



# Standard Practice for Quality Assurance of Laboratories Performing Seized-Drug Analysis<sup>1</sup>

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.

## 2. Referenced Documents

2.1 *ASTM Standards*:<sup>2</sup>

E2328 Terminology Relating to Seized-Drug Analysis<sup>3</sup>

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 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 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*—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.

<sup>1</sup> 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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<sup>2</sup> For referenced ASTM standards, visit the ASTM website, [www.astm.org](http://www.astm.org), or contact ASTM Customer Service at [service@astm.org](mailto:service@astm.org). For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

<sup>3</sup> Withdrawn. The last approved version of this historical standard is referenced on [www.astm.org](http://www.astm.org).

### 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 baccalaureate degree or equivalent (generally a three to four year post-secondary degree) in a natural/physical science. Coursework shall include lecture and associated laboratory classes in general, organic and analytical chemistry.

#### 6.3.4 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 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:*

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.

## 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 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.

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.

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

9.1.4 Laboratories shall monitor analytical processes using appropriate controls and traceable standards.

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

9.1.6 Analytical procedures shall be validated in compliance with Section 14.

9.1.7 Analysts shall take measures to be assured that identifications are correct and relate to the right submission. This is best established by the use of at least two appropriate techniques based on different principles and two independent samplings.

### 9.2 *Verification of Drug Reference Materials:*

9.2.1 The identity of certified reference materials shall be verified prior to their first use.

9.2.2 The identity of uncertified reference materials shall be verified prior to use by methods such as mixed melting point determination, Mass Spectrometry, Infrared Spectroscopy, or Nuclear Magnetic Resonance Spectroscopy.

9.2.3 Verification shall be performed on each new lot of reference material.

9.2.4 All verification testing shall be documented and include the name of the individual who performed the identification, date of verification, verification test data, and reference identification.

## 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 reference materials, test mixtures, calibration standards, or blanks.

10.1.2 Instrument performance monitoring shall be documented.

10.2 *Equipment*—Use of unsuitable or improperly operating equipment is discouraged. 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 should 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:*

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

- 12.2.1.1 Identity of 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, and
- 12.2.1.12 Uncertainty.

### 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 written competency testing and proficiency testing program. Each laboratory shall have documented protocols for monitoring the competency and proficiency of its analysts.

### 13.2 *Proficiency Testing:*

13.2.1 Laboratories shall perform proficiency testing in order to verify the laboratory's performance in comparison to other laboratories. 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.

14.1.1 For qualitative analysis, the parameters that need to be checked are specificity, limit of detection, and reproducibility.

14.1.2 Minimum acceptability criteria should be described along with means for demonstrating compliance.

14.1.3 Validation documentation is required.

14.2 Laboratories adopting methods validated elsewhere should verify these methods and establish their own limits of detection and reproducibility.

## 15. Laboratory Audits

15.1 Audits of laboratory operations should be conducted at least once a year.

15.2 Records of each audit shall be maintained and should 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.

16.2 This policy shall include the following:

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

NOTE 1—Deviations from established policy shall have documented management approval.

16.2.2 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;

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

16.2.4 A requirement for evaluation of the impact that deficiency may have had on other activities of the individual(s) or other analysts;

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

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

NOTE 2—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 Material 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

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