Designation: E2549 – 14

Standard Practice for Validation of Seized-Drug Analytical Methods[1]

This standard is issued under the fixed designation E2549; 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 addresses the validation of qualitative and quantitative seized-drug analytical methods. It discusses the validation of analytical methods in terms of their part in analytical schemes and in terms of performance characteristics including brief mention of measurement uncertainty and quality control parameters.

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

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

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E2327 Practice for Quality Assurance of Laboratories Performing Seized-Drug Analysis

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

3. Significance and Use

3.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. There are numerous documents that address the topic of validation but there are few validation protocols for methods specific to seized drug analysis. This practice makes recommendations for the validation of both qualitative and quantitative methods used for the analysis of seized drugs.

4. Analytical Scheme

4.1 An analytical scheme shall be comprised of validated methods that are appropriate for the analyte.

4.2 The combinations of methods chosen for a particular analytical scheme shall identify the specific drug of interest, preclude a false positive and minimize false negatives.

4.3 For quantification the method should reliably determine the amount of analyte present.

4.4 If validated methods are used from published literature or another laboratory's protocols, then the methods shall be verified within each laboratory

4.5 If non-routine validated methods are used, then the method shall be verified prior to use.

4.6 Verification should, at a minimum, demonstrate that a representative set of reference materials has been carried through the process and yielded the expected results.

5. Individual Laboratory Responsibility

5.1 Each laboratory should determine whether their current standard operating procedures have been validated, verified, or require further validation/verification.

6. Operational Environment

6.1 All methods shall be validated or verified to demonstrate that they will perform in the normal operational environment when used by individuals expected to utilize the methods on casework.

7. Documentation

7.1 The entire validation/verification process shall be documented and the documentation shall be retained for a period in accordance with laboratory policy. Documentation shall include, but is not limited to the following:

7.1.1 Personnel involved;

7.1.2 Dates;

7.1.3 Observations from the process;

7.1.4 Analytical data;

7.1.5 A statement of conclusions or recommendations, or both; and

7.1.6 Authorization approval signature.

[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 March 1, 2014. Published March 2014. Originally approved in 2009. Last previous edition approved in 2009 as E2549 – 09. DOI: 10.1520/E2549-14.

[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.