Designation: E2327 – 04

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 standard 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 Standards are meant to apply only to the practice of qualitative seized-drug analysis.

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E2328 Terminology Relating to Seized-Drug Analysis[3]

2.2 *Other Document:*

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

3. Terminology

3.1 Terms that may assist in interpreting this standard are found in Terminology E2328.

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 The standards are to be practiced 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 analysis, and reporting. A documented quality management system must be established and maintained. Personnel responsible for this must be clearly designated and have direct access to the highest level of management concerning laboratory policy.

5.2 The quality management system must 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*—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.

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] Withdrawn.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

6.3 *Qualifications/Education*:

6.3.1 Technical Support Personnel will:

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 will:

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 Analysts will:

6.3.3.1 Have a minimum of a bachelor's degree or equivalent in a natural science or applied science, including criminalistics or forensic science, which shall include lecture and associated laboratory classes in general, organic, and analytical chemistry, or

6.3.3.2 By January 1, 2005, have a minimum of five (5) years practical experience in the area of seized-drug analysis, and have demonstrated competency following the completion of a formal, documented training program and post training competency assessment.

6.3.4 Supervisory Analysts will:

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 must establish and document a training program and qualifying procedure for all new technical personnel. A documented 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 must 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 will 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*:

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

6.5.1.1 Training must be relevant to the laboratory's analytical mission.

6.5.1.2 Training completed must be documented.

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 must meet required health and safety building codes.

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

7.1.4 Chemical fume hoods must be provided. They must 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 must be provided to ensure the proper safekeeping of physical evidence, standards and records.

7.1.7 Appropriately secured storage must 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 must maintain records of requests for analysis and of the respective items of evidence. A unique identifier must be assigned to each case file or record. This file or record must 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, must 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 must be included.

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

8.4 *Storage of Evidence*—Access to the evidence storage area must 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 must 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.