

**NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM**

**Proposed Revision to Forensic Toxicology Standards
Comment Period: April 1, 2016 to May 27, 2016**

Any Forensic Toxicology standards not addressed here remain in effect.

| Proposed Standard | Proposed Guidance |
|---|---|
| <p>Forensic Toxicology Sustaining Standard of Practice 19 (FT S19): Confirmation Method Periodic Re-Validation</p> <p>In addition to the initial validation of confirmatory test methods, the laboratory shall demonstrate, annually thereafter, the following performance characteristics:</p> <ul style="list-style-type: none"> a) accuracy and precision at the cutoff concentration; b) accuracy and precision at 40 percent of the cutoff concentration; c) upper limit of linearity; d) limit of detection; e) limit of quantification; f) analytical specificity; and, g) carryover. | <p>Documentation of method validation, as required by Validation Sustaining Standard 2 (VAL S2): Use of Validated Procedures, must clearly state the study design, the analytical findings, conclusions, and source of specimens and how they were characterized.</p> <p>Limit of quantification means the lowest concentration of analyte that can be identified (mass spectrometric criteria for identification are met) and measured within assay performance specifications for accuracy.</p> <p>Limit of detection means the lowest concentration of analyte that can be identified (mass spectrometric criteria for identification are met), but not quantified within performance specifications (typically, +/- 20%).</p> <p>Analytical specificity validation should entail the analysis of validation materials that contain the target drug at 40% cutoff and potentially interfering drugs at high concentrations consistent with overdose.</p> |
| <p>Forensic Toxicology Sustaining Standard of Practice 23 (FT S23): Confirmation Method Quality Control</p> <p>Each batch of specimens for confirmatory testing shall contain, minimally, 10% calibrators and/or quality control samples as follows:</p> <ul style="list-style-type: none"> a) at least one control certified to contain no drug or metabolite; b) at least one control with drug or metabolite concentration at 25 percent above the cutoff concentration; c) at least one control or calibration material with drug or metabolite concentration at or less than 40 percent of the cutoff concentration; and, d) a control to assess the efficiency of hydrolysis, where appropriate. | |