OSAC 2025-S-0015
Standard Practices for Quality Management Systems for Forensic Toxicology Laboratories and Breath Alcohol Programs[1]

Forensic Toxicology Subcommittee
Chemistry: Seized Drugs & Toxicology Scientific Area Committee (SAC)
Organization of Scientific Area Committees (OSAC) for Forensic Science

[1] When "forensic toxicology laboratory" or "toxicology section" is used in this document, it is implied as both forensic toxicology testing laboratories and breath alcohol programs.

OSAC Proposed Standard

DRAFT OSAC 2025-S-0015 Standard Practices for Quality Management Systems for Forensic Toxicology Laboratories and Breath Alcohol Programs

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Foreword

This standard describes a forensic toxicology laboratory's quality management (QM) system. The QM system encompasses all aspects of the laboratory, including personnel, equipment, procedures, and continuous improvement. Accreditation requirements provide the framework for an effective QM system for a forensic laboratory and this document delineates QM practices specific to the forensic toxicology discipline.

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This document was revised, prepared, and finalized as a standard by the Toxicology Consensus Body of the AAFS Standards Board. The draft of this standard was developed by the Toxicology Subcommittee of the Organization of Scientific Area Committees (OSAC) for Forensic Science. 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.

ASB procedures are publicly available, free of cost, at www.aafs.org/academy-standards-board.

Keywords: *quality management; forensic toxicology; breath alcohol instrument calibration*

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Standard Practices for Quality Management Systems for Forensic Toxicology Laboratories and Breath Alcohol Programs

1 Scope

This document provides specific minimum requirements for a quality management system in a forensic toxicology laboratory. The quality management system is designed to ensure the quality and forensic integrity of the reported results and the overall competency of the laboratory.

This document applies to laboratories performing forensic toxicological analysis in the following sub-disciplines: postmortem forensic toxicology, human performance toxicology (e.g., drug-facilitated crimes, driving-under-the-influence of alcohol and/or drugs, breath alcohol calibration), non-regulated employment drug testing, court-ordered toxicology (e.g., probation and parole, drug courts, child services), and general forensic toxicology (non-lethal poisonings or intoxications). This document does not apply to breath alcohol testing activities.

2 Normative References

The following references are documents that are indispensable for the application of the standard. The latest edition of the referenced document (including any amendments) applies.

ANSI/ASB Standard 017, *Standard for Metrological Traceability in Forensic Toxicology*[2].

ANSI/ASB Standard 036, *Standard Practices for Test Method Selection, Development, Validation and Verification in Forensic Toxicology*[2].

ANSI/ASB Best Practice Recommendation 037, *Guidelines for Opinions and Testimony in Forensic Toxicology*[2].

ANSI/ASB Standard 053, *Standard for Report Content in Forensic Toxicology*[2].

ANSI/ASB Standard 054, *Standard for a Quality Control Program in Forensic Toxicology Laboratories*[2].

ANSI/ASB Standard 055, *Standard for Breath Alcohol Measuring Instrument Calibration*[2].

ANSI/ASB Standard 056, *Standard for Evaluation of Measurement Uncertainty in Forensic Toxicology*[2].

ANSI/ASB Standard 098, *Standard for Mass Spectral Analysis in Forensic Toxicology*[2].

ASB/ANSI Standard 113, *Standard for Identification Criteria in Forensic Toxicology*[2].

[2] Available from: https://www.aafs.org/academy-standards-board

ANSI/ASB Standard 118, *Standard for Breath Alcohol Instrument Specifications*[2].

ANSI/ASB Standard 119, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicological Testing of Blood in Medicolegal Death Investigations*[2].

ANSI/ASB Standard 120, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicological Testing of Blood in Impaired Driving Investigations*[2].

ANSI/ASB Standard 121, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicological Testing of Urine in Drug-Facilitated Crime Investigations*[2].

ANSI/ASB Best Practice Recommendation 122, *Best Practice Recommendation for Performing Alcohol Calculations in Forensic Toxicology*[2].

ANSI/ASB Standard 152, *Standard for the Minimum Content Requirements of Forensic Toxicology Procedures*[2].

ANSI/ASB Standard 153, *Standard Practices for Proficiency Testing for Forensic Toxicology Laboratories and Breath Alcohol Programs*[2].

ANSI/ASB Best Practice Recommendation 156, *Best Practices for Specimen Collection and Preservation for Forensic Toxicology*[2].

ANSI/ASB Standard 173, *Standard for Education, Training, Continuing Education and Certification of Forensic Toxicology Personnel*[2].

International Organization for Standardization (ISO), ISO/IEC 17025:2017 *General Requirements for the competence of testing and calibration laboratories* (Geneva, Switzerland: ISO, 2017)[3].

ISO/IEC 21043-2 Forensic Science – Part 2: *Recognition, recording, collecting, transport and storage of items*[3].

3 Terms and Definitions

Terms and definitions used in this document are defined within the normative references.

4 Requirements

4.1 Quality Management Systems

4.1.1 The laboratory shall be accredited to the International Organization for Standardization (ISO), ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (Geneva, Switzerland: ISO, 2017), as a testing and/or calibration laboratory.

[3] Available from: https://webstore.ansi.org/

4.1.1.1.1 The laboratory shall be accredited by a signatory to the International Laboratory Accreditation Cooperation, Mutual Recognition Arrangement (ILAC MRA).

4.1.1.1.2 Recognition of the accrediting body by ILAC shall be based on ISO/IEC 17011 Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies.

4.1.2 The toxicology section should be assessed by the accrediting body at least every two years.

4.1.3 The laboratory should seek additional accreditation to discipline-specific requirements, where available, such as those published by the American Board of Forensic Toxicology (ABFT).

4.1.4 The laboratory shall have documentation (e.g., organizational chart) that specifies the individual(s) responsible for assuring quality in the forensic toxicology section.

4.1.5 The toxicology section shall define the types of activities it performs (e.g., breath alcohol calibration, postmortem testing, human performance testing).

4.1.5.1 The toxicology section shall adhere to ANSI/ASB Standard 119, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicological Testing of Blood in Medicolegal Death Investigations*, ANSI/ASB Standard 120, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicological Testing of Blood in Impaired Driving Investigations* and ANSI/ASB Standard 121, *Standard for the Analytical Scope and Sensitivity of Forensic Toxicological Testing of Urine in Drug-Facilitated Crime Investigations* for the types of activities performed.

4.1.6 The toxicology section shall define any testing activities performed that are not within the scope of accreditation.

4.1.7 The toxicology section shall have a policy for the review of forensic toxicology policies and procedures at least annually, including the scope and sensitivity of the section's analytical methods and evaluation of new drug trends in the communities served by the laboratory.

4.1.8 The toxicology section should request feedback from customers and stakeholders in order to evaluate the scope of analytical methods.

4.1.9 The laboratory shall have a contingency plan to protect the integrity of toxicological evidence and provide for the continuance of laboratory services in the event of a prolonged disruption (e.g., power outage, loss of temperature control).

4.2 Personnel

4.2.1 Forensic toxicology personnel shall meet the minimum requirements described in ANSI/ASB Standard 173, *Standard for Education, Training, Continuing Education and Certification of Forensic Toxicology Personnel*.

4.3 Human Factors

4.3.1 The laboratory should document the evaluation of human factors that may influence the analysis, reporting, and interpretation of forensic toxicology results.

4.3.2 The evaluation should identify steps in laboratory procedures in which human perception or judgment may affect the outcome (e.g., review of case history, test selection, visual assessments).

4.3.3 The laboratory should evaluate and implement mitigation strategies to minimize the negative impact of human factors. For example, where contextual information from case history is considered by the analyst when directing testing, the laboratory would consider how to include this information in conjunction with the final report.

NOTE: The use of quality control acceptance criteria, prescribing the number of calibrators employed, and defining criteria for an acceptable calibration curve are examples of mitigation strategies for human factors during analytical testing.

4.4 Evidence Control

4.4.1 The laboratory shall make available to their customers ANSI/ASB Best Practice Recommendation 156, *Best Practices for Specimen Collection and Preservation for Forensic Toxicology.*

4.4.2 Specimens and chain of custody shall be maintained in accordance with ISO 21043-2 Forensic Science – Part 2: Recognition, recording, collecting, transport, and storage of items.

4.4.3 The laboratory shall establish a procedure to ensure the integrity of specimens (from initial sampling through the final products of sample preparation) that minimizes the risk of loss, conversion (degradation or production), contamination, or alteration.

4.4.4 During each task, specimen storage containers shall be opened individually and closed (e.g., stopper, lid replaced) prior to opening the next specimen container.

4.4.5 Specimens retained within the secured toxicology section shall be sealed with a tamper-evident seal (e.g., tamper evident seal on evidence items or on secondary containers) within 60 days of the final report being issued to the customer.

4.4.6 Evidence items or secondary containers shall have a tamper-evident seal when stored or transported outside the secured toxicology section.

4.5 Method Validation

4.5.1 Laboratory test methods shall adhere to ANSI/ASB Standard 036, *Standard Practices for Test Method Selection, Development, Validation and Verification in Forensic Toxicology*.

4.5.2 Breath alcohol program calibration methods shall adhere to ANSI/ASB Standard 055, *Standard for Breath Alcohol Measuring Instrument Calibration*.

4.6 Analytical Procedures

4.6.1 The laboratory shall adhere to ANSI/ASB Standard 152, *Standard for Minimum Content Requirements of Forensic Toxicology Procedures*.

4.6.2 The laboratory shall adhere to ANSI/ASB Standard 113*, Standard for Identification Criteria in Forensic Toxicology* and ANSI/ASB Standard 098*, Standard for Mass Spectral Analysis in Forensic Toxicology*.

4.6.3 The laboratory shall verify positive forensic toxicology results by one of the following: 1) Analyze separate aliquots of the same specimen in two independent analytical runs (batches) or 2) analyze two specimens from the same case in the same batch or two independent batches.

4.6.4 The breath alcohol program shall adhere to ANSI/ASB Standard 055, *Standard for Breath Alcohol Measuring Instrument Calibration*.

4.6.5 The laboratory and breath alcohol program shall adhere to ANSI/ASB Best Practice Recommendation 122, *Best Practice Recommendation for Performing Alcohol Calculations in Forensic Toxicology.*

4.7 Equipment

4.7.1 The laboratory shall adhere to ANSI/ASB Standard 017, *Standard for Metrological Traceability in Forensic Toxicology* for equipment, including reference materials.

4.7.1.1 The laboratory shall have a procedure for annual review of credentials (e.g., accreditation, traceability) for external providers of reference materials or testing and calibration services to verify ongoing compliance with the criteria used for initial approval.

4.7.2 The laboratory shall adhere to ANSI/ASB Standard 056, *Standard for Evaluation of Measurement Uncertainty in Forensic Toxicology* for equipment factored into the measurement uncertainty.

4.7.3 The laboratory shall adhere to ANSI/ASB Standard 054, *Standard for a Quality Control Program in Forensic Toxicology Laboratories*.

4.7.4 The breath alcohol program shall adhere to ANSI/ASB Standard 055, *Standard for Breath Alcohol Measuring Instrument Calibration* and ANSI/ASB Standard 118, *Standard for Breath Alcohol Instrument Specifications*.

4.8 Documentation and Review

4.8.1 Testing Laboratories

4.8.1.1 The laboratory shall have a policy for the review of each batch, chromatographic or non-chromatographic, and its components (e.g., sequence, calibrators, controls, blanks, case specimens, results to be reported) using predefined acceptance criteria (e.g., retention times, ion ratios, chromatography, presence of carryover) by at least two authorized individuals (to include individual performing testing, if authorized). The individuals' names, dates of review, and any limitations of the batch shall be documented.

4.8.1.2 In the event of a disagreement between the individuals performing the reviews regarding acceptability of the batch or reporting of results, the laboratory shall have a policy to address what action to take.

4.8.1.3 Laboratory test reports shall adhere to ANSI/ASB Best Practice Recommendation 037, *Guidelines for Opinions and Testimony in Forensic Toxicology*, ANSI/ASB Standard 053, *Standard for Report Content in Forensic Toxicology* and ANSI/ASB Standard 056, *Standard for Evaluation of Measurement Uncertainty in Forensic Toxicology*.

4.8.1.4 The laboratory shall have a procedure for technical review of all final test reports by the author and at least one additional authorized individual, to include all case-specific data and case-related details (e.g., case history, requested testing). The individuals' names and dates of review shall be documented.

4.8.1.4.1 The laboratory shall define acceptance criteria used to determine agreement when more than one quantitative result is obtained from a single specimen, for a specific analyte.

NOTE: Specimen type (antemortem, postmortem), rounding/truncation of results and measurement uncertainty are examples of factors to consider when determining acceptance criteria.

4.8.1.5 The laboratory shall have a procedure that verifies the accuracy of transcribed non-analytical information on reports (e.g., subject name, submitting agency case number).

4.8.2 Breath Alcohol Programs

4.8.2.1 The breath alcohol program shall have a policy for the initial evaluation of each calibration using predefined acceptance criteria for accuracy and precision of the certified reference material by an authorized individual. The individual's name and date of review shall be documented.

4.8.2.2 The breath alcohol program shall have a policy that all calibrations are reviewed by an authorized individual separate from the individual who performed the calibration. The individual's name and date of review shall be documented.

4.8.2.3 Breath alcohol program calibration certificates shall adhere to the minimum requirements described in ANSI/ASB Standard 055, *Standard for Breath Alcohol Measuring Instrument Calibration*.

4.8.2.4 The breath alcohol program shall have a policy that all prepared calibration certificates are reviewed by an authorized individual separate from the individual who prepared the certificate. The individual's name and date of review shall be documented.

4.9 Competency and Proficiency Testing

4.9.1 The laboratory shall adhere to ANSI/ASB Standard 173, *Standard for Education, Training, Continuing Education and Certification of Forensic Toxicology Personnel*.

4.9.2 The laboratory shall adhere to ANSI/ASB Standard 153, *Standard Practices for Proficiency Testing for Forensic Toxicology Laboratories and Breath Alcohol Programs*.

4.10 Internal Audits

4.10.1 The scope of the laboratory's internal audit shall include direct observation of personnel performing different aspects of laboratory tasks (e.g., evidence handling [receiving, accessioning, and storage], sample preparation, instrumental analysis, calibration of breath alcohol instrument, data processing, technical review, administrative review, testimony).

4.10.1.1 The laboratory shall perform a review of casework that encompasses all areas included in their scope of work (e.g., specimen type, test methods, and reporting).

4.10.1.2 The laboratory shall ensure the review of casework includes pre-analytical, analytical, and post-analytical processes.

4.11 Nonconforming Work (Continuous Quality Improvement)

4.11.1 The laboratory shall have a procedure for identifying nonconforming work and, where corrective action is warranted, the investigation shall include a root cause analysis (RCA).

4.11.1.1 Nonconforming work which does not result in corrective action shall be documented (e.g., nonconformance log), to allow for review and monitoring of trends.

4.11.1.2 The root cause analysis process shall be designed to focus on procedural improvements in the laboratory, mitigating recurrence, and promoting self-reporting.

4.11.1.3 The root cause analysis investigation should be handled separately from personnel disciplinary issues.

4.11.1.4 The extent of any nonconforming work and assessment of risk shall be considered as part of the RCA. This includes what impact the root cause may have had on case work, other analytical methods, other staff, other equipment, or other final reports.

4.11.1.5 The laboratory shall not utilize the decommissioning of a method, or revoking an employee's authorization to perform the method, to preclude performing an investigation into the root cause of nonconforming work.

4.11.1.6 For a nonconformance related to proficiency testing, solely re-testing the sample is not sufficient. Additional investigation, including root cause analysis, shall be performed.

4.11.1.7 The laboratory's corrective action process for a proficiency test failure shall define the scope and breadth of the investigation of work performed[4].

4.12 Records Retention

4.12.1 The laboratory shall have a retention policy for maintenance of records that support the validity of test results.

4.12.2 The policy shall evaluate the risk of destroying records to the laboratory's ability to support the validity of its results.

4.12.3 Records shall be retained in a secured environment as required by other ANSI/ASB published standards (e.g., ANSI/ASB Standard 036, *Standard Practices for Method Validation in Forensic Toxicology*) or jurisdictional legal requirements, and for no fewer than five years.

The following records, where available, shall be described in the retention policy (note this list is not exhaustive):

4.12.3.1 Case-specific data that supports reported results

4.12.3.2 Method validation records

4.12.3.3 Standard operating procedure versions

4.12.3.4 Equipment maintenance records

4.12.3.5 Training and competency records

4.12.3.6 Proficiency testing results

4.12.3.7 Audit records

4.12.3.8 Investigation of nonconforming work and corrective action records

[4]American Board of Forensic Toxicology (ABFT), Guidelines for Performing Corrective Action for Deviations in Proficiency Test Results (December 2012). Available from: https://abft.org.

Annex A
(informative)

Bibliography

The following bibliography is not intended to be an all-inclusive list, review, or endorsement of literature on this topic. The goal of the bibliography is to provide examples of publications addressed in the standard.

1] American Board of Forensic Toxicology (ABFT). “Forensic Toxicology Laboratory Accreditation Checklist.”. January 2023, https://abft.org.

2] Hamnett, H., Dror, I. “The effect of contextual information on decision-making in forensic toxicology.” *Forensic Science International: Synergy,* Vol. 2, 2020, pp. 339-348.

3] Spellman, B., Eldridge, H., Bieber, P. “Challenges to reasoning in forensic science decisions.” *Forensic Science International: Synergy*, Vol. 4, 2022, 100-200.