P905 - A2LA Metrological Traceability Policy

For ISO 15189 Laboratory Testing

March 2014

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A2LA Metrological Traceability Policy for CLIA/ISO 15189 Laboratory Testing

I. Introduction

This document is intended for all A2LA-accredited and enrolled clinical laboratories, pursuing accreditation or accredited to ISO 15189, or ISO 15189 jointly with the Clinical Laboratory Improvement Amendments (CLIA) requirements.

Each day, clinicians evaluate laboratory results to diagnose and treat their patients. To rely on these results for diagnosis, the clinicians need assurance these laboratory results are both accurate and reliable. Traceability and measurement uncertainty are the main elements that support this assurance. These two concepts are intricately related (traceability is not possible without the associated uncertainty); however, this policy focuses only on traceability. (For further guidance and requirements on estimating measurement uncertainty, please refer to A2LA policy P903: Policy on Estimating Measurement Uncertainty for ISO 15189 Testing Laboratories.) The desired outcome of traceability in laboratory medicine is to provide linkage of measurements from a patient sample to a commonly accepted reference, making them comparable across measurement systems, location, and time.¹

Challenges exist to traceability of measurements made within a clinical laboratory.

See ISO 17511²:
“In many cases, at present, there is no metrological traceability above the manufacturer's selected measurement procedure or the manufacturer's working calibrator. In such cases, trueness is referred to that level of the calibration hierarchy until an internationally agreed reference measurement procedure and/or calibrator becomes available."

ISO 17511 further indicates²:
“… it is important to recognize that different procedures purporting to measure the same quantity may in fact give different results when applied to a particular sample or reference material. This may arise, for example, when two or more immuno procedures purporting to measure the concentration of a hormone such as thyrotropin (thyroid stimulating hormone, TSH) are applied to a reference material of the hormone, because the respective reagents recognize and react to different extents with various epitopes in the material, thus leading to results for different although related quantities.”

The immuno procedure example above illustrates that many variables can lead to variation in laboratory results. For example, variation in a laboratory value can result from at least the following:

1. The manufacturer’s product calibrator, which is traceable to a primary reference material (or primary reference procedure).
2. The laboratory’s routine measurement procedure (method)
3. The source of reagents (manufacturer or third party)
4. The device itself
5. Use of co-factors

To minimize the impact of variation, this policy establishes a consistent application of traceability concepts by accredited clinical laboratories. Additionally, it serves as an authoritative document for A2LA assessors to evaluate the clinical laboratory’s compliance with ISO 15189, clause 5.6.3.

II. Terms

Ancillary Equipment: includes laboratory equipment used for measurement of temperature, weight (mass), humidity, or speed of rotation, for example. See Table 1 for a complete listing.

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, uses this information to establish a relation for obtaining a measurement result from an indication (VIM: 2.39). For the purposes of this policy, calibration means that a correction or similar action may be taken to adjust a measurement taken in terms of the relationship between the device or process under study and the standard. (Derived from Title 42 - Part 493, Laboratory Requirements, Clinical Laboratory Improvement Act).

Certified Reference Material (ISO Guide 35:2006): 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.

Medical Device: For purposes of this document, includes diagnostic equipment that is unmodified and FDA-approved, or diagnostic equipment that is modified and may not be FDA approved and is used to measure the concentration of a specific measurand (analyte) in a human specimen sample.

Metrological Traceability: The concept that ensures the result of a measurement process can be traced back to a primary reference measurement procedure or calibrator through an unbroken chain of comparisons, known as a traceability chain.

Qualification: For the purposes of this policy, qualification is the confirmation by examination and provision of objective evidence that specified requirements for a medical device are met. An example of qualification is the installation and qualification of devices when evidence is gathered to demonstrate the specifications of the manufacturer can be fulfilled by that device. (Adapted from Title 21 CFR 820).

L:\Medical-15189 – 900 Series\15189 Requirements\P905 – A2LA Metrological Traceability Policy for ISO 15189 Laboratory Testing
**Reference Material** (ISO Guide 35:2006): 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. To further explain, material or substance, one or more of whose property values are sufficiently homogenous and well established to be used for the calibration of a measuring system, the assessment of a measurement procedure, or for assigning values to materials (ISO 15195).

**Reference Method** (ISO Guide 30:1992): Thoroughly investigated method, clearly and exactly describing the necessary conditions and procedures, for the measurement for one or more property values that has been shown to have accuracy and precision commensurate with its intended use and can therefore be used to assess the accuracy of other methods for the same measurement. In other words, it is the method to which other methods are compared.

**Reference Standard** (ISO Guide 30:1992): Standard, generally having the highest metrological quality available at a given location or in a given organization, from which subsequent measurements are derived.

**Traceability Chain**: Sequence of measurement standards and calibrations that are used to relate a measurement result to a reference (VIM, 2.42); also known as a calibration chain. These chains are the defined pathways from patient analyte measurement to the measurement process available for that analyte with the minimal measurement uncertainty.

**Traceability**: Property of a measurement result whereby the result can be related to a reference through documented unbroken chain of calibrations, each contributing to the measurement uncertainty. (VIM, 2.41)

**Validation**: Verification, where the specified requirements are adequate for an intended use. (VIM, 2.45) For purposes of this policy, after qualification, confirmation by examination and provision of objective evidence that the particular requirements of the process can be consistently fulfilled for a specific intended use.

**Verification**: Provision of objective evidence that a given item fulfills specified requirements (VIM, 2.44). For purposes of this policy, periodic confirmation by examination and provision of objective evidence that specified requirements continue to be fulfilled. For the purposes of this policy, verification is used when evaluating a completed activity; that is, verification looks back at a determined outcome to assess if that outcome is still stable.
III. A2LA Metrological Traceability Policy for ISO 15189 Laboratory Testing

(M1) A2LA accredited clinical laboratories are required to ensure that:

(A) All calibrations and verifications of measuring and test equipment and reference standards be conducted by:

- A calibration laboratory accredited to ISO/IEC 17025 by a mutually recognized Accreditation Body; or,

- A recognized National Metrology Institute (NMI) including designated institutes. Recognition of the NMI is based on the Institute or designated institute being a signatory to the CIPM (Comité International des Poids et Mesures) MRA (Mutual Recognition Arrangement) and supporting the measurement comparison activities of the CIPM. A listing of these recognized Institutes can be found at http://www.bipm.org/en/cipm-mra/participation/signatories.html; or,

- A laboratory accredited by A2LA to ISO 15189 and found to meet the M4 requirements of this document for their in-house calibrations; or


(B) When possible, and/or not in conflict with the manufacturer’s instructions for use, all reference materials shall be obtained from:

- A reference material producer accredited to ISO Guide 34 in combination with ISO/IEC 17025 by a recognized Asia Pacific Laboratory Accreditation Cooperation (APLAC) signatory recognized for accrediting reference material producers; or,

- A recognized National Metrology Institute (NMI) or designated institute.

Note: This requirement does not apply to routine quality control materials.

(M2) A2LA requires that:

(A) For those external calibrations and verifications performed by an A2LA Accredited calibration laboratory or a calibration laboratory accredited by an MRA partner, these must be recorded in a calibration certificate or report and must include:
1. An endorsement by the recognized Accreditation Body’s symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body);

2. Inclusion of the A2LA-accredited organization’s A2LA certificate number with every use of the A2LA Accredited symbol (or narrative reference) (see R105, Section 1.4.4); and,

3. The measurement uncertainty.

(B) For those external calibrations and verifications performed by an NMI, these must be recorded in a calibration certificate or report and must include:

1. An endorsement by the National Metrology Institute (NMI); and,

2. The measurement uncertainty.

(C) For internal calibrations and verifications performed by the clinical laboratory, those requirements outlined in requirement M4 of this document apply.

(D) When possible for reference materials, these must be recorded in a certificate meeting the requirements of ISO Guide 31 and must also include:

1. An endorsement by the recognized Accreditation Body’s symbol (or otherwise makes reference to accredited status by a specific, recognized accreditation body); and

2. An indication of the type of entity that is accredited (e.g., “reference material producer”) or endorsed by the recognized NMI. A2LA-accredited reference material producers are required to include their A2LA certificate number to meet this requirement (see R105, Section 1.4.4).

3. It is common practice for a reference material producer to package their reference materials under a different organization’s name. In these instances, it is possible for the reference materials to meet the A2LA Traceability Policy if the accompanying certificate includes reference to the specific, recognized accreditation body, an indication of the type of entity that is accredited and the accreditation certificate number.

(M3) All A2LA-Accredited clinical laboratories must define their policy for achieving measurement traceability and also for achieving traceability for reference materials if applicable. The policy shall ensure compliance with this policy document.

A. Achievement of traceability means the measurements made by medical devices or ancillary equipment are traceable to the SI through calibration performed by a national metrology institute (NMI) such as the National Institute for Standards and Technology.
(NIST), or by a calibration laboratory that is accredited by an ILAC signatory accreditation body.

This policy applies to calibrations traceable to the SI (e.g. balance calibration, temperature calibrations) and also addresses traceability of reference materials and medical devices (see Table 1).

B. If a clinical laboratory uses a commercially available or other outside source of calibration for any of the Reference Standards or Working Standards within Table 1, the calibration laboratory, or reference material producer where possible, must be accredited by an ILAC signatory accreditation body and the type and range of calibration performed must be within the scope of accreditation for that accredited calibration laboratory or reference material producer.

C. Scopes of accreditation are documents that define specifically the measurements a laboratory or reference material producer is accredited to make. In addition, the scope defines the ranges of the accredited measurand along with the associated best measurement capability expressed as an uncertainty for each measurand and range. Before placing work with an accredited calibration laboratory or reference material producer, it is important that the clinical laboratory request a copy of the calibration laboratory’s or reference material producer’s scope (not the certificate) of accreditation so that the clinical laboratory can ensure that the calibration laboratory or reference material producer is accredited to perform the needed measurements. In addition, customers must ensure that the calibration laboratory or reference material producer’s measurement uncertainties are suitable for their needs.

For example, if a calibration laboratory performs the calibration of thermometers that measure between 0 and 32° C at the clinical laboratory, not only must the calibration laboratory be accredited to calibrate thermometers at a range of temperature between 0 and 32° C, but it must also be accredited to perform calibration in the field for the particular calibration.

D. Calibration laboratories are not permitted to claim a Calibration and Measurement Capability (CMC) on their scope of accreditation that is smaller than the CMC claimed by the National Metrology Institute (as stated in the key comparison database listed on the Bureau International des Poids et Mesures [BIPM] website, www.bipm.org) through which traceability is achieved unless allowance is made by A2LA. A2LA may accept uncertainties smaller than the NMI’s “commercial” uncertainty that is provided to its own customers on a case-by-case basis.
(M4) If a clinical laboratory chooses to calibrate its own Reference Standards or Working Standards within Table 1, the clinical laboratory must meet the following requirements:

A. The in-house clinical laboratory must maintain documented procedures for the in-house calibrations.

B. The in-house calibrations must be evidenced by a calibration report, certificate, or sticker, or other suitable method;

C. Calibration records must be retained for an appropriate, prescribed time;

D. The in-house clinical laboratory must maintain training records for calibration personnel and these records must demonstrate the technical competence of the personnel performing the calibrations: evidence of competence includes, for example, documented training and the results of measurement audits;

E. The in-house clinical laboratory shall be able to demonstrate traceability to national or international standards of measurement by procuring calibration services from appropriately accredited calibration labs or an NMI for the reference standards and/or purchasing reference materials from appropriately accredited reference material producers or an NMI;

F. The in-house clinical laboratory must have and apply procedures for evaluating measurement uncertainty. Measurement uncertainty shall be calculated in accordance with the Guide to the Expression of Uncertainty in Measurement (GUM) for each type of calibration and records of these calculations shall be maintained. Measurement uncertainty must be taken into account when statements of compliance with specifications are made.

G. Reference standards must be recalibrated at appropriate intervals to ensure that the reference value is reliable. Policy and procedures for establishing and changing calibration intervals must be based on the historical behavior of the reference standard.

A2LA NOTE1: A separate document (P907 – Policy on Requesting an Exception to Measurement Traceability for ISO 15189 Laboratory Testing) outlines the requirements to request and receive an exception to the traceability policy.

WHAT IS REQUIRED ON ACCREDITED CALIBRATION CERTIFICATES?

(M5) Traceability statement, statement of compliance, accreditation symbol endorsement:

A. For the purpose of demonstrating measurement traceability, calibration certificates shall, wherever applicable, indicate the traceability to national or international standards of
measurement and should provide the measurement result and associated uncertainty of measurement.

B. Wherever applicable, and when suitable for customer requirements, a statement of compliance with an identified method or procedural specification can be accepted instead of measurement results and associated uncertainties.

C. Only calibration certificates or reports endorsed by a recognized accreditation body’s symbol (or which otherwise makes reference to accredited status by a specific, recognized accreditation body) that is accompanied by an indication of the type of entity accredited (e.g., “calibration laboratory”, “reference material producer”) are considered to satisfy traceability requirements. By definition, such an endorsed certificate or report will contain an appropriate statement of measurement results and/or a statement of compliance with an identified metrological specification accompanied by an appropriately defined uncertainty statement and a suitable statement of traceability.

Determination and Statement of Measurement Uncertainty

A crucial element of the concept of measurement traceability is measurement uncertainty.

(M6) Where measurement uncertainty analysis is applicable\(^2\), A2LA requires laboratories to calculate measurement uncertainty in accordance with the ISO “Guide to the Expression of Uncertainty in Measurement.” These uncertainties shall be reported as the expanded uncertainty with a defined coverage factor, \(k\) (typically \(k = 2\)) and the confidence interval (typically to approximate the 95% confidence level).

(M7) If a calibration certificate or test report contains a statement of the measurement result and the associated uncertainty, then the uncertainty statement must be accompanied by an explanation of the meaning of the uncertainty statement. An example of such an explanation might be the statement “Reported uncertainties represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage factor of \(k = 2\)”.

Statements of uncertainty which do not specify at least the coverage factor and the confidence level are incomplete and they are inadequate for the purpose of demonstrating that measurement traceability has been achieved.

(M8) Test uncertainty ratios (TURs) must be calculated using the expanded uncertainty of the measurement, not the “collective uncertainty of the measurement standards”\(^3\).

(M9) Implicit uncertainty statements must be accompanied by words to the effect that the uncertainty ratio was calculated using the expanded measurement uncertainty. In addition

\(^2\) Measurement uncertainty analysis is required for all calibrations. For applicability of testing, please see the P903 - Policy on Estimating Measurement Uncertainty for ISO 15189 Testing Laboratories

\(^3\) This is the language in ANSI/NCSLI Z540-1-1994 section 10.2.b.
the coverage factor and confidence level must be stated.

**Statements of Traceability**

This statement will affirm that the calibration reported was conducted using standards whose values are traceable to an appropriate national, international, or mutual consent standard. For example, if the traceability chain for a given laboratory originates at NIST, then the statement will affirm that “This calibration was conducted using standards traceable to the SI through NIST”, or words to that effect.

**Calibration certificates and reports which do not contain equivalent statements of traceability, or which only refer to NIST report of test numbers as evidence of traceability are insufficient to demonstrate measurement traceability.**

(M10) In addition to the information required in the above sections, calibration reports and certificates must contain a traceability statement.\(^4\)

**IV. Medical Device and Ancillary Equipment Traceability**

Clinical laboratories must identify those devices and equipment that deliver measurements critical to the integrity of the test result. (See M3 above.) Table 1 provides information regarding those devices and ancillary equipment.

If a piece of ancillary equipment is not critical to the result, such as using a pipette to aliquot a sample for storage, that ancillary equipment is exempt from this policy.

If the device or ancillary equipment is critical to the test result, that device or ancillary equipment must be calibrated in a way that establishes traceability to an acceptable reference standard in terms of international units. (See Section III above).

Ideally, traceability involves an unbroken chain of calibrations, with each successive calibration adding to the estimation of uncertainty. Thus, the initial calibration measurement taken against the accepted reference standard would be used to determine the next level of calibration measurement, and so on. The measurement procedure at the top of the hierarchy demonstrates the lowest uncertainty, while the measurement procedure at the bottom of the hierarchy demonstrates the largest uncertainty (See Figure 1).

Any calibration material, for the method or for a device, must demonstrate traceability to an acceptable reference standard, and every “link” in the traceability chain that connects to that

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reference standard adds uncertainty. Figure 1 provides an illustration of this relationship, while Figure 2 illustrates a flow of activities to establish traceability.

**Traceability by Supplier or Manufacturer**

Manufacturers are responsible for establishing traceability for commercially available assays. Clinical laboratories do not need to define traceability if the lab is compliant with the manufacturer’s instructions.

However, even with FDA-approved test systems, the clinical laboratory is responsible to verify that the manufacturer has established traceability. Documentation of statements regarding reagents, procedures or the test system must be available when the manufacturer provides traceability.

If a laboratory modifies the defined FDA device/procedure or develops its own device/method, then the clinical laboratory must establish the traceability chain for the devices to a stated reference.

If a manufacturer cannot establish traceability to a stated reference, or if no reference is available, the laboratory must have some means to provide confidence in the device/method. See ISO 15189-2012, section 5.3.1.4. Examples include:

- use of certified reference materials;
- examination or calibration by another procedure;
- mutual consent standards or methods which are clearly established, specified, characterized and mutually agreed upon by all parties concerned
V. References

10. Code of Federal Regulations Title 42- Public Health, Part 493; Laboratory Requirements, Clinical Laboratory Improvement Act

**Document Revision History**

<table>
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<tr>
<th>Date</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
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<td>Revised to address CC issues</td>
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<tr>
<td></td>
<td>TUR defined (M8)</td>
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<td></td>
<td>T4 references updated to M4 references</td>
</tr>
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<td>Title change.</td>
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<tr>
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<td>Editorial change to M2-A-2 and M2-D-2 to reference R105 instead of P101 and to include the correct requirement from R105.</td>
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</tbody>
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Table 1: Supporting Measurement Traceability in a Clinical Laboratory – Calibration and Verification for Equipment Found in Clinical Laboratories

(Applicable to laboratory equipment critical to the results of the accredited tests)

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Minimum Action</th>
<th>Frequency</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Devices- In Scope of Accreditation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Devices (FDA approved)</td>
<td>-Verify operational performance according to manufacturers’ requirements</td>
<td>-At a minimum, meet manufacturers’ requirements</td>
<td>Approved by a national regulatory body</td>
</tr>
<tr>
<td>Medical Devices (modified)</td>
<td>-Verify operational performance and validate performance for its intended use</td>
<td>-Before first use</td>
<td>Develop basis for approval for intended use</td>
</tr>
<tr>
<td><strong>Reference Standards</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weights (Mass)</td>
<td>-Mass must be certified by an accredited Calibration Laboratory with endorsed certificate or section M4 of A2LA P605 with appropriate records applies.</td>
<td>- As defined by the laboratory or required by the relevant standard.</td>
<td>- Requires traceability at least to an NMI</td>
</tr>
<tr>
<td></td>
<td>- Check condition of weights at each use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td>Minimum Action</td>
<td>Frequency</td>
<td>Justification</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Thermometer                                   | - Reference thermometer must be certified by an accredited laboratory with an endorsed certificate or directly traceable to an NMI for internal calibrations of temperature.  
  - Using the Reference Thermometer, calibrate temperature of the target device at Ice Point or Boiling Point or at Temperature of Use (versus Reference temperature device). M4 of P605 applies. OR, calibrate temperature using an accredited Calibration Laboratory for Initial Calibration or Recalibration  
  - Maintain an Endorsed Certificate for all calibrated equipment.  
  - Check condition of thermometers at each use |
| Thermocouple                                  | - Accredited Calibration Laboratory for Initial Calibration (Purchase) or Recalibration  
  - Endorsed Certificate  
  - A2LA P605, sec M4 OK With records  
  - at Ice-Point or Boiling Point                                                                                                                        | - As defined by the laboratory or required by the standard  
  - Intermediate checks as determined by the lab or required by the relevant standard.                                                             | Requires traceability at least to an NMI |
| Stage Micrometer (used for calibration checks of ocular micrometers and reticles for optical microscopy) | - Calibrate at Purchase or Recalibrate as required                                                                                                      | - Initial Calibration  
  - Re calibrate at intervals as determined by lab or required by the relevant standard.                                                             | Requires traceability at least to an NMI |

- Requires traceability at least to an NMI
### Equipment

<table>
<thead>
<tr>
<th>Working Standards</th>
<th>Minimum Action</th>
<th>Frequency</th>
<th>Justification</th>
</tr>
</thead>
</table>
| Working Weights (Mass) | - Verify against Reference Weights  
- Check condition of weights at each use  
- Verify Measurement of Mass is within acceptance criteria | - As defined by the laboratory or required by the relevant standard. | - To meet test method requirements |
| Working Thermometers | - Verify against Reference Thermometer  
- Verify Measurement of Temperature is within acceptance criteria or correction factor applied | - As defined by the laboratory or required by the relevant standard. | - To meet test method requirements |
| Working Thermocouples | - Verify against Reference Thermocouple or manufacturers’ requirements  
- Verify Measurement of Temperature is within Acceptance Criteria or Correction Factor applied | - As defined by the laboratory or required by the relevant standard.  
- Would also apply to computerized systems | - To meet test method requirements |

### Reference Materials

**NOTE Sections M1(b) and M2(d) of the A2LA P605 apply to this section.**

<table>
<thead>
<tr>
<th>Trace Metals (as the measurand)</th>
<th>- Obtain from a Reference Material Producer</th>
<th>- Upon Purchase</th>
<th>- Requires traceability to an NMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trace Organics (Volatile, Semi-Volatile, Pesticides) as the measurand</td>
<td>- Obtain from a Reference Material Producer</td>
<td>- Upon Purchase</td>
<td>- Requires traceability to an NMI</td>
</tr>
<tr>
<td>Anions &amp; Cations (as the measurand)</td>
<td>- Obtain from a Reference Material Producer</td>
<td>- Upon Purchase</td>
<td>- Requires traceability to an NMI</td>
</tr>
<tr>
<td>pH Buffers</td>
<td>- Obtain from a Reference Material Producer</td>
<td>- Upon Purchase</td>
<td>- Requires traceability to an NMI</td>
</tr>
<tr>
<td>Equipment</td>
<td>Minimum Action</td>
<td>Frequency</td>
<td>Justification</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>--------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Biological Standards</td>
<td>- Obtain from a Reference Material Producer</td>
<td>- Upon Purchase</td>
<td>- Product characterization appropriate to use in the laboratory</td>
</tr>
<tr>
<td><strong>Ancillary/Equipment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Balances                          | - Compare to Reference Weights: Can be done with Accredited Calibration Laboratory (section M1 of A2LA P605) or In-House calibration in which case M4 applies.  
- Verify Measurement of Mass is within lab’s acceptance criteria  
- Should do Intermediate Check with working weights | - As defined by the laboratory or required by the relevant standard  
- Intermediate Check depending on use | - Is a component of overall uncertainty of measurement  
- Already part of test method uncertainty |
| Pipettors and Other Volumetric Delivery Devices | - Calibrate before use and at regular intervals using an accredited calibration service or calibrate internally in which case M4 of the A2LA P605 applies.  
- Verification with Weight of Water or Spectrophotometrically  
- Should do Intermediate Checks | - As defined by the laboratory or the relevant standard.  
- Intermediate Check depends on use | - Potentially significant component of overall uncertainty of measurand  
- Already part of test method uncertainty |
<table>
<thead>
<tr>
<th>Equipment</th>
<th>Minimum Action</th>
<th>Frequency</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH Meter/Electrode</td>
<td>- Follow manufacturers’ recommendations for electrode responsiveness and slope</td>
<td>- Each Day of Use</td>
<td>- Small component of overall uncertainty of measurand - Already part of test method uncertainty</td>
</tr>
<tr>
<td>Refrigerators, Freezers, Incubators, Water Baths, Ovens, Muffle Furnaces, etc.</td>
<td>- None required, unless the device has its own temperature sensing device, in which case the temperature sensing device needs to be verified annually - Using appropriate and calibrated working thermometers or working thermocouples is required.</td>
<td>- As defined by the laboratory or any supplemental Clinical Program Requirements or standard</td>
<td>- Component of overall uncertainty of measurand - Already part of test method uncertainty</td>
</tr>
<tr>
<td>Autoclaves</td>
<td>- Verify fitness for use - Calibrate for temperature and pressure using an accredited calibration service or internally in which case M4 of the A2LA P605 applies.</td>
<td>- As defined by the laboratory or any supplemental Clinical Program Requirements or standard</td>
<td>- Assures effective outcomes</td>
</tr>
</tbody>
</table>
| Safety Cabinets, Fume Hoods, Laminar Flow Hoods | - Verify fitness for use as required by local, regional or national safety requirements | - As defined by the laboratory or any supplemental Clinical Program Requirements or standard | - Assures effective outcomes.
<table>
<thead>
<tr>
<th>Equipment</th>
<th>Minimum Action</th>
<th>Frequency</th>
<th>Justification</th>
</tr>
</thead>
</table>
| Centrifuges       | Calibrate for time, temperature, and speed using an accredited calibration service or internally in which case M4 of P605 on Measurement Traceability applies.  
- Calibrate for volume for cell washers using an accredited calibration service or internally in which case M4 of P605 on Measurement Traceability applies. | - As defined by the laboratory or any supplemental Clinical Program Requirements or relevant standard.  
- Component of overall uncertainty of measurand  
- Already part of test method uncertainty |                                                                                                                                  |
| Cell washers      |                                                                                   |                                                                           |                                                                                                                                  |
| Irradiators       | - Verify performance to manufacturers’ specifications  
- As required by local, regional or national safety requirements | - As defined by the laboratory or relevant Program Requirements or standard. | - Assures effective outcomes.                                                                                                                   |
Figure 1: Pyramid of Traceability and Uncertainty

Bureau of Weights and Measures (BIPM)
SI = International Standard Units

NMI

Reference Metrology Labs

Working Metrology Labs

General Calibration

Process Measurement

Uncertainty Increases
Figure 2: Flow of activities to establish traceability

- Certified Reference Material/Device Documentation
- In-House Reference Standard → YES or NO
- Is the Measurement Critical?
- Policy Does Not Apply
- Evaluate Working Devices or Methods
- Are Corrections Allowed?
  - YES → Calibration
  - NO → Verification
- Is Measurement Within Defined Measurement Uncertainty?
  - YES → Accept For Use
  - NO → Remove From Use
- Supplier Must be Accredited by Mutual Recognition Agreement Signatory; Activity Must be Within Scope of Accreditation; Activity Must Demonstrate a Desirable Measurement Uncertainty
- Is Calibration Done In-House?
  - YES → See A2LA P102, Section T9
  - NO

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