Scientific Working Group for SWGTOX Forensic Toxicology

Changes to SWGTOX Document 003
following Public Comment
Published May 20, 2013

Following the public comment of *Scientific Working Group for Forensic Toxicology (SWGTOX) Standard Practices for Method Validation in Forensic Toxicology*, the following changes were made to the document:

Section 1: Introduction Minor changes within this section to provide greater clarity.

Section 2: Definitions Modified wording of some definitions for clarity. Removed definitions not needed in this document (e.g., robustness and recovery). Replaced . Introduced working range .

Section 3: When to Validate Methods No changes.

Section 4: Method Development and Optimization Minor modifications for clarity.

Section 5: Establishing a Validation Plan No changes.

Section 6: Required Validation Parameters Based on Scope of Method Added validation parameters that were inadvertently left out in previous version. These are parameters that were listed as required, if applicable.

Section 7: Specific Requirements for Conducting Method Validation Experiments Added statement of conducting validation in a manner similar to casework. Provided instruction on preparation of fortified matrix samples used in validation.

- Section 7.1: Bias and Precision - The term *bias* replaced *accuracy* throughout the document. Clarified instructions on samples to use for determining bias and precision. Modified definition of low and high concentration samples used for validation studies to allow for more flexibility. Provided clarity on determining precision for immunoassays and changed concentration requirements of samples used for these studies from ±20% of the decision point concentration to ±50%. Minor changes for clarity throughout this section.

- Section 7.2: Calibration Model Introduced term working range. Modified for clarity.

- Section 7.3: Carryover Minor changes for clarity.

- Section 7.4: Interference Studies Minor changes for clarity.

- Section 7.5: Ionization Suppression/Enhancement Added instruction that impact of ionization suppression/enhancement must also be evaluated for the

internal standard. Removed comparison of retention times of isotopically-labeled internal standards and analytes of interest. Other minor modifications for clarity.

- Section 7.6: Limit of Detection Minor modifications for clarity.

- Section 7.7: Limit of Quantitation Minor modifications for clarity.

Section 8: Additional Validation Parameters
and robustness) from the document. Minor changes for clarity.

- Section 8.1: Dilution Integrity No significant changes.

- Section 8.2: Stability Minor modifications for clarity.

Section 9: Required Revalidation of Previously Validated Methods No significant changes.

Section 10: Documentation Requirements for Method Validation Added requirement for documentation of management review and approval of validation.

Section 11: Efficiency With Validation No significant changes.

Section 12: References No significant changes.

Appendix A: Changes for clarity and to reflect modifications made in main document. Replaced standardized residual plots.

Appendix B: Revisions for clarity and to reflect modifications made in main document. Changed example to reflect benzodiazepine immunoassay to better explain when precision must be evaluated and when it is not necessary.

Appendix C: Modified to reflect changes in main document.

Appendix D: No significant changes.

Appendix E: Modified to reflect changes in main document.