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Standard Practice for Quality Assurance of Forensic Science Service Providers Performing Forensic Chemical Analysis[1]

This standard is issued under the fixed designation E3255; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice discusses procedures for quality assurance of forensic science service providers performing forensic chemical analysis. This practice provides a framework of quality in the processing of evidence, including: maintaining a quality management system; personnel duties, qualifications, training, and education; facility considerations; evidence handling; analytical procedures; instrument and equipment performance; chemicals and reagents; casework documentation and reporting; proficiency and competency testing; method validation and verification; audits; deficiency of analysis; and documentation requirements. Annex A1 – Annex A3 provide additional procedures that are discipline-specific.

1.2 This practice cannot replace knowledge, skills, or abilities acquired through appropriate education, training, and experience (see Practice E2917), and is to be used in conjunction with professional judgment by individuals with such discipline-specific knowledge, skills, and abilities.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E620 Practice for Reporting Opinions of Scientific or Technical Experts
E1459 Guide for Physical Evidence Labeling and Related Documentation
E1492 Practice for Receiving, Documenting, Storing, and Retrieving Evidence in a Forensic Science Laboratory
E1732 Terminology Relating to Forensic Science
E2917 Practice for Forensic Science Practitioner Training, Continuing Education, and Professional Development Programs

2.2 *ISO Standards:*[3]

ISO Guide 30 Reference ~~Materials~~materials — Selected ~~Terms~~terms and ~~Definitions~~definitions

[1] This practice is under the jurisdiction of ASTM Committee E30 on Forensic Sciences and is the direct responsibility of Subcommittee E30.11 on Interdisciplinary Forensic Science Standards.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

ISO 17034 General ~~Requirements~~requirements for the ~~Competence of Reference Material Producers~~competence of reference material producers
ISO/IEC 17020 Conformity assessment – Requirements for the operation of various types of bodies performing inspection
ISO/IEC 17025 General ~~Requirements~~requirements for the ~~Competence~~competence of ~~Testing~~testing and ~~Calibration Laboratories~~calibration laboratories
ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing

3. Terminology

3.1 *Definitions*—For definitions of terms that can assist in interpreting this standard, refer to Terminology E1732.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *blank, n*—a control where a specified component(s) is not present.

3.2.1.1 *Discussion*—
Blanks with various designations can be specified, such as system blank, process blank, method blank, reagent blank, solvent blank, etc. Certain blanks may also serve as a negative control.

3.2.2 *certified reference material, n*—reference material (RM) characterized by a metrologically valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

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3.2.3 *equipment, n*—set of laboratory tools, apparatus, and hardware used to process test items (for example, ovens, beakers, pipettes, vortexers, fume hoods, etc.)

3.2.4 *forensic science practitioner, n*—an individual who (*1*) applies scientific or technical practices to the recognition, collection, analysis, or interpretation of evidence for criminal and civil law or regulatory issues; and (*2*) issues test results, provides interpretations, or opinions through reports or testimony with respect to such evidence. **derived from *Defining Forensic Science and Related Terms*[4]**

3.2.5 *forensic science service provider, n*—a forensic science agency or forensic science practitioner providing forensic science services. **derived from *Defining Forensic Science and Related Terms*[4]**

3.2.6 *instrument, n*—equipment capable of performing measurements used to generate analytical data (for example, GC-MS, IR, NMR, balances, etc.).

3.2.7 *interlaboratory comparison, n*—organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. **ISO/IEC 17043**

3.2.8 *intralaboratory comparison, n*—organization, performance and evaluation of measurements or tests on the same or similar within the same laboratory in accordance with predetermined conditions. **ISO/IEC 17025**

3.2.9 *negative control, n*—a material of established origin that is used to confirm that a procedure does not produce an unintended result.

3.2.10 *positive control, n*—a material of established origin that is used to confirm that a procedure will produce the expected result.

~~3.2.11 *reference material, n*—material, sufficiently homogeneous and stable with respect to one or more specific properties, which has been established to be fit for its intended use in a measurement process. **ISO Guide 30**~~

[4] National Commission on Forensic Science, *Defining Forensic Science and Related Terms*, May 2016, available from https://www.justice.gov/archives/ncfs/file/786571/download.

3.2.11 *standardized method, n*—a method published by a recognized international, regional, or national standard development organization (for example, ASTM, ASB, AOAC, etc.).

4. Significance and Use

4.1 These are minimum standards of quality assurance applicable to forensic science service providers performing forensic chemical analysis on evidence.

4.2 This practice is to be used by forensic science practitioners performing chemical analysis on evidence and reinforced by forensic science service provider management.

5. Quality Management System

5.1 It is the goal of a forensic science service provider's evidence analysis program to provide customers with high quality analyses that produce reliable and accurate results.

5.2 A documented quality management system shall be established and maintained.

5.2.1 Personnel responsible for the quality management system (that is, quality assurance manager) shall be clearly designated.

5.2.2 The quality management system shall cover all procedures and reports associated with analysis.

5.2.3 The quality management system shall conform to an international standard, such as ISO/IEC 17025 or ISO/IEC 17020.

6. Personnel

6.1 Personnel shall have defined responsibilities, duties, educational requirements and required skills.

6.2 Forensic science service providers shall conform to Practice E2917.

6.3 Designated key personnel and responsibilities shall be established and maintained. An individual (however named) can be responsible for more than one of the duties detailed in 6.4 to 6.9.

6.4 *Director*—A designated person who is responsible for the overall operation and administration of the forensic science service provider, including the employment and training of personnel and assuring compliance with applicable regulations.

6.5 *Quality Assurance Manager*—A designated person who is responsible for maintaining the quality management system (including an annual review of the program) and who ensures conformance with the program.

6.6 *Technical Support Personnel*—A person who performs basic forensic science duties (for example, calibration checks, making solutions, glassware washing, etc.), but does not analyze evidence. Technical support personnel shall:

6.6.1 Have education, skills, and abilities commensurate with their responsibilities; and

6.6.2 Have on-the-job training specific to the responsibilities of their position.

6.7 *Technician*—A person who analyzes evidence, but does not issue reports of analytical results or interpretations. Technicians shall:

6.7.1 Have education, skills, and abilities commensurate with their responsibilities; and

6.7.2 Have formal training in evidence handling and those aspects of their duties specific to analysis. These include:
(1) Successful and documented completion of written or oral examinations,
(2) Successful and documented completion of competency testing, and

(3) Successful and documented completion of a moot/mock court exercise.

6.8 *Forensic Science Practitioner*—A designated person who may be authorized to: examine and analyze materials, or direct such examinations to be performed; interpret data, issue reports for court or investigative purposes; and conduct, method validation, training, and technical review of reports. Forensic science practitioners shall:

6.8.1 Meet all the requirements of a technician (6.7), and

6.8.2 Have at least a bachelor's degree or equivalent (generally, a four-year postsecondary degree) in a natural or physical science. The individual shall have successfully completed lecture and laboratory classes' in chemistry specific to their particular discipline, and

6.8.3 Conform to Practice E2917.

6.9 *Technical Leader*—A designated person or team of individuals who have the overall responsibility and authority for the technical operations associated with evidence analyses. Technical operations include maintaining protocols, developing analytical methodology, conducting method validation, and performing technical review of reports. The technical leader shall:

6.9.1 Meet all the requirements of a forensic science practitioner (6.8), and

6.9.2 Have a minimum of three (3) years of experience as a qualified forensic science practitioner performing independent evidence analyses in the specific discipline.

7. Physical Plant[5]

7.1 Forensic science service providers shall provide:

7.1.1 Adequate safety and security for personnel and operations;

7.1.2 Facilities that meet required health and safety standards and applicable building codes;

7.1.3 Suitable space to perform required analytical functions and prevent contamination;

7.1.4 Environmental and procedural controls to prevent incidental contamination;

7.1.5 Engineering devices and personal protective equipment (for example, chemical fume hoods, safety showers, gloves, safety glasses, etc.) to protect personnel from chemical hazards; and

7.1.6 Facilities that ensure safe and secure storage of evidence, chemicals, reagents, reference materials and records.

8. Evidence Control

8.1 Forensic science service providers shall follow a documented control system to ensure the integrity of evidence.

8.2 See Guide E1459 for physical evidence labeling and related documentation.

8.3 See Practice E1492 for receiving, documenting, storing, and retrieving evidence.

8.4 *Integrity of Evidence*—Evidence shall be properly secured and sealed. Appropriate storage conditions shall ensure that, insofar as possible, the composition of evidentiary material is not altered. The integrity of the evidence shall be protected in ways that safeguard against loss, deterioration or contamination. Alteration of the evidence or packaging shall be documented.

8.5 *Accounting for Evidence*—Evidence that is maintained by the forensic science service provider shall be inventoried, at a minimum, annually.

[5] *Forensic Science Laboratories: Handbook for Facility Planning, Design, Construction, and Relocation*, June 2013, available from https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=913987.

8.6 *Disposition of Evidence*—Records shall be kept regarding the disposition of all items of evidence (see Practice E1492).

9. Method Validation and Verification

9.1 Validation is required to demonstrate that methods are suitable for their intended purpose.

9.2 Forensic science service providers adopting methods validated elsewhere shall verify the validity and reliability of those methods used in their environment, with their instrumentation, equipment, reagents and chemicals, and forensic science practitioners prior to use.

9.3 New methods developed for characterization, identification, and comparison of chemicals shall be based on accepted scientific principles. The forensic science service provider shall perform validation studies to establish both the method's validity and reliability prior to use in casework.

9.3.1 Minimum acceptance criteria shall be established for method performance and be described along with means for demonstrating compliance.

9.4 Method validation and verifications shall address selectivity, precision, and other relevant performance characteristics and limitations.

9.4.1 Validations and verifications involving quantitative analysis shall also address limits of detections, lower limit of quantitation, linearity, accuracy, and uncertainty of the measurement process.

9.5 Validation and verifications shall be approved by the technical leader or other designated personnel prior to use in casework.

9.6 Validation and verification data and documentation shall be maintained.

10. Analytical Procedures

10.1 *Analytical Procedures:*

10.1.1 Forensic science service providers shall follow documented, validated, and authorized analytical methods.

10.1.1.1 The technical leader or other designated individual shall be responsible for evaluation and authorization of the analytical procedures used by the forensic science service provider, including reviews of method validations and verifications. All evaluations and authorizations shall be documented and retained.

10.1.1.2 A chemical/material identification, quantification or comparison shall be based on specific characteristics defined in the validated method, and decisions on the type/source of the material should be based on pre-established decision-thresholds.

10.1.1.3 Relevant limitations of chemical/material identifications or comparisons shall be evaluated and reported.

10.1.1.4 Forensic science service providers shall have in place protocols for the sampling of evidence.

10.1.1.5 When applicable, forensic science service providers should employ a statistically based protocol when an inference is to be made regarding a specified proportion of a submission for qualitative or quantitative determinations.

10.1.2 Published or standardized methods are recommended. Laboratory-developed or modified methods can also be used.

10.1.2.1 The forensic science service provider shall verify published or standardized methods by in-house performance testing.

10.1.2.2 The use of laboratory-developed or modified methods shall be validated and approved by the technical leader or other designated individual according to forensic science service provider policy.

10.1.3 Work practices shall be established to prevent contamination of evidence during analysis.

10.1.3.1 The processing of trace/residue samples should be separated in space from bulk evidence submissions to prevent incidental contamination. If space does not allow for this, then the processing of bulk and trace/residue samples shall be separated by time with thorough cleaning between processing steps.

10.1.3.2 Forensic science practitioners shall take measures to be assured that identifications are correct (for example, excluding contamination, instrument carryover, etc.) and relate to the correct submission.

10.1.4 Forensic science service providers shall follow documented procedures for the evaluation and acceptance of data based on the method utilized.

10.1.5 Forensic science service providers shall monitor analytical processes using appropriate blanks, positive and negative controls and reference materials.

10.1.5.1 Negative controls shall be run concurrently with evidence to demonstrate that the sampling devices, chemicals, instruments and extraction processes do not result in contamination of the evidence.

10.1.5.2 The forensic science service provider shall have a procedure for routinely testing the reliability of the analytical processes with known reference materials (positive control). This can be done concurrently with each analysis or on a predefined schedule.

10.1.6 Reference materials and associated data shall be used to demonstrate the reliability of test results. A positive test result shall meet the acceptance criteria defined in the method validation and operating protocol. In descending order of preference, the acceptance criteria should be based on:

10.1.6.1 Comparison of instrumental test/case sample data to suitable reference material data analyzed under the same analytical conditions (that is, instrument, instrumental methods, and stationary phase). If reference material data is collected on a different instrument than the test/case sample, it shall be demonstrated that both instruments produce comparable data. The reference material may be analyzed:

(1) Contemporaneously with test/case sample (for example, same sequence/batch);
(2) As part of routine quality control (for example, daily check solutions); or
(3) At a previous date (for example, method validation, internal reference collection).

10.1.6.2 Comparison of instrumental test/case sample data to external reference data when a reference material is unavailable. External reference data shall be assessed and demonstrated to be fit for purpose. Factors include:

(1) Origin of the data;
(2) Validation of the data;
(3) Peer review of the data; and
(4) Comparability of analytical conditions.

10.1.6.3 Structural elucidation techniques, when applicable by discipline, and when neither reference materials nor external reference data are available. Structural elucidation techniques may be employed by forensic science practitioners that are competent in structural elucidation interpretation.

10.2 *Assessment of Reference Materials:*

10.2.1 Forensic science service providers shall have a process for assessing that reference materials are fit for purpose.

10.2.1.1 Assessments are not required for reference materials obtained from a provider accredited under ISO 17034.

10.2.1.2 The assessment and purpose (for example, qualitative or quantitative) of a reference material shall be documented. The documentation shall include: identity; source; assigned unique identifier; date and name of the individual who performed the assessment; and verification test data.

10.2.1.3 To be fit for purpose, reference materials shall meet minimum specifications defined in the forensic science service provider's validated methods.

10.2.1.4 The assessment shall be performed on each lot of reference materials.

10.2.1.5 The assessment shall be completed prior to casework analysis.

10.2.2 Reference materials shall only be used for the purpose defined by the forensic science service provider. For example, a reference material may be deemed suitable for qualitative but not quantitative determinations.

10.2.2.1 Fit for purpose for qualitative work requires an assessment of chemical identity. Examples of verification of chemical identity by analysis include:

(1) Comparison of the results to peer-reviewed published data,
(2) Data produced by an accredited forensic science service provider,
(3) Data produced from a previously verified reference material, or
(4) Evaluation of data from in-house structural elucidation analysis of the material.

10.2.2.2 Fit for purpose for quantitative work requires traceability and assessment of purity or concentration, or both, as appropriate to the application and its associated uncertainty of measurement in addition to 10.2.3. Examples of verification of purity by analysis utilizing validated methods include:

(1) Quantitative nuclear magnetic resonance spectroscopy,
(2) Quantitative ultraviolet-visible spectroscopy,
(3) Quantitative emission spectroscopy, or
(4) Comparison to previously verified material.

10.2.2.3 For quantitative determinations, different sources of reference material should be used for calibration and quality control. Where this is not feasible, two different lots of the same source may be used or lastly a single source of reference material can be subdivided and each part assigned a specific purpose.

10.2.2.4 Certified reference materials are preferred, but not required, as they are not typically available for many chemicals.

10.2.3 The specifications in 10.2 can be described in a certificate, statement of analysis, data sheet or label supplied with the material or can be determined by in-house analysis or reference to published literature.

10.2.4 The forensic science service provider shall assess the veracity of the information supplied with a reference material even if the material meets the definition of a certified reference material.

10.2.5 Reference materials that degrade or otherwise change in composition or concentration over time shall have an expiration date.

10.2.5.1 If the material is not supplied with an expiration date, one should be assigned at the first assessment (10.2.1).

10.2.5.2 If the expiration date passes before the material is fully used, then the material can be re-assessed and the expiration date extended. The forensic science service provider protocol for extending expiration dates shall be documented and include analysis of the material.

11. Instrument/Equipment Performance

11.1 *Instruments*—A performance check of each instrument shall be conducted prior to being initially used for casework. This performance check and the data collected shall be documented and include:

11.1.1 Analysis and comparison of known materials to include expected analytes, in order to demonstrate its suitability for intended use.

11.1.2 Comparison of data created to that of comparable published data.

11.2 *Instrument Performance*—Instruments shall be routinely optimized and monitored to ensure that proper performance is maintained.

11.2.1 Acceptance criteria for monitoring instrument performance shall be defined and documented.

11.2.2 Monitoring shall include, at a minimum, the use of reference materials, test mixtures and blanks when applicable.