Designation: E2327 – 15ε1

Standard Practice for Quality Assurance of Laboratories Performing Seized-Drug Analysis[1]

This standard is issued under the fixed designation E2327; 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.

ε[1] NOTE—9.2.7.1 was corrected editorially in December 2015.

1. Scope

1.1 This practice covers quality assurance issues in forensic laboratories performing seized-drug analysis including evidence handling, analytical procedures, report writing, method validation, documentation, proficiency testing, audits, and health and safety.

1.2 This practice is meant to apply only to qualitative seized-drug analysis.

1.3 This practice does not replace knowledge, skill, ability, experience, education, or training and should be used in conjunction with professional judgment.

1.4 *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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E620 Practice for Reporting Opinions of Scientific or Technical Experts

E1732 Terminology Relating to Forensic Science

E1459 Guide for Physical Evidence Labeling and Related Documentation

E1492 Practice for Receiving, Documenting, Storing, and Retrieving Evidence in a Forensic Science Laboratory

E2326 Practice for Education and Training of Seized-Drug Analysts

E2329 Practice for Identification of Seized Drugs

E2548 Guide for Sampling Seized Drugs for Qualitative and Quantitative Analysis

E2549 Practice for Validation of Seized-Drug Analytical Methods

E2764 Practice for Uncertainty Assessment in the Context of Seized-Drug Analysis

2.2 *Other Documents:*

ISO Guide 34 General Requirements for the Competence of Reference Material Producers[3]

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories[3]

Scientific Working Group for the Analysis of Seized Drugs Recommendations for: Education and Training, Quality Assurance, Methods of Analysis[4]

3. Terminology

3.1 Terms that may assist in interpreting this standard are found in Terminology E1732.

4. Significance and Use

4.1 These are minimum standards of quality assurance applicable to laboratories where analysis of seized-drug submissions is performed.

4.2 This practice is to be used by forensic analysts performing seized-drug analysis and promoted/supported by laboratory management.

5. Quality Management System

5.1 It is the goal of a laboratory's drug analysis program to provide customers of the laboratory's services access to quality drug analysis. It is the goal of this standard to provide a framework of quality in the processing of drug evidence, including evidence handling, management practices, qualitative and quantitative analysis, and reporting. A documented quality management system shall be established and maintained. Personnel responsible for this shall be clearly designated and have direct access to the highest level of management concerning laboratory policy.

[1] This practice is under the jurisdiction of ASTM Committee E30 on Forensic Sciences and is the direct responsibility of Subcommittee E30.01 on Criminalistics.

Current edition approved May 1, 2015. Published June 2015. Originally approved in 2004. Last previous edition approved in 2010 as E2327 – 10. DOI: 10.1520/E2327-15E01.

[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.

[4] Available from Scientific Working Group for the Analysis of Seized Drugs, http://www.swgdrug.org.

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

6. Personnel

6.1 *Job Description*—Job descriptions for all personnel should include responsibilities, duties, and required skills.

6.2 *Designated Personnel and Responsibilities*—An individual (however titled) may be responsible for more than one of the following duties:

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

6.2.2 *Health and Safety Manager*—A designated person who is responsible for maintaining the Laboratory Health and Safety program (including an annual review of the program) and who monitors compliance with the program.

6.2.3 *Technical Support Personnel*—A person who performs basic laboratory duties, but does not analyze evidence.

6.2.4 *Technician/Assistant Analyst*—A person who analyzes evidence, but does not issue reports for court purposes.

6.2.5 *Analyst*—A designated person who:

6.2.5.1 Examines and analyzes seized drugs or related materials, or directs such examinations to be done;

6.2.5.2 Independently has access to unsealed evidence in order to remove samples from the evidence for examination; and

6.2.5.3 As a consequence of such examinations, signs reports for court or other purposes.

6.2.6 *Supervisory Analyst*—A designated person who has the overall responsibility and authority for the technical operations of the drug analysis section. Technical operations include, but are not limited to, protocols, analytical methodology, and technical review of reports.

6.3 *Qualifications/Education:*

6.3.1 Technical Support Personnel shall:

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

6.3.1.2 Have on-the-job training specific to their position.

6.3.2 Technicians/Assistant Analysts shall:

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

6.3.2.2 Have on-the-job training specific to their position.

6.3.3 All new Analysts shall have at least a bachelor's degree or equivalent (generally, a three to four year post-secondary degree) in a natural/physical science. The individual shall have successfully completed lecture and associated laboratory classes in general, organic, and analytical chemistry (see Practice E2326).

6.3.4 New Supervisory Analysts shall:

6.3.4.1 Meet all the requirements of analyst (6.3.3),

6.3.4.2 Have a minimum of two (2) years of experience as an analyst in the forensic analysis of drug evidence, and

6.3.4.3 Exhibit knowledge necessary to evaluate analytical results and conclusions.

6.4 *Training for New Analysts*—The laboratory shall establish and document a training program and qualifying procedure for all new technical personnel (see Practice E2326).

6.5 *Maintaining Qualifications*—All forensic scientists have an ongoing responsibility to remain current in their field (see Practice E2326).

7. Physical Plant

7.1 *Physical Plant Requirements:*

7.1.1 Laboratories shall provide adequate safety and security for personnel and operations.

7.1.2 Laboratories shall meet required health and safety building codes.

7.1.3 Laboratories shall contain adequate space to perform required analytical functions and prevent contamination.

7.1.4 Chemical fume hoods shall be provided. They shall be properly maintained and monitored according to an established schedule.

7.1.5 A laboratory-cleaning schedule should be established and implemented.

7.1.6 Adequate facilities shall be provided to ensure the proper safekeeping of physical evidence, standards and records.

7.1.7 Appropriately secured storage shall be provided to prevent contamination of chemicals and reagents.

8. Evidence Control

8.1 Laboratories shall have and follow a documented evidence control system to ensure the integrity of physical evidence.

8.2 *Receiving and Identifying Evidence*—Laboratories shall maintain records of requests for analysis and of the respective items of evidence (see Practice E1492). This file or record shall include, at least, the following:

8.2.1 Submission documents or copies,

8.2.2 Identity of party requesting analysis and date of request,

8.2.3 Description of items of evidence submitted for analysis,

8.2.3.1 Any significant irregularities identified, during a comparison of evidence described in accompanying paperwork and examination prior to analysis, shall be documented and included in case file or record.

8.2.4 Unique case identifier,

8.2.5 Chain of custody record, and

8.2.6 Identity of person who actually submits evidence, along with date of submission. For evidence not delivered in person, descriptive information regarding mode of delivery and tracking information shall be included.

8.3 *Integrity of Evidence*—Evidence shall be properly secured and sealed. Appropriate storage conditions shall ensure that, insofar as possible, the composition of seized material is not altered. All items shall be safeguarded against loss or contamination. Any alteration of the evidence (for example, repackaging) shall be documented. Procedures shall be implemented to assure that samples are properly labeled throughout the analytical process (see Guide E1459).

8.4 *Storage of Evidence*—Access to the evidence storage area shall be controlled, it being granted only to authorized personnel. A system shall be established to document a chain of custody for evidence in laboratory custody.

8.5 *Disposition of Evidence*—Records shall be kept regarding the disposition of all items of evidence.

8.6 *Security of Analytical Documentation Associated with Evidence*—All laboratory records such as analytical results, measurements, notes, calibrations, chromatograms, spectra, and reports shall be retained in a secure fashion.

9. Analytical Procedures

9.1 *Analytical Procedures for Drug Analysis:*

9.1.1 Laboratories shall have and follow documented analytical procedures.

9.1.2 Laboratories shall have in place protocols for the sampling of evidence (see Practice E2548).

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

9.1.4 Laboratories shall have and follow documented guidelines for the acceptance and interpretation of data.

9.1.5 Laboratories shall monitor analytical processes using appropriate blanks, controls and reference materials.

9.1.6 Reference materials and reference data are critical to demonstrating the validity of quantitative and qualitative 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:

9.1.6.1 Comparison to data obtained from a suitable drug reference material analyzed under the same analytical conditions as the test/case sample. The reference material may be analyzed:

(1) Contemporaneously with test/case sample;

(2) As part of routine quality control (for example, daily check solutions); or

(3) At a previous date (for example, method validation, in-house library).

9.1.6.2 Comparisons to external reference data may be used where a reference material is unavailable. External reference data shall be shown to be fit for purpose. The veracity of the data shall be considered and assessed. Factors include:

(1) Origin of the data,

(2) Validation of the data,

(3) Peer review of the data, and

(4) Comparability of analytical conditions.

The use of external reference data rather than a reference material shall be documented and where applicable the limitation expressed within the report.

9.1.6.3 When neither reference materials nor external reference data are available, structural elucidation techniques may be employed providing the analyst has the appropriate skills for their interpretation. Such interpretations shall be made only by analysts competent in structural elucidation interpretation. The absence of a reference material and external data shall be documented and the impact on the interpretation of reported results assessed.

9.1.7 Analytical procedures shall be validated in compliance with Practice E2549.

9.1.8 Analysts shall take measures to be assured that identifications are correct and relate to the right submission (see Practice E2329).

9.2 *Assessment of Drug Reference Materials:*

9.2.1 Laboratories shall have a process for assessing that reference materials are fit for purpose.

9.2.1.1 The assessment and purpose of a reference material shall be documented. The documentation shall include the name of the individual who performed the assessment, the date of the assessment, verification test data, and details of all reference materials and reference data used.

9.2.2 To be fit for purpose, the reference material must meet the minimum specification defined in the validation process (see Practice E2549).

9.2.2.1 The assessment shall be done on each lot of reference material.

9.2.2.2 This assessment shall be completed prior to or alongside casework analysis as appropriate.

9.2.2.3 Reference materials shall only be used for the purpose defined by the laboratory. For example a reference material may be deemed suitable for qualitative but not quantitative determinations.

9.2.3 Fit for purpose for qualitative work requires an assessment of chemical identity.

9.2.4 Fit for purpose for quantitative work requires an assessment of purity or concentration, or both, as appropriate to the application and its associated uncertainty of measurement in addition to 9.2.3.

9.2.4.1 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 sub-divided and each part assigned a specific purpose.

9.2.5 These parameters in 9.2.3 and 9.2.4 may be described in a certificate, statement of analysis, data sheet or label supplied with the material or may be determined by in-house analysis or reference to published literature.

9.2.6 The laboratory shall assess the reliability of the information supplied with a reference material even if the material meets the definition of a certified reference material.

9.2.6.1 For reference materials obtained from a provider accredited under ISO Guide 34, the information contained in the accompanying certificate is considered reliable and can be accepted as correct if the material is stored and used in accordance with the manufacturer's instructions. In these circumstances the assessment need not include analysis.

9.2.6.2 For reference materials obtained from a provider not accredited under ISO Guide 34 the identity of the reference material shall be verified by analysis. If the reference material will be used for quantitative analyses the purity and/or concentration, as appropriate to the application shall also be verified by analysis. When verification by analysis is not possible, this shall be documented and where applicable the limitation expressed within the report. Other information may

be evaluated as needed. Examples of verification of chemical identity by analysis include:

(1) Analysis and comparison of the results to peer-reviewed published data;

(2) Data produced by a laboratory accredited under ISO/IEC 17025;

(3) Data produced from a previously verified reference material; or

(4) Evaluation of data from in-house structural elucidation analysis of the material.

Examples of verification of purity by analysis utilizing validated methods include:

(1) Quantitative nuclear magnetic resonance spectroscopy;

(2) Quantitative ultraviolet-visible spectroscopy; or

(3) Comparison to previously verified material.

9.2.6.3 Where a reference material has no or limited supporting documentation or is produced in-house (by synthesis or from a case sample), then the chemical identity shall be determined in sufficient detail to demonstrate that it is fit for purpose. In addition, for quantitative work the purity and/or concentration, as appropriate to the application and associated uncertainty of measurement shall also be determined.

9.2.7 Reference materials should have an expiration date.

9.2.7.1 If the material is not supplied with an expiration date, one should be assigned at the first assessment (9.2.3 and 9.2.4). If the expiration date passes before the material is fully used, then the material can be re-assessed and the expiration date extended. The laboratory protocol for extending expiration dates shall be documented and should include analysis of the material.

9.2.7.2 If expiration dates are not assigned to reference materials, the laboratory must have a documented protocol for assessing the validity of the reference material each time it is used.

10. Instrument/Equipment Performance

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

10.1.1 Monitoring shall include, at least, the use of blanks and reference materials, test mixtures, or calibration standards.

10.1.2 Instrument performance monitoring shall be documented.

10.2 *Equipment*—Unsuitable or improperly operating equipment shall not be used. Equipment performance parameters should be routinely monitored and documented.

10.2.1 The manufacturer's operation manual and other relevant documentation for each piece of equipment should be readily available.

11. Chemicals and Reagents

11.1 Chemicals and reagents used in drug testing shall be of the appropriate grade for the test performed.

11.2 There shall be documented procedures for the formulation of all chemical reagents produced within the laboratory.

11.2.1 Documentation for reagents prepared within the laboratory shall include identity, concentration (when appropriate), date of preparation, identity of the individual preparing the reagents, storage conditions (if appropriate), and the expiration date (if appropriate).

11.3 The efficacy of all test reagents shall be checked prior to their use in casework. Results of these tests shall be documented.

11.4 Chemical and reagent containers shall be dated and initialed when received and when first opened.

11.5 Chemical and reagent containers shall be labeled as to their contents.

12. Casework Documentation, Report Writing, and Review

12.1 *Casework Documentation:*

12.1.1 Documentation shall contain sufficient information to allow a peer to evaluate the notes and interpret data.

12.1.2 Evidence handling documentation shall include chain of custody, information regarding packaging of evidence upon receipt, the initial weight/count of evidence to be examined (upon opening), a description of evidence, and communications regarding the case.

12.1.3 Analytical documentation should include procedures, standards, blanks, observations, test results, and supporting documentation including charts, graphs, and spectra generated during analysis.

12.1.4 Casework documentation shall be preserved according to documented laboratory policy.

12.2 *Report Writing (see Practice E620):*

12.2.1 Reports issued by laboratories shall be accurate, clear, objective, and meet the requirements of the jurisdictions served. Reports shall include:

12.2.1.1 Identity and location of the testing laboratory,

12.2.1.2 Case identifier,

12.2.1.3 Identity of contributor,

12.2.1.4 Date of receipt,

12.2.1.5 Date of report,

12.2.1.6 Descriptive list of submitted evidence,

12.2.1.7 Identity of analyst,

12.2.1.8 Analytical techniques employed,

12.2.1.9 Results,

12.2.1.10 Conclusions,

12.2.1.11 Sampling (see Guide E2549), and

12.2.1.12 Uncertainty (see Practice E2764).

12.2.2 If elements listed in 12.2.1 are not included on the report, the laboratory shall have documented reasons, such as specific accreditation, customer or jurisdictional considerations for not doing so.

12.3 *Case Review:*

12.3.1 Laboratories shall have a documented policy establishing protocols for technical and administrative case review.

12.3.2 Laboratories shall have a documented policy for resolving instances where analyst and reviewer disagree.

13. Proficiency and Competency Testing

13.1 Each laboratory shall establish a documented competency testing and proficiency testing program. Each laboratory shall have documented protocols for monitoring the competency and proficiency of its analysts.

NOTE 1—In this context, competency tests measure the ability of the analyst to produce accurate results. Proficiency tests are an ongoing process in which a series of proficiency samples, the characteristics of which are not known to the participants, are sent to laboratories on a regular basis. Each laboratory is tested for its accuracy in identifying the presence (or concentration) of the drug using its usual procedures.

13.2 *Proficiency Testing:*

13.2.1 Laboratories shall perform proficiency testing in order to verify the laboratory's performance. The frequency of proficiency testing shall be at least annually and at least one of these proficiency tests should be from a recognized proficiency-test provider external to the laboratory.

13.2.2 Proficiency-test samples should be representative of the laboratory's normal casework.

13.2.3 Methodology required to perform proficiency tests should be in concert with that normally practiced in the laboratory.

13.3 *Competency Testing:*

13.3.1 Laboratories shall test the competency of their analysts prior to assigning them independent casework responsibilities.

13.3.2 Competency-test samples should be representative of the laboratory's normal casework.

13.3.3 Methodology required to perform competency tests should be in concert with that normally practiced in the laboratory.

14. Method Validation and Verification

14.1 Method validation is required to demonstrate that methods are suitable for their intended purpose (see Practice E2549).

15. Laboratory Audits

15.1 Internal audits of laboratory operations shall be conducted at least once a year.

15.2 Records of each audit shall be maintained and include the scope, date of audit, name of auditor(s), findings, and corrective actions taken.

16. Deficiency of Analysis

16.1 In the course of examining seized-drug samples and related materials, laboratories may expect to encounter some operations or results that are deficient in some manner. Each laboratory shall have a documented policy to deal with such deficiencies. This policy shall include the following:

16.1.1 A definition of a deficiency is any erroneous analytical result or interpretation, or any unapproved deviation from an established policy or procedure in an analysis;

NOTE 2—Deviations from established policy shall have documented management approval.

16.1.2 A requirement for immediate cessation of the activity or work of the individual(s) involved, if warranted by the seriousness of the deficiency, as defined in the documented policy;

16.1.3 A requirement for administrative review of the activity or work of the individual(s) involved;

16.1.4 A requirement for evaluation of the impact that deficiency might have had on other operations, equipment, materials, or laboratory personnel;

16.1.5 A requirement for documentation of follow-up action taken as a result of the review; and

16.1.6 A requirement for communication to appropriate employees of any confirmed deficiency, which may have implications for their work.

NOTE 3—It should be recognized that to be effective, the definition for "deficiency of analysis" must be relatively broad. As such, deficiencies may have markedly different degrees of seriousness. For example, a misidentification of a controlled substance would be very serious and perhaps require that either the methodology or the analyst be suspended pending appropriate remedial action, as determined by management. However, other deficiencies might be more clerical in nature, requiring a simple correction at the first line supervisory level, without any suspension of methodology or personnel. Thus, it may well be advantageous to identify the differing levels of seriousness for deficiencies and make the action required commensurate with the seriousness.

17. Health and Safety

17.1 Laboratories shall have a documented health and safety program.

17.2 *Health and Safety Requirements:*

17.2.1 All personnel should receive appropriate health and safety training.

17.2.2 Laboratories shall have policies, regarding employee conduct, that comply with relevant health and safety statutory regulations.

17.2.3 Laboratory health, chemical hygiene plans, and safety manual(s) shall be readily available to all laboratory personnel.

17.2.4 Safety Data Sheets shall be readily available to all laboratory personnel.

17.2.5 All chemicals, biohazards and supplies shall be stored and disposed of according to applicable government regulations and laboratory policy.

17.2.6 Safety hazards such as syringes, items with sharp edges, or noxious substances should be so labeled.

18. Additional Documentation

18.1 In addition to casework documentation, laboratories shall maintain documentation on the following topics:

18.1.1 Test methods/procedures for drug analysis,

18.1.2 Reference materials (including source and verification),

18.1.3 Preparation and testing of reagents,

18.1.4 Evidence handling protocols,

18.1.5 Instrument and equipment calibration and maintenance,

18.1.6 Instrument and equipment inventory (for example, manufacturer, model, serial number, acquisition date),

18.1.7 Proficiency testing,

18.1.8 Personnel training and qualification,

18.1.9 Quality assurance protocols and audits,

18.1.10 Health, safety, and security protocols,

18.1.11 Validation data and results, and

18.1.12 Uncertainty data.

19. Keywords

19.1 forensic laboratories; quality assurance; seized-drug analysis