Designation: ~~E2327 – 10~~ E2327 – 15

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.

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

~~E2328~~E1732 Terminology Relating to ~~Seized-Drug Analysis~~Forensic Science ~~(Withdrawn 2005)~~

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 ~~Document:~~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 ~~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 ~~E2328~~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.

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[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.

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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] ~~The last approved version of this historical standard is referenced on www.astm.org.~~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.

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.

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 ~~*Personnel*~~ *Technical* ~~*Support*~~ *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~~Analysts shall have at least a ~~baccalaureate~~bachelor's degree or equivalent ~~(generally~~(generally, a three to four year post-secondary degree) in a natural/physical science. ~~Coursework shall include~~ The individual shall have successfully completed lecture and associated laboratory classes in general, organic, and analytical ~~chemistry.~~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. A documented~~personnel (see Practice E2326~~training program, approved by laboratory management, should focus on the development of the theoretical and practical knowledge, skills and abilities necessary to examine seized-drug samples and related materials. It shall include:~~).

~~6.4.1 A training syllabus providing descriptions of the knowledge and skills in which analysts are to be trained for specific topic areas, milestones of achievement, and methods of testing or evaluating competency;~~

~~6.4.2 Documented standards of performance and a plan for assessing theoretical and practical competency against these standards, for example, written and oral examinations, critical reviews, analysis of unknown samples, mock casework, etc. per specific topic area;~~

~~6.4.3 A period of documented, supervised casework representative of the type they shall be required to perform; and~~

~~6.4.4 A verification document demonstrating that trainees have achieved the required competence level per specific topic area.~~

6.5 *Maintaining* ~~*Qualifications:*~~ *Qualifications*—

~~6.5.1 Minimum annual training required for continuing professional development of laboratory analysts is twenty (20) hours.~~

~~6.5.1.1 Training shall be relevant to the laboratory's analytical mission. Professional development may include training related to ancillary duty assignments and supervision/management responsibilities.~~

~~6.5.1.2 Training completed shall be documented.~~

~~6.5.1.3 Training can be face-to-face interaction with an instructor, distance learning, self-directed, or computer-based.~~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. A unique~~evidence (see Practice E1492~~identifier shall be assigned to each case file or record.~~). 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.~~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.~~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 ~~traceable standards.~~reference materials.

9.1.6 ~~Laboratories shall have and follow documented guidelines for the acceptance and interpretation of data.~~ 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;