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Standard for Metrological Traceability in Forensic Toxicology

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Foreword

This Standard was developed to provide minimum requirements for establishing metrological traceability in forensic toxicology. The fundamental reason for establishing traceability of a measurement is to ensure confidence and reliability in forensic toxicological test and calibration results.

This 2nd Edition includes several substantive changes from the 1st Edition. The scope was revised to clarify the subdisciplines of forensic toxicology for which the standard is applicable. ANSI/ASB Standard 054, *Standard for a Quality Control Program in Forensic Toxicology Laboratories* was included as an additional normative reference. Some of terms and definitions were modified to apply to both forensic toxicology testing and calibration of alcohol measuring instruments. The Calibration Program section from the 1st Edition was determined to not be within the scope of the document, so was removed in this edition. Changes were made to the section title of Certified Reference Materials and a requirement was added to address situations when a CRM is unavailable. The Reference Standards section title was also changed and the requirement for mass reference standard calibration frequency was revised. The requirement for calibration of rulers was moved to its own section and revised. The requirement for calibration of thermometers was removed from the document. Finally, the title of the Conformance section was changed and the requirement revised.

The American Academy of Forensic Sciences established the Academy Standards Board (ASB) in 2015 with a vision of safeguarding Justice, Integrity and Fairness through Consensus Based American National Standards. To that end, the ASB develops consensus based forensic standards within a framework accredited by the American National Standards Institute (ANSI), and provides training to support those standards. ASB values integrity, scientific rigor, openness, due process, collaboration, excellence, diversity and inclusion. ASB is dedicated to developing and making freely accessible the highest quality documentary forensic science consensus Standards, Guidelines, Best Practices, and Technical Reports in a wide range of forensic science disciplines as a service to forensic practitioners and the legal system.

The 1st edition of this document was developed by the Toxicology Subcommittee of the Organizational Scientific Area Committee. That version and this subsequent revision were prepared and finalized as a standard by the Toxicology Consensus Body of the ASB.

Questions, comments, and suggestions for the improvement of this document can be sent to AAFS-ASB Secretariat, asb@aafs.org or 401 N 21st Street, Colorado Springs, CO 80904.

All hyperlinks and web addresses shown in this document are current as of the publication date of this standard.

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Standard for Metrological Traceability in Forensic Toxicology

1 Scope

This standard defines the minimum requirements for establishing metrological traceability in forensic toxicology. Specifically, it is intended for the subdisciplines of postmortem forensic toxicology, human performance toxicology (e.g., drug-facilitated crimes and driving-under-the-influence of alcohol or drugs), non-regulated employment drug testing, court-ordered toxicology (e.g., probation and parole, drug courts, child services), general forensic toxicology (non-lethal poisonings or intoxications) and calibration of breath alcohol measuring instruments.

2 Normative References

The following references are documents that are indispensable for the application of the standard. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

International Bureau of Weights and Measures (BIPM)-International Committee for Weights and Measures (CIPM) *Mutual Recognition Arrangement*[1]

International Laboratory Accreditation Cooperation (ILAC), ILAC P10:07/2020 *ILAC Policy on Metrological Traceability of Measurement Results*[3]

International Laboratory Accreditation Cooperation (ILAC) *Mutual Recognition Arrangement*[4]

International Organization for Standardization (ISO), ISO/IEC 17025:2017 *General requirements for the competence of testing and calibration laboratories* (Geneva, Switzerland: ISO, 2017)[5]

ANSI/ASB Standard 054, *Standard for a Quality Control Program in Forensic Toxicology Laboratories*. First Edition (2021)[6]

3 Terms and Definitions

For purposes of this document, the following definitions and acronyms apply.

3.1
accreditation[7]
Third party attestation of a forensic science service provider conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities.

[1] More information about the BIPM is available at: http://www.bipm.org/en/cipm-mra/
[3] ILAC document available for download at: https://ilac.org/?ddownload=123220
[4] ILAC documents available for download at: https://ilac.org/publications-and-resources/ilac-policy-series
[5] ISO documents available for purchase at: http://www.iso.org/iso/home/store/catalogue_ics.htm or from other authorized distributors
[6] Available from: https://www.aafs.org/academy-standards-board
[7] International Organization for Standardization (ISO), ISO/IEC 17000:2020 Conformity assessment — Vocabulary and general principles (Geneva, Switzerland)

3.2
accuracy[8](Modified)
Closeness of agreement between a measured quantity value and a true quantity value of a measurement.

3.3
calibration[8](Modified)
Operation that, under specified conditions, establishes a relation between the quantity value and corresponding indications.

3.4
calibrator[8]
Measurement standard used in calibration.

3.5
certified reference material[9]
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.

3.6
control
Material of known composition used to evaluate the performance of a method.

3.7
decision point
Administratively defined cutoff or concentration that is at or above the method's limit of detection or lower limit of quantitation and is used to discriminate between a negative and positive test result.

3.8
limit of detection
LOD
Estimate of the lowest concentration of an analyte in a sample that can be reliably differentiated from blank matrix and meets identification criteria.

3.9
lower limit of quantitation
LLOQ
Estimate of the lowest concentration of an analyte in a sample that can be reliably measured with acceptable bias and precision.

[8] Joint Committee for Guides in Metrology (JCGM), International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd ed. (Sèvres, France)
[9] International Organization for Standardization (ISO), ISO Guide 30:2015 Reference Materials – Selected Terms and Definitions (Geneva, Switzerland)

3.10
forensic science service provider
Forensic science agency or forensic science practitioner providing forensic science services.

3.11
measurement[8]
Process of experimentally obtaining one or more quantity values that can reasonably be attributed to a quantity.

3.12
quantity[8]
Property of a phenomenon, body, or substance, where the property has a magnitude that can be expressed as a number and a reference**.**

3.13
quantity value[8]
Number and reference together expressing magnitude of a quantity.

3.14
reference standard[8](Modified)
Measurement standard that is used to calibrate or verify (working reference standard) measuring instruments or measuring systems.

3.15
metrological traceability[8]
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.

3.16
reference material[9]
Material, sufficiently homogeneous and stable with reference to specified properties, which has been established to be fit for its intended use in a measurement or in examination of nominal properties.

4 Background

Measurement relates to the entire process of obtaining a quantity value. Some measurement processes require only a single step, whereas others may require more than one step and are made in different ways in testing and calibration processes. Examples of measurements include:

a) a reported test result;

b) a reported calibration result; or

c) a quantitative decision point (cutoff) that results in a qualitative test report.

Measurements may be used as the basis for an interpretation or opinion.

Metrological traceability can be characterized by the following essential elements:[10]

a) *Unbroken Chain of Comparisons* – A documented system of comparisons with each step having the essential elements of metrological traceability going back to a stated reference acceptable to the parties, usually a national or international standard.

b) *Documented Measurement Uncertainty* – The measurement uncertainty for each step in the traceability chain must be calculated according to defined methods and must be stated so that an overall uncertainty for the whole chain may be calculated.

c) *Documented Measurement Procedure* – Each step in the chain must be performed according to documented, generally-accepted procedures and the results must be documented.

d) *Technical Competence* – The laboratories or bodies performing one or more steps in the chain must maintain and supply evidence of technical competence (e.g., by maintaining appropriate training records, participating in inter-laboratory comparisons, and by demonstrating that they are accredited by a recognized accreditation body).

e) *Realization of SI Units* – The chain of comparisons must, where possible, end at the realization of the International System of Units (SI).

f) *Documented Calibration Intervals* – Calibrations must be repeated at established and appropriate intervals to preserve metrological traceability; and

g) *Measurement Assurance* – A proper measurement assurance program [however named] must be established to ensure the validity of the measurement process and to ensure the calibration status of equipment, reference standards and reference materials.

5 Requirements for Metrological Traceability

5.1 General

Forensic science service providers shall establish traceability of a measurement process by:

a) making one or more measurements using equipment that has been calibrated with established metrological traceability and/or,

b) through the use of calibrators in the test or calibration method that are undiluted certified reference materials or that have been prepared using reference material and calibrated equipment.

Proper handling and storage procedures which meet or exceed manufacturer's recommendations shall be followed for equipment, certified reference materials, and non-certified reference materials used to establish and maintain metrological traceability.

[10] See "GMP 13 Good Measurement Practice for Ensuring Metrological Traceability" GMP 13 Ensuring Metrological Traceability (nist.gov)

5.2 Calibration Service Provider

5.2.1 If traceability of a measurement will be established through the calibration of equipment used to make the measurement, then this calibration shall be performed by an appropriately accredited calibration service supplier that, if available, that is either:

a) a National Metrology Institute (NMI) that is a signatory to the BIPM - CIPM *Mutual Recognition Arrangement*, with the calibration to be performed listed in Appendix C of the BIPM *Key Comparison Database* (KCDB); or

b) a service supplier accredited to ISO/IEC 17025:2017 by an accrediting body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) *Mutual Recognition Arrangement*, with the calibration to be performed listed in a scope of accreditation.

5.2.2 If an appropriately accredited calibration service supplier is not available (as defined above), then the forensic science service provider shall:

a) perform their own evaluation;

b) ensure the external service supplier meets the competence, metrological traceability, and measurement capability requirements of ISO/IEC 17025:2017 or in the *ILAC Policy on the Traceability of Measurement Results*[11];

c) keep objective evidence of this evaluation; and

d) perform a re-evaluation of services at least every two years.

5.3 Reference Materials

5.3.1 If available, a CRM shall be obtained by the forensic science service provider from a supplier that is either:

a) a National Metrology Institute (NMI) that is a signatory to the BIPM - CIPM *Mutual Recognition Arrangement,* with the CRM to be purchased included in the BIPM key comparison database (KCDB); or

b) an accredited Reference Material Producer that is accredited to ISO 17034:2016 by an accrediting body that is a signatory to a mutual or multilateral recognition arrangement in an ILAC recognized regional accreditation cooperation or the ILAC *Mutual Recognition Arrangement*, with a scope of accreditation covering the CRM.

5.3.2 If a CRM is not available from a supplier that meets the above requirement, then the forensic science service provider shall:

a) perform an evaluation of the CRM supplier;

[11] Reference to ILAC P10 https://ilac.org/?ddownload=123220/

b) ensure the CRM supplier meets the competence, metrological traceability, and measurement capability requirements of ISO/IEC 17025:2017 or in the *ILAC Policy on the Traceability of Measurement Results;*

c) keep objective evidence of this evaluation; and

d) perform a re-evaluation of services at least every two years.

5.3.3 If a CRM is not available, a non-certified reference material can be used to prepare a calibrator. The RM quantitative value and fitness-for-purpose shall have been established as required in ANSI/ASB Standard 054, *Standard for a Quality Control Program in Forensic Toxicology Laboratories*.

5.3.4 If a reference material used to establish traceability, whether certified or not, is diluted, such as preparing a stock or working solution, then the equipment used shall be calibrated as delineated in Section 5.2.

5.4 Implementation of Metrological Traceability

5.4.1 A decision shall be made during the method development process regarding how metrological traceability will be established**.**

5.4.2 Metrological traceability shall be established during method validation and routine analysis for:

a) qualitative methods with an established decision point concentration

Examples:

1) immunoassay method with a cutoff concentration

2) chromatography-based method with a decision point concentration

b) quantitative methods.

5.4.3 Metrological traceability shall be established in forensic toxicology through the use of one or more metrologically-prepared calibrators.[12]

NOTE While not used to establish metrological traceability, controls that are metrologically-prepared may be used.

5.5 Equipment

5.5.1 General

5.5.1.1 The equipment listed in Section 5.5.2 shall be calibrated by appropriately accredited calibration service suppliers that meet those requirements in Section 5.2.1.

[12] Calibrators may be undiluted CRM(s) or calibrators prepared using appropriately calibrated equipment and CRMs, or reference material(s) (RM) shown to be fit for purpose, as defined in 5.3.

5.5.1.2 A forensic toxicology laboratory shall have a procedure that:

a) includes the frequency of calibration and acceptability/tolerance specifications for equipment;

b) requires equipment to be calibrated prior to use;

c) requires equipment to be calibrated at a point or within a range consistent with typical use; and

d) determines if intermediate checks of the calibration status are required between calibrations based on, but not limited to, the frequency of use, work volume, occurrence of unexpected shutdown and equipment maintenance and if so, the schedule and procedure for those intermediate checks.

5.5.1.3 The following calibration documentation shall be maintained:

a) accredited calibration service suppliers' conformance to Section 5.2.1; and

b) the date the calibration is performed, the calibration status and the date the next calibration is due.

5.5.1.4 If intermediate checks are performed, the policy and procedure shall:

a) require the intermediate checks to be carried out using calibrated equipment (e.g., mass reference standards, equipment used to monitor environmental conditions);

b) include the frequency and specifications for intermediate checks; and

c) specify the actions to be taken when the specifications are not met.

5.5.2 Calibration of Analytical Equipment

The following equipment requires calibration when used to establish metrological traceability and when the measurement accuracy affects the validity of the reported result:

5.5.2.1 Analytical Balances

Analytical balances shall be calibrated at least annually by an appropriately accredited calibration service supplier.

5.5.2.2 Mass Reference Standards

Mass reference standards used to verify the accuracy of equipment shall be:

a) calibrated at least once every two years by an appropriately accredited calibration service supplier;[13]

[13] GMP 11 "Good Measurement Practice for Assignment and Adjustment of Calibration Intervals for Laboratory Standards" NIST GMP 11

b) adjusted by an accredited calibration service supplier, and the reference standards shall be calibrated before and after any adjustment; and

c) dedicated for this purpose, unless the forensic toxicology laboratory has demonstrated that their integrity as reference standards are maintained.

5.5.2.3 Volumetric Glassware

Class A volumetric glassware that is used for the preparation of calibrators shall be:

a) dedicated for this purpose;

b) calibrated by an appropriately accredited calibration service supplier; and

c) recalibrated at least once every ten years by an appropriately accredited calibration service supplier.[14]

5.5.2.4 Pipettes, Diluters, and Syringes

All pipettes, pipette diluters, automatic diluters, and syringes used for the preparation of calibrator solutions that require metrological traceability or in sample preparation (e.g. sample aliquoting and other steps that affect overall measurement uncertainty) shall be calibrated at least annually by an appropriately accredited calibration service supplier.

NOTE Autosampler syringes used for sample introduction to analytical instrumentation (e.g., gas chromatograph, liquid chromatograph, or immunoassay) do not require calibration.

5.5.2.5 Rulers

Rulers shall be calibrated at least once every ten years by an appropriately accredited calibration service supplier.

5.5.2.6 Breath Alcohol Calibration Equipment

5.5.2.6.1 Simulator thermometers, multi-meters and barometers, as applicable, shall be calibrated at least every two years by an appropriately accredited calibration service supplier, as defined in 5.2.1.

5.5.2.6.2 Sections 5.5.2.1 to 5.5.2.6 apply to equipment used in the preparation of breath alcohol measurement standard used in a breath alcohol calibration method.

5.5.3 Other Equipment

General laboratory equipment used during sample preparation (e.g., centrifuges, rotators, shakers, water baths, evaporators, extraction manifolds, and heating blocks) that does not significantly affect the validity of the reported result, do not require calibration to establish metrological

[14] The National Institute of Standards and Technology (NIST) Important Technical Guidance on Glassware https://www.nist.gov/system/files/documents/2017/05/09/h-008.pdf

traceability. A forensic toxicology laboratory may choose to use calibration or verification as a maintenance procedure to ensure proper functioning of the equipment.

6 Document Retention

Forensic science service providers shall define the length of time they are required to maintain documentation that is used to verify conformance with the above requirements.

Annex A
(informative)

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