Proposed Forensic Toxicology Standards – Comments and Responses

Proposed Standards were made available to New York State permitted laboratories and laboratories in application for a permit on March 4th, 2020. The announcement was by e-mail to the facility and laboratory contact person's e-mail address and the Proposed Standards were posted to the CLEP website.

The comment period ended June 15th, 2020. Comments received from any regulated parties and responses are shown here.

Standards will be adopted July 13th, 2020, with an effective date of August 1st, 2020.

General Forensic Toxicology Standards Comments

COMMENT 1:
Proficiency Testing – Is proficiency testing required for forensic toxicology? In the new guidelines, QA F1 was removed.

RESPONSE 1:
Laboratories seeking or holding a New York State Clinical Laboratory Permit must comply with all applicable General Systems and Specialty Requirements by Category Standards. Please refer to the General Systems Standards for all proficiency testing requirements. There is no change to the standards based on the comment received.

COMMENT 2:
We ask that instead of "laboratory director' it state: laboratory director or assistant director(s) holding an appropriate certificate of qualification.
For the following Standards: FT S3, FT S7, FT S15, FT S16, FT S31

RESPONSE 2:
Responsibilities may be delegated in writing by the laboratory director. The laboratory director is responsible for ensuring that all delegated responsibilities are performed by staff (CLIA 493.1407(b) and 10NYCRR 19.3(c)). There are no changes to the standards based on the comment received.

Toxicology	
Forensic Toxicology	
Standard	***Guidance***
Application of Standards as Currently Numbered: All Forensic Toxicology Permitted Laboratories: FT: 1-9, 22, 24, 25, 29, 30, 32, 40-42. Initial Testing Laboratories Only: FT: 10, 11, 12, 15, 16, 17, 31 Comprehensive Permitted Laboratories Only: FT: 18, 19, 20, 23, 33 All Forensic Toxicology Permitted Laboratories performing SVT: FT: 26, 27a, 27b, 27c, 27d, 27e	

COMMENT:

In the introduction block, all of the standards that are pointed at different types of laboratories and for all laboratories are intermingled. Perhaps group them better so that all of the standards that affect all of the laboratories are first and then segregate them to the initial, comprehensive, and then SVT. It is a little hard to follow who the standard is pointing too and to have to scroll back to the front of the standards and not find that it is designated to a section. It is a little confusing. By separating out the sections, it would also help when auditing to have all of the standards that you are auditing against together in a row and not have to jump around to find all that are required for one area.

RESPONSE:

The standards are currently grouped by subject matter. The type of permit held by the laboratory determines which standards apply from the subject matter.

Forensic Toxicology Standards Comments

Forensic Toxicology

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 15 (FT S15): Confirmation Testing Method Principle Confirmation testing must use: a) a new aliquot of the specimen taken from the original container; and b) a method that differs in physical and/or chemical principle from the initial test, and where possible a procedure that combines chromatographic separation and mass spectrometric identification, or method acceptable to the laboratory director.	The aliquot used for initial testing, substitution or adulteration testing is not acceptable for confirmatory testing, with the possible exception of specimens that cannot be re-collected.

Forensic Toxicology Standard of Practice 15 (FT S15): Confirmation Testing Method Principle

COMMENT:

Proposed (b) requires a method that differs from the initial test in physical and/or chemical principle from the initial test. In the most recent HHS and DOT guidelines for workplace drug testing, alternate screening methodologies are permitted (i.e. non-immunoassay tests). When a chromatographic/MS method is used for both screening and confirmation, testing is performed on separate aliquots but methodologies are the same. Our laboratory suggests that this section be revised to account for those circumstances.

RESPONSE:

The proposed standard does not prohibit a chromatographic/MS method being repeated for both screening and confirmation. Part b) allows the laboratory director to ultimately decide if the confirmation testing method principle is satisfactory. There is no change to the standard based on the comment received.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 16 (FT S16): Confirmation/Definitive Method Periodic Re-Validation In addition to the initial validation of confirmatory test methods, and the requirements in Test Performance Specification Standards of Practice 1 and 2, the laboratory must verify and document, ~~every six (6) months~~ annually, the following performance characteristics: a) accuracy and precision at all reported cutoff concentrations; b) accuracy and precision at the lower limit of quantitation; c) accuracy and precision at the upper limit of quantitation; d) limit of detection with statistical significance as determined by the director; e) analytical specificity; f) carryover at physiologically relevant concentrations; and g) evaluation of any collection devices designed to alter the specimen (such as blood collection tubes that contain preservatives, buffers, diluents, or additives, or oral fluid collection devices) that have not previously	Analytical specificity validation should include validation materials that contain the potentially interfering drugs at physiologically relevant concentrations. Some examples of device alterations of the specimen include: dilution, addition of buffers and/or preservatives, addition of internal standards, addition of reagents, and absorption or adsorption by a material.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
been evaluated, or have been substantially changed by the manufacturer, as part of sample preparation.	

Forensic Toxicology Standard of Practice 16 (FT S16): Confirmation/Definitive Method Periodic Re-Validation

COMMENT 1:
Reword to, in section g) evaluation of any collection devices designed to alter the specimen that have not previously been evaluated. Initial validation for confiramtory testing should already cover collection devices, why complete the same work over every 6 months. This would be burdensome and unwarranted to recheck the same types of collection devices. Re-validation should not be used to lot check a collection device provided by a manufacturer. Laboratories cannot control what type of collect device is used by a client unless they provide them with the device and even then, you cannot force them to use that specific collection device.

RESPONSE 1:
The standard has been revised based on the comment received.

COMMENT 2:
Our laboratory disagrees with these proposed revisions. The requirement for reverification every six months differs from HHS/NLCP requirements of annual method reverification. In addition, this requirement does not appear to address assays that include calibrators and controls across the range of the AMR in each batch. Carryover is also monitored in each batch as required by FT S20. Furthermore, the requirement for evaluation of collection devices at any periodic interval beyond initial validation is excessive. Oral fluid collection devices are cleared by the FDA and are required to meet specifications included in the HHS Mandatory Guidelines for Workplace Drug Testing. Unless there is a change to the collection device – e.g. device material or buffer – there is no reason to require periodic revalidation of these devices.

RESPONSE 2:
The standard has been revised based on the comment received.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 17 (FT S17): Confirmation/Definitive Method Reference Standards The laboratory must: a) maintain a record of the purity of all drug standard(s) for the period they are in use, and for two (2) years thereafter, according to Document and Specimen Retention Standard of Practice 8; b) verify drug concentration(s) for calibration standards (standard curves, solutions) and/or control materials before being placed into use; and c) if appropriate calibrators for the matrix and state of the drug (e.g., calibrators for hair analysis) are not available, the laboratory must calibrate: i. using samples that include reference materials (e.g., NIST traceable or PT survey-validated), or ii. when such materials are not available, through comparative analyses.	Calibrator materials and/or control materials prepared using the standards must be linked by lot number and dates of preparation.

Forensic Toxicology Standard of Practice 17 (FT S17): Confirmation/Definitive Method Reference Standards

COMMENT:

FT S17 – laboratories should be able to document the purity of drug standards by referring to a vendor's certificate of analysis, which may be kept in electronic form.

RESPONSE:

This standard does not prohibit the electronic storage of copies of vendor's records documenting the purity of purchased drug standards. Records must also include traceability of stock solutions and the verification and documentation of verification by the laboratory of "drug concentration(s) for calibration standards (standard curves, solutions) and/or control materials before being placed into use."

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 18 (FT S18): Full Scan Analyte Identification The laboratory must identify untargeted analytes by: a) performing a full scan identification of analytes using a commercially available library that is verified by the laboratory; or b) using a mass spectra reference library established on the same instrument by the laboratory using authentic standards.	This standard only applies to the untargeted or "open-scan" identification of analytes.

Forensic Toxicology Standard of Practice 18 (FT S18): Full Scan Analyte Identification

COMMENT:

FT S18. This appears to require full-scan identification of analytes for labs using mass spectrometry for confirmatory analysis. This change is entirely unnecessary and at odds with all other forensic standards we know of. Almost every lab performing mass spectrometric determinations in forensic laboratories uses Selected Ion Monitoring (SIM) if using GC/MS, or Multiple Reaction Monitoring (MRM) mode when using LC-MS/MS. One gains no significant analytical power with scan mode and can lose significant

sensitivity. This is particularly important when working in matrices in which drug / drug metabolite is present in low concentrations. We recommend restoring the previous language, which included "if used", allowing the laboratory the option of using the far more common SIM or MRM modes of analysis.

RESPONSE:

This standard has been modified to clarify that it only applies to untargeted or "open-scan" identification of analytes. Guidance has also been added to the standard based on the comment received.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 19 (FT S19): Confirmation/Definitive Method Quality Control Each batch of specimens for confirmatory testing must contain, minimally, ten (10) percent calibrators and/or quality control samples as follows: a) at least one (1) control established to contain no drug or metabolite; b) at least one (1) positive control with drug or metabolite concentration at twenty-five (25) percent above the cutoff concentration; c) at least one (1) control or calibration material with drug or metabolite concentration at or below the cutoff; d) a control to assess the efficiency of hydrolysis, where appropriate; and e) a control to assess extraction efficiency where appropriate.	a), b) and c) Additional recommended concentrations for calibrators and controls are: cutoff (or other decision) concentrations; the test method Limit of Quantitation (LOQ) concentration; Upper limit of linearity (ULOL) or quantitation (ULOQ) concentration. d) and e) These controls do not need to be separate samples, if compliance can be demonstrated with the current experimental design.

Forensic Toxicology Standard of Practice 19 (FT S19): Confirmation/Definitive Method Quality Control

COMMENT:

Section B is supposedly written for confirmatory testing. Reword section b) at least one positive control with drug or metabolite concentration set at 3 times the cut off for quantitative methods.
This is industry standard for quantitative confirmatory testing.

RESPONSE:

These are the minimum quality control requirements. This standard does not prohibit additional quality control concentrations. The standard will remain unchanged.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 24 (FT S24): (Urine only) Specimen Validity Testing Calibration and Control Requirements – Specific Gravity For **urine specimen validity testing (SVT)**, each batch of test subject specimens must include the following calibrators and controls for tests performed by the laboratory. **Specific Gravity SVT (all methods)** Specific gravity initial and confirmatory tests must include: a) a calibrator (within the measurement range); b) at least two (2) different control concentrations covering the measurement range; and c) the refractometer used to confirm presumptive	Laboratories that hold the Forensic Toxicology – Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology ~~Sustaining~~ Standard of Practice 13 (FT S13)~~: Referral of Specimens~~, any specimen (including negatives) identified as adulterated, substituted or invalid must be forwarded to an approved laboratory for additional testing to confirm adulteration or substitution before any finding can be reported. Negative, dilute specimens need not be referred. Specimen Validity criteria decision points test subject are required to be listed in the laboratory's standard operating procedure. The current specimen validity criteria from SAMHSA are recommended.

abnormal samples must display to a minimum four (4) decimal places.	

Forensic Toxicology Standard of Practice 24 (FT S24): (Urine only) Specimen Validity Testing Calibration and Control Requirements – Specific Gravity

COMMENT:

FT S24 item c) requires that the refractometer used to determine specific gravity in urine specimens display to a minimum of four decimal places. The fourth decimal place requires an expensive digital refractometer, which is not more accurate than the widely used, inexpensive three-digit refractometer, nor does it allow for improved discrimination between dilute and non-dilute specimens. We recommend the four-digit requirement be dropped.

RESPONSE:

This technology has been the industry standard since 2004. The proposed standard has been modified based on the comment received to require the four-decimal refractometer for confirmation of presumptive abnormal (dilute, adulterated, invalid) samples only.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 25 (FT S25): (Urine only) Specimen Validity Testing Calibration and Control Requirements – ~~Specific Gravity~~ pH For **urine specimen validity testing (SVT)**, each batch of test subject specimens must include the following calibrators and controls for tests performed by the laboratory. **pH SVT (all methods)**	Laboratories that hold the Forensic Toxicology – Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology ~~Sustaining~~ Standard of Practice13 (FT S13)~~: Referral of Specimens~~, any specimen (including negatives) identified as adulterated, substituted or invalid must be forwarded to an approved laboratory for additional testing to confirm adulteration or substitution before

pH initial and confirmatory tests must include: a) at least two (2) calibrators of different pH concentrations; and b) at least three (3) control levels, covering the measurement range.	any finding can be reported. Negative, dilute specimens need not be referred. Specimen Validity criteria decision points test subject are required to be listed in the laboratory's standard operating procedure. The current specimen validity criteria from SAMHSA are recommended.

Forensic Toxicology Standard of Practice 25 (FT S25): (Urine only) Specimen Validity Testing Calibration and Control Requirements – pH

COMMENT:
Please Clarify: Standard is referencing pH requirements - not specific gravity.

REPONSE:
The standard has been changed based on the comment received.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 27 (FT S27): Non-Urine Matrix Specimen Validity Testing Calibration and Control Requirements – ~~Specific Gravity~~ Non-Urine Matrix SVT Laboratories must establish written test procedures and test acceptance criteria for specimen validity testing (SVT) on matrices where specimen collection is unmonitored or reasonably subject to adulteration.	Laboratories that hold the Forensic Toxicology – Initial Testing Only permit may conduct tests for specimen validity; however, in accordance with Forensic Toxicology ~~Sustaining~~ Standard of Practice 13 (FT S13)~~: Referral of Specimens~~, any specimen (including negatives) identified as adulterated, substituted or invalid must be forwarded to an approved laboratory for additional testing to confirm adulteration or substitution before any finding can be reported.

Non-Urine Matrix SVT Tests must include: a) an appropriate calibrator near the laboratory's cutoff for the adulterant; b) a control without the adulterant (i.e., a confirmed negative control); and c) at least one (1) control containing an adulterant at a measurable concentration.	

Forensic Toxicology Standard of Practice 27 (FT S27): Non-Urine Matrix Specimen Validity Testing Calibration and Control Requirements – Non-urine Matrix SVT

COMMENT 1:
Please Clarify: Standard is referencing Urine Matrix SVT requirements - not specific gravity.

RESPONSE 1:
The standard has been changed based on the comment received.

COMMENT 2:
The title of this section includes a reference to Specific Gravity. However, the section does not appear to apply to the standard. Our laboratory suggests clarification regarding which matrix this section refers to. For example, current oral fluid collection procedures require collection of the specimen under observation of the collector. Accordingly, the proposed requirements of this section should not apply to those collections.

RESPONSE 2:
The standard has been changed based on the comment received.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 32 (FT S32): Confirmation Testing Report Content In addition to the requirements in Reporting Standard of Practice 2, reports issued by laboratories holding a permit in Forensic Toxicology – Comprehensive must include: a) initial and confirmatory test cut-off concentrations for all drugs and metabolites tested; b) each result presented as either positive or negative; c) the method used for confirmatory testing, if performed; d) results and test cut-off concentrations of specimen validity testing; e) the name of the certifying scientist releasing the report; f) all non-negative test results; and g) for retests, each result presented as "Reconfirmed" or "Failed to Reconfirm".	b) The laboratory may report the drug concentration for drug(s) reported as positive. d) Only the cut-off concentrations and a qualitative reporting of the interpretation are required by this standard. f) The laboratory should report numerical values that support a specimen that is reported dilute, adulterated, or substituted.

Forensic Toxicology Standard of Practice 32 (FT S32): Confirmation Testing Report Content

COMMENT:

Proposed (d) is a change from the previous standard (f) that required SVT results reported if specimens are determined to be dilute, adulterated, substituted or invalid. The revised standard appears to require reporting of all SVT results. This is inconsistent with current HHS/NLCP requirements. Our laboratory disagrees with this change and suggests that requirements should remain consistent with other workplace drug testing standards.

RESPONSE:

The proposed standard (d) does not require quantitative reporting of all SVT results, only qualitative interpretations such as VALID and the cutoffs employed are required. Guidance has been added based on the comment received.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 33 (FT S33): Reporting Criteria – Split Specimen Agreement Where a split specimen is collected: a) if the ~~measured~~ physical ~~properties~~ appearances of the split specimen are clearly different; and b) the primary specimen was screened negative for drugs, then specimen must be reported as invalid.	

Forensic Toxicology Standard of Practice 33 (FT S33): Reporting Criteria – Split Specimen Agreement

COMMENT:

FT S33 pertains to split specimens. The proposed standard states that:

"if the measured physical properties of the split specimen are clearly different; and the primary specimen was screened negative for drugs, then specimen must be reported as invalid."

Most forensic labs never analyze bottle B (the split specimen) because this is usually kept under seal and sent out to a referral lab only if directed by a Medical Review Officer, a court, or the client. Therefore, the laboratory would not measure physical properties of the split specimen and would be unable to comply with this standard. The previous standard calls for observation of the physical *appearance* of the split versus the primary specimen. We recommend the previous language be retained.

RESPONSE:
The standard has been changed based on the comment received.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology Standard of Practice 34 (FT S34): Specimen Retention Laboratories must retain specimens that were reported positive, adulterated, substituted or invalid for a minimum of one (1) year in secured storage under conditions appropriate for retesting, according to Document and Specimen Retention Standard of Practice 10, or for postmortem investigation samples, follow all specimen retention regulations of the referring Medical Examiner, when applicable. Specimen retention must be extended on written request by the persons authorized to order the test.	Laboratories holding a permit in Forensic Toxicology – Initial Testing Only may discard specimens that test negative after the report has been released.

Forensic Toxicology Standard of Practice 34 (FT S34): Specimen Retention

COMMENT:
Recommend that this specimen retention be required for SVT only and not all Forensic toxicology. This is not standard practice for post mortem testing.

RESPONSE:
The standard has been revised based on the comment received.

Toxicology	
Forensic Toxicology	
Proposed Standard	***Proposed Guidance***
Forensic Toxicology ~~Sustaining~~ Standard of Practice 35 (FT S35): Records Retention The laboratory must retain all records necessary to re-create the test process for a minimum of two (2) years according to Document and Specimen Retention Standard of Practice 8, unless the analyses are under legal contest, in which case the records must be retained for an indefinite period.	This includes the following records: • Standards, calibrators, controls and reagents associated with each analytical run, including the identification of the person who prepared each material, and/or the source and date of receipt; • Instrument printouts, chromatograms and similar documentation of data or results generated during the analysis, such as worksheets; • Cross-reference between chain of custody forms and the identity of the ~~individual tested~~ specimen tested; • Identity of analyst(s); and Evidence of review and certification of the report by a person qualified as a certifying scientist.

Forensic Toxicology Sustaining Standard of Practice 35 (FT S35): Records Retention

COMMENT:

FT S35 refers to records necessary to re-create the test process, including, in the Guidance, “Cross-reference between chain of custody forms and the identity of the individual tested” Standard Federal CCF forms do not contain the identity of the individual tested on the laboratory copy of the form. The link, therefore, cannot be made in the laboratory records, since the identity of the donor is kept at the collection site, MRO, agency, or the donor him(her) self. The guidance should read “Cross-reference between chain of custody forms and the identity of the specimen tested”.

RESPONSE:

The guidance was modified based on the comment received.