that at least 50% of the baggies contain cocaine.
  - 99% confidence that at least 90% of the baggies contain cocaine.

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Sampling vs Sample Selection

- Sampling Procedure - A defined procedure used to collect a sample or samples from the larger whole, to ensure that the value obtained in the analysis is representative of the whole. The sampling procedure may include details about size and number of sample(s) to be collected, locations from which to collect the sample(s), and a method to ensure the homogeneity of the larger whole (or to make it so.) *Source: ASCLD/LAB*

- Once the number of sub-items to be tested has been determined, the sampling procedure will provide the details of how the sub-items were selected.
  - Standardized written procedure or analyst determined and noted in the case record

Sampling vs Sample Selection

- Sampling Procedure
- A few examples of possible choices that all meet the required minimum:
  - 95% confidence that at least 90% of the baggies contain cocaine.
    - 23 items will be tested
  - 95% confidence that at least 50% of the baggies contain cocaine.
    - 5 items will be tested
  - 99% confidence that at least 90% of the baggies contain cocaine
    - 33 items will be tested

ASCLD/LAB Policy:

- The laboratory must fully test each unit comprising the sample to meet the requirements for the identification of that substance.

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Sampling vs Sample Selection

Reporting ASCLD/LAB Policy:

- 7.1 For Drug Chemistry cases in which a sampling plan is used, information about the sampling plan, including confidence levels and corresponding inferences of the population must be in the report, or an attachment to the report (e.g. 95% confidence that at least 90% of the baggies contain cocaine).

- Example 1: Item #7 contains 100 plastic bags containing white powder
- Laboratory analyzes the content of 33 plastic bags
- One possible Report Statement:
  - Item 1 contained 100 plastic bags all obtained from the same source and all similar in appearance. A hypergeometric sampling plan was used for the analysis of Item 1. Item 1 was found to contain cocaine with a 95% level of confidence that at least 90% of the 100 bindles contain cocaine.

Sampling vs Sample Selection

- Other Applications - Sampling:
  - Drug Chemistry
    - Single homogenous item:
      - A single unit that appears to be homogeneous, or is made so
        - Examples – single layer liquid; kilo of cocaine
      - Sampling
        - A written sampling procedure(s) must be in place when the laboratory wishes to control how the analyst removes a portion of a homogeneous item for testing.
        - If the sampling procedure is up to the analyst, then the procedure used must be specified in the case record
      - Report a conclusion for the entire item

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Sampling vs Sample Selection

- Other Applications - Sampling:
  - Toxicology
    - Single homogenous item:
      - 2 tubes of blood collected sequentially into similar containers
      - Homogeneity is assumed
      - A sampling procedure commonly addresses the mixing of the samples to ensure homogeneity
      - The reported results pertain to the entire item, not only the tested amount or tube.

Sampling vs Sample Selection

- Other Applications – Sample Selection:
  - Biology
    - A bed sheet is submitted
    - 30 bloodstains are identified
    - The analyst collects 6 of the 30 bloodstains
    - Sample selection, based on the knowledge and experience of the examiner
    - Subsequent testing results:
      - Individually for each of the 6 stains

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Sampling vs Sample Selection

- Other Applications – Sample Selection:
  - Trace – Glass Analysis
    - Suspect's shoes
      - Laboratory collects 10 pieces of glass from the right shoe and 6 pieces of glass from the left shoe
    - Laboratory uses sample selection in the analysis of the glass fragments collected from the Suspect's shoes
      - Performs refractive index testing on 5 pieces collected from the right shoe
    - Laboratory report only on the 5 pieces of glass tested

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- Update on the number of laboratories accredited by ASCLD/LAB
- Recent focus areas:
  - Sampling vs Sample Selection
  - **Measurement Traceability**
  - Measurement Uncertainty

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ASCLD/LAB Policy Status

- ASCLD/LAB Policies on Traceability of Measurement Results, Reference Standards and Reference Materials and on Measurement Uncertainty
  - Completed Public Comment Period January 12 – March 12, 2012
  - March 30, 2012 - Policy implementation date was suspended
    - Public comments will be reviewed
    - ASCLD/LAB Board will adopt policy
    - Period for implementation
  - Available at: http://www.ascld-lab.org
    - Three Guidance Documents are also available

Measurement Traceability

- 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.
  - Measurement: process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity
    - Typically of physical, chemical, or biological nature.
  - Measurand: the quantity intended to be measured

- *Source: International vocabulary of metrology – Basic and general concepts and associated terms* (**VIM**)

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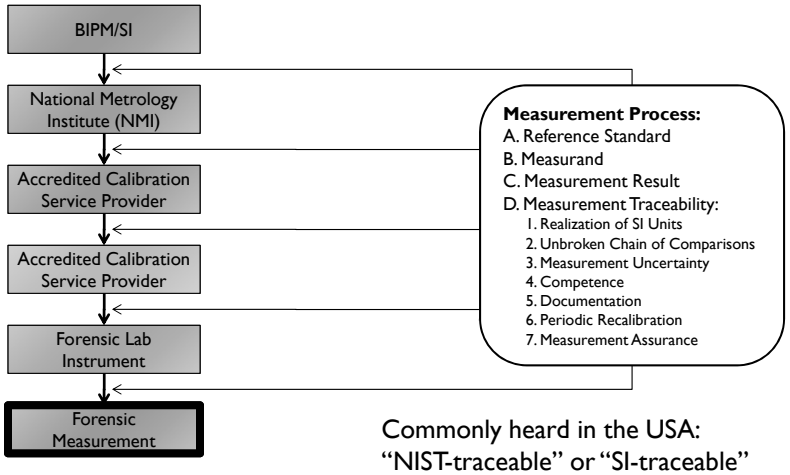
Measurement Hierarchy - Reference Standard
used in the calibration of a piece of equipment



Commonly heard in the USA:
"NIST-traceable" or "SI-traceable"

Reference:
Reference Standard OR Reference Material

- Reference (Measurement) Standard: measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location
  - Working (measurement) standard: measurement standard that is used routinely to calibrate or verify measuring instruments or measuring systems
    - *Source: International vocabulary of metrology – Basic and general concepts and associated terms* (**VIM**)

- Used **in the calibration** of other reference standards or equipment

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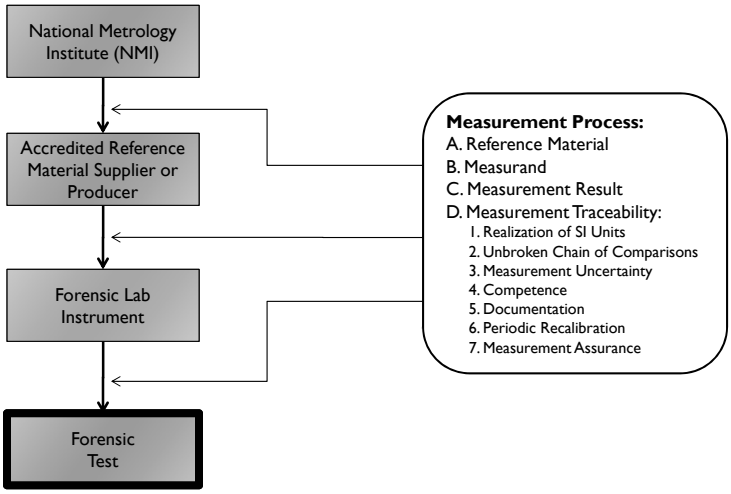
Measurement Hierarchy
Reference Material



Reference:
Reference Standard OR Reference Material

- Reference Material: Material, 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.
  - ISO GUIDE 30:1992(E)/Amd.1:2008, *Terms and definitions used in connection with reference materials*

Reference Standards and Reference Materials are often collectively referred to as **Measurement Standards**

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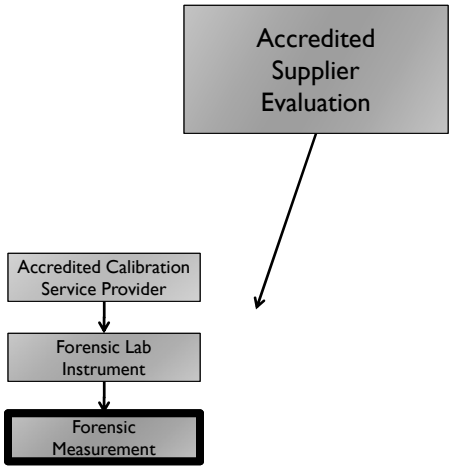
Measurement Hierarchy - Reference Standard
used in the calibration of a piece of equipment



- Focus:
  - Proper Supplier Evaluation

Traceability Requirements
ISO/IEC 17025, Clause 5.6.2.1.1

- "…When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. .."

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Traceability Requirements ASCLD/LAB Policy

- 3.4.7.1 and 3.4.7.2
- " ASCLD/LAB-*International* accredited calibration and testing laboratories shall use an external calibration laboratory accredited to ISO/IEC 17025:2005 (see 3.4.7.5) for all calibrations of reference standards and for equipment where the calibration of the equipment has a significant effect on the accuracy or validity of the laboratory's sampling or calibration result."

Traceability Requirements ASCLD/LAB Policy

- 3.4.7.3 "For equipment where the calibration does not have a significant effect on sampling, the test result, or the calibration result, ASCLD/LAB-*International* accredited laboratories must determine if a calibration will be performed and what constitutes a reliable calibration laboratory."

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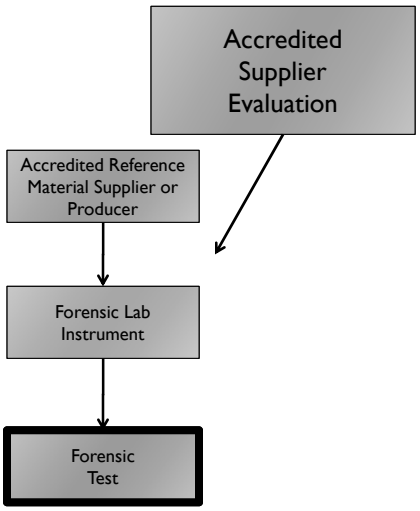
Measurement Hierarchy
Reference Material



- Focus:
  - Proper Supplier Evaluation

Traceability Requirement
ISO/IEC 17025, Clause 5.6.3.2

Reference standards and reference material

- "Reference materials shall, where possible, be traceable to SI units of measurement, or to a certified reference material."

- CRM: reference material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability
  - ISO GUIDE 30:1992(E)/Amd.1:2008, *Terms and definitions used in connection with reference materials*

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Traceability Requirement ASCLD/LAB Policy

- 3.4.7.4 "Reference material from an National Metrology Institute (NMI) or a Reference Material Producer that is accredited to ISO Guide 34:2009 in combination with ISO/IEC 17025:2005 is considered to have valid traceability."

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  - Measurement Traceability
  - **Measurement Uncertainty**

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Approach

- Measurement Uncertainty is an element of Measurement Traceability

- 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.
  - *Source: International vocabulary of metrology – Basic and general concepts and associated terms* (**VIM**)

Measurement Uncertainty

- Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.
  - *Source: International vocabulary of metrology – Basic and general concepts and associated terms* (**VIM**)

- Value associated with the result of a measurement (calibration or test) that defines the range (±) of values that could reasonably be attributed to the measured quantity.

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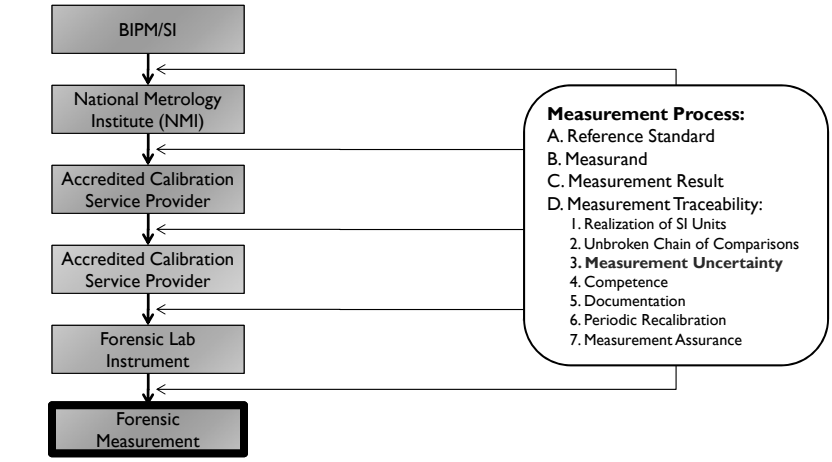
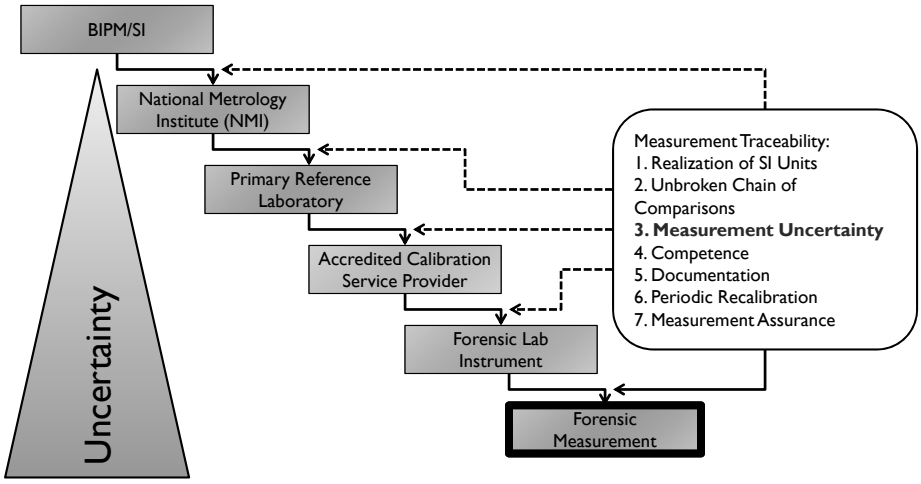
Measurement Hierarchy - Reference Standard

used in the calibration of a piece of equipment



Measurement Uncertainty & the Measurement Hierarchy



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ASCLD/LAB Policy on Measurement Uncertainty

- Scope:
  - Requires a laboratory to estimate the measurement uncertainty for any area of testing or calibration where:
    - the customer makes a request;
    - jurisdiction or statute requires such, and
    - for specified reported quantitative measurements

ASCLD/LAB Policy Measurement Uncertainty

- Scope:
- Required Uncertainty Estimates
  - Quantity (mass or volume) controlled substance
  - Presence of a controlled substance when it is reported as a percentage (mass or volume fraction) of the whole sample
  - Concentration (mass or volume fraction) of a drug in a toxicology sample - including blood alcohol
  - Firearm barrel and overall length
  - Calibration of Breath Alcohol measuring devices
  - Calibration of Breath Alcohol reference materials

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ASCLD/LAB Policy GUM

- ASCLD/LAB's intention is to conform to the GUM
- ISO/IEC Guide 98 Part 3: 2008, *Guide to the Expression of Uncertainty in Measurement (GUM)* or the equivalent BIPM JCGM 100:2008.

  www.bipm.org

ASCLD/LAB Policy Measurement Uncertainty

- Contributions from all recognized sources of uncertainty shall be evaluated
  - These contributions must be evaluated using Type A methods and Type B methods
    - Type A evaluation (of uncertainty) - a method of evaluation of uncertainty by the statistical analysis of a series of observations. (GUM 2.3.2)
    - Type B evaluation (of uncertainty) - a method of evaluation of uncertainty by means other than the statistical analysis of a series of observations. (GUM 2.3.3)

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ASCLD/LAB Policy
Reporting Measurement Uncertainty

- "The estimated measurement uncertainty, communicated as an expanded uncertainty, including the coverage factor and the coverage probability, must be in the test or calibration report or in an attachment to the report that is communicated to the customer."
  - Laboratories are allowed to have an arrangement with the appropriate legal customer if MU reporting is only required around a legal specification.
    - is in writing
    - is readily available for review in the laboratory
    - is scientifically/mathematically reasonable.

ASCLD/LAB Policy
Reporting Measurement Uncertainty

- This measurement result shall include the measured quantity value, *y*, along with the associated expanded uncertainty, *U*, and this measurement result shall be reported as $y \pm U$ and be consistent with the units of *y*.
- Report coverage factor (*k*) and the coverage probability.
  - The coverage probability shall not be less than approximately 95%.
- The numerical value of the expanded uncertainty shall be reported to at most two significant digits.

- Example Report Statement: The net weight of Item 1 was found to be 30.03 g +/- 0.07 g at a coverage factor of $k=2$ and a coverage probability of approximately 95%.

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ASCLD/LAB Policy Reporting Measurement Uncertainty

- Specifications
  - A laboratory may provide additional information in your report
    - Ensure that evaluation of compliance with a specification uses the expanded uncertainty and determined level of confidence
- Example Report Statement: The net weight of Item 1 was found to be 30.03 g +/- 0.07 g at a coverage factor of k=2 and a coverage probability of approximately 95%. Taking the estimated measurement uncertainty into consideration the weight of Item 1 is greater than one ounce (28.35 g).

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Quality is everyone's responsibility.
W. Edwards Deming

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