American Board of
ABFT
Forensic Toxicology ™

FORENSIC TOXICOLOGY LABORATORY ACCREDITATION CHECKLIST

*****Effective July 1, 2023*****

Laboratory: _____

Assessor(s): _____

Date performed: _____

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NOTE: Where practical and applicable, all criteria are considered mandatory. All deficiencies are to be addressed as soon as possible, although laboratories will be given a reasonable period of time to address deficient items, depending on their scope and nature. Where correction of the deficiencies is anticipated to take longer than 30 days, the laboratory must provide a corrective action plan outlining the actions proposed and the time required for completion.

Instructions to Inspectors:

Conforms: Responses should be Yes / No / or Not Applicable (NA)

Findings of "No" must include sufficient information to explain the non-conformity.

Findings of "Not Applicable" must contain information on why the requirement is Not Applicable.

Findings of "Yes" may also include one or more comments.

Comments relating to non-conformities and suggestions may be entered under the relevant standard.

The number of the relevant standard should then be entered in the summary portion of the section, under the "Non-conformities…" or "Suggestions…" sections, as applicable.

Section A: MANAGEMENT AND ADMINISTRATION

A-1 The laboratory must have a written statement of its mission or objectives.

For example, this may be to provide a medical examiner or coroner system with comprehensive toxicology services that will assist in determining the cause and manner of death. Some laboratories may also provide support services for law enforcement agencies by providing analyses for alcohol or other drugs in biological fluids seized from motor vehicle drivers, other transportation operators, or from victims of drug-facilitated sexual assault.

Conforms?

A-2 Laboratory staff must have reasonable access to the forensic, medical, and other scientific literature.

This should include a compendium of analytical data for common drugs, basic pharmacology and toxicology texts, and a compendium of prescription drug monographs. Examples might include *Disposition of Toxic Drugs and Chemicals in Man* (Baselt), *Clarke's Analysis of Drugs and Poisons*, *The Pharmacological Basis of Therapeutics* (Goodman & Gilman), *Clinical Toxicology of Commercial Products*, and the *Physicians' Desk Reference* (PDR).

Conforms?

A-3 The laboratory must have a procedure to communicate to staff changes to methods or procedures.

It is important that there is effective, documented communication between the Laboratory Director (or other senior staff) and all other laboratory staff. In some laboratories this may be accomplished by holding periodic meetings (e.g., weekly, monthly). However, communication can be via e-mail and other electronic or analogue means (e.g., posted documents, etc.).

Conforms?

A-4 The laboratory must have an organizational chart or other means to clearly define the reporting structure of the laboratory, including to whom QA/QC staff is responsible.

Conforms?

A-5 The laboratory must have a written policy that addresses the confidentiality of client information and results. This policy must minimally address:

- **the storage and release of information to third parties;**
- **precautions required to prevent release to unauthorized persons; and**
- **who is authorized to provide interpretation of results.**

The exact precautions taken will depend on the jurisdiction and, for example, how well staff knows the police or other requesting agencies.

Conforms?

A-6 There must be a procedure that addresses the resolution of complaints against the laboratory. This procedure must require a documented response to all complaints received in writing (e-mail and analogue) and, when necessary, corrective action.

From time to time, complaints against a laboratory may be received, covering everything from slow turnaround times, questioned accuracy, or inability to conduct certain tests.

Conforms?

Section A: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section B: PERSONNEL

B-1 The laboratory must have a Director with the following experience and qualifications:

- **comparable to the qualifications for a Diplomate or Fellow in "forensic toxicology" by the American Board of Forensic Toxicology, (i.e., D-ABFT-FT and F-ABFT, respectively) with a minimum of a Master's Degree; or**
- **Doctoral Degree in a chemical or biological discipline and at least three years of full-time laboratory experience in forensic toxicology; or**
- **Master's Degree in a chemical or biological discipline and at least five years of full-time laboratory experience in forensic toxicology.**
- **The Director must have the appropriate education and experience to assume the required professional, organizational, educational and administrative responsibilities.**

Note 1: The term "Director" refers to the most senior qualified toxicologist in the toxicology unit or laboratory who may have an alternate title such as "supervisor", "unit head", "team lead", etc., but does not necessarily refer to the director of a multidisciplinary laboratory who may or may not be a toxicologist. A director may serve multiple toxicology or related laboratories within a single state system.

The Director may not necessarily have the experience to interpret all results generated by that laboratory, providing that the laboratory also employs or contracts other people with the required expertise. For example, a laboratory director may be very experienced in the field of impaired driving by drugs, but have limited experience in postmortem toxicology. That is generally acceptable, providing that the laboratory also has another toxicologist with adequate experience in postmortem toxicology. Similarly, the Director may have extensive experience with postmortem toxicology, but limited experience with impaired driving toxicology.

Note 2: Those toxicologists with a minimum of bachelor's degree, who supervise an ABFT or ANAB accredited toxicology laboratory or unit (as described above), who otherwise meet the requirements of 'director' at the time of adoption of these ABFT standards, will be considered as meeting the requirements as "director" of the ABFT accredited laboratory in which they are employed at the time of the adoption of these standards.

Conforms?

B-2 The laboratory must have at least one forensic toxicologist on staff or under contract with sufficient experience and qualifications to interpret, as necessary, the results generated by the laboratory.

Conforms?

B-3 A record of the Director's education and experience must be maintained.

Examples of acceptable supporting documentation of Director's experience and qualifications include: an up-to-date curriculum vitae; up-to-date list of professional publications and presentations; copies of diplomas, certificates, and licenses; court testimony; research; and participation in continuing education programs.

Conforms?

B-4 The Director must be familiar with all aspects of the laboratory's operations and be responsible for, or delegate responsibility for:

- **daily management of the laboratory;**
- **preparation and revision of the standard operating procedure manual;**
- **establishing procedures for validating new assays;**
- **maintaining a quality assurance program; and**
- **training laboratory staff.**

Conforms?

B-5 The laboratory must designate one or more qualified employees who can perform supervisory and other functions for the Director in their absence, or an alternate contingency plan in the event of an extended absence of the Laboratory Director.

The range and type of duties of laboratory personnel will vary according to the size and the scope of the laboratory. It is important that laboratories have an individual(s) who has (or together have) sufficient training and experience to substitute for the Director in case of their absence. The primary focus of the contingency is to have an employee(s) with sufficient experience to supervise the analytical toxicology functions of the laboratory, recognizing that those persons may not have the depth of experience to fully interpret all results.

Conforms?

B-6 Laboratory personnel must be trained appropriately. A training program must minimally include:

- **theory and practice of methods and procedures that the individual performs;**
- **understanding quality control practices and procedures;**
- **maintenance of chain of custody;**
- **laboratory safety; and**
- **testimony, commensurate with the job description.**

Training and development of personnel is essential in order to increase productivity, improve performance and enable them to assume greater responsibilities. A training program to develop technical skills of an employee is important in each area of expertise. Personnel have to be familiar with all areas of toxicology testing within their responsibility and understand how their responsibilities relate to the operation of the laboratory as a whole.

Training does not necessarily have to be specific for every individual drug or drug group, but should cover the different sample processing techniques used (e.g., liquid-liquid extraction versus solid-phase extraction) and different instrumentation types (e.g., GC/MS versus LC/MS/MS versus LC/Q-TOF for the required manufacturer platforms).

Conforms?

B-7 Analysts must have demonstrated competency in the work that they are approved to perform.

Competency should be demonstrated at the completion of initial training. Ongoing and continued demonstration of competency may be demonstrated in a number of ways, including documented participation in proficiency tests, as well as peer review of routine casework.

Conforms?

B-8 Personnel qualifications, experience and training must be documented and current. Documentation to include, as appropriate:

- **training checklists or summaries (mandatory for technical staff); (See Note 1 below)**
- **résumé or curriculum vitae that summarizes education and experience;**
- **continuing education summaries;**
- **evidence of competency;**
- **job description;**
- **copies of certificates (See Note 2 below), diplomas, and licenses; and**
- **testimony experience (dates and case jurisdiction).**

Note 1: Training checklists are not expected for every single analyte, especially if multiple analytes use the same or similar methods of sample preparation and instrumentation.

Note 2: It is the responsibility of the employer to verify the authenticity of academic or other required qualifications.

Conforms?

B-9 The laboratory must have sufficient technical personnel to handle the workload.

There should be sufficient technical personnel to encompass method development, quality control, administration, and routine analytical testing. The Accreditation Committee and Board will carefully evaluate a negative response to this question. A negative response to this question will generally only result in punitive action if it is clear that the laboratory does not have the necessary personnel to fulfill their mandate. Long turnaround times alone will not normally be sufficient to result in failure to award accreditation or suspension of accreditation. Under-staffing sufficient to warrant withholding accreditation or to cause suspension of accreditation will normally also result in a failure to meet other critical standards of the ABFT Accreditation Program.

Conforms?

B-10 The laboratory must have a written policy for the continuing education of technical personnel that includes a description of options available to staff.

Management of the laboratory should recognize the importance of the continued training of the technical staff, commensurate with their job function. Supervisory or lead technical personnel may require periodic specialist training, which may or may not be available from within the institution. The training of more junior technical personnel might typically be by supervisory personnel. Forensic toxicologists who testify or provide interpretation are encouraged to review the forensic literature on a regular basis and at least periodically attend relevant local or other forensic conferences. Continuing education can include such activities as lunchtime seminars, appropriate webinars, commercial or other short presentations, as well as documented publication review. Attendance at online seminars is increasingly available on a regular basis. The documentation can be via a certificate issued by the activity provider or by internal memorandum from a laboratory director or supervisor.

Conforms?

B-11 All staff are required to review, agree to, and adhere to ethical guidelines for performance of their job annually.

The ethical guidelines may be those drafted by the employer (e.g., government or corporate entity), a professional organization (e.g., AAFS, SOFT), other professional standard (e.g., SWGTOX), or other suitable professional standard drafted by laboratory management.

Conforms?

Section B: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section C: STANDARD OPERATING PROCEDURE MANUAL

C-1 The laboratory must have a Standard Operating Procedure (SOP) Manual which covers the laboratory's general administrative operations and all of the analytical methods. At a minimum, the SOP Manual must contain sections on:

- **specimen receiving, accessioning, aliquoting, and storage;**
- **procedures for recording the transfer of specimens;**
- **procedures for retention and disposal of specimens;**
- **procedures for the set-up and normal operation of instruments;**
- **description of the quality assurance and quality control program;**
- **criteria for the acceptance of analytical data; and**
- **protocols for recording, reviewing, and reporting results.**

Conforms?

C-2 The laboratory must have a documented procedure for SOP change control. This procedure must ensure that:

- **the current version of the SOP is used;**
- **a revision history is maintained; and**
- **information on changes from the previous version are available to staff.**

Conforms?

C-3 The scope of the analytical screening or detection methods in the SOP must be consistent with the laboratory's stated mission. Postmortem toxicology routine analysis must include alcohol, drugs of abuse, over-the-counter drugs, other therapeutic agents, and toxic chemicals with screening technology including GC/MS[MS] and/or LC/MS[MS] and/or LC/TOF (or LC/Q-TOF). Human performance toxicology routine analysis must include those substances that may modify human performance or behavior.

To meet the goal of assisting the medical examiner in determining the cause and manner of death through the analysis of postmortem specimens and through the interpretation of the analytical results, it is important that screening methodology is sensitive enough to detect potentially toxic concentrations of potent opioids such as fentanyl. It is recognized that for some smaller laboratories the range of drugs or other analytes quantified may be limited.

For a laboratory involved in human performance toxicology, the mission statement would be different and reflect its goal of assisting law enforcement agencies in the detection of the "impaired driver". This goal would require the analysis of body fluids (primarily blood, serum, or urine) and the interpretation of the results, if necessary, in a court of law.

For a laboratory performing testing on drug-facilitated crime victims (DFC; also referred to as drug-facilitated assault), a critical factor is the sensitivity of the screening and confirmation methods. The LOD of these methods should be considerably lower than generally applied to postmortem and DUID casework. With some exceptions, the LOD for most drugs in urine from DFC victims should be less than 100 ng/mL, and the screening methodologies of laboratories performing DFC testing should reflect this.

The judgment of the inspector is important in assessing the effectiveness of the screening tests performed. However, there are two considerations in answering this question. First, what is the mission of the laboratory and what does the client (e.g., police, pathologist) require. A "drug screen" may be inherently limited, but the client is aware of and willing to accept those limitations. For example, for DUI work, some jurisdictions may only require an immunoassay screen for drugs of abuse with appropriate confirmation of "positives". The second consideration is whether the

laboratory is conducting a “limited screen”, but implying from the wording of the report that a reasonably comprehensive drug screen has been performed. However, it is recognized that for most private and many public laboratories, the scope and sensitivity of testing may be determined by statute or contract with their client(s).

Conforms?

C-4 If the laboratory relies solely on targeted screening methods, there must be a documented policy to annually review and update the list of drugs screened for.

Some laboratories rely exclusively on one or more screening tests that target specific groups or panels of drugs (e.g., immunoassay, LC/MS[MS], LC/TOF[MS]). While those panels may serve the laboratory and its clients very well, the overall effectiveness of the laboratory to detect new or emerging drugs is diminished over time unless there is a policy to periodically review and update the list of drugs screened for. Where full-scan methods such as GC/MS are used and the mass spectral libraries periodically updated, the ability to detect a broad range of drugs is maintained within the limitation of the technology.

Conforms?

C-5 The SOP must contain guidelines as to which tests are to be performed on different types of cases, consistent with the laboratory’s stated mission.

It is recognized that different clients may request different tests for the same type of case. It is also recognized that reference laboratories in particular may have a limited ability to select specific tests unless the client selects or authorizes them. However, where the laboratory partially directs the specific tests to be performed (e.g., broad screen GC/MS or LC/MS or LC/TOF for a medical examiner/coroner or crime laboratory), the tests run should be of sufficient scope and sensitivity to satisfy the requirements of the case. It is also recognized that tests performed by some laboratories may be dictated by the specific requests of the client.

Conforms?

C-6 The Laboratory Director must approve administrative procedures in the SOP Manual that are within the purview of the Director and reviewed at least once every two years to ensure they are accurate and appropriate for the mission of the laboratory.

Individual procedures or methods can be approved by notation on the first page of the document, or other suitable means. While each page may be signed by the Laboratory Director, it is not essential. Software programs that control documents and apply electronic signatures in an appropriate manner are acceptable.

Conforms?

C-7 The Laboratory Director must approve new analytical procedures and SOPs.

Subsequent minor changes or updates may be approved by the Laboratory Director or a designee. If used, the designee may be an individual with supervisory responsibility for the scientific aspects of the laboratory or qualified quality assurance staff. Documentation of changes should be by signature (tracked electronic change or physical signature or initials on paper). Analytical procedures should be reviewed at least once every two years to ensure they are accurate and appropriate for the mission of the laboratory.

Conforms?

C-8 The laboratory SOP, or the appropriate sections of the SOP, must be readily available to staff in the laboratory.

Conforms?

C-9 If the laboratory uses abbreviated procedures (e.g., index cards) at the bench, they must have a procedure to ensure that they are consistent with the approved SOP.

Conforms?

C-10 The analytical procedures in the SOP must contain sufficient detail to allow analysts to perform the assay and must include, but not be limited to, the following:

- **the principle of each analytical procedure;**
- **details for the preparation of reagents, standards, calibrators, and controls;**
- **specimen requirements;**
- **protocol for analyzing specimens using a different volume than the approved SOP specifies;**
- **calibration procedure and parameters;**
- **assay acceptance and reporting criteria;**
- **potential interferences (where likely or known); and**
- **references (not mandatory, but as appropriate for referencing published procedures on which an analytical method may be based).**

Some of these criteria may be included in more general documents (e.g., QA/QC SOP).

Conforms?

C-11 The laboratory must have written criteria for acceptable instrument performance and specified actions to be taken when performance is not acceptable.

In most instances this will be described as part of a section on the set-up and operation of the particular instrument and may be general in nature (e.g., no GC or LC peaks, peaks too small, retention times irreproducible, etc.). More extensive troubleshooting may be referenced to the appropriate manufacturer's manual which can supplement but cannot take the place of information in the SOP.

Conforms?

C-12 The laboratory must retain at least 5 years of archived SOPs, including the dates they were in effect.

Copies of outdated SOPs are required to be kept so that the laboratory has an accurate record of the analytical procedures that were in effect when particular results were generated in case of legal challenge. The duration of retention will be determined by the laboratory, but a minimum of 5 years is required. Those records may be in electronic or paper format.

Conforms?

C-13 The laboratory must have a protocol for handling deviations from the SOP that requires approval by the Laboratory Director or designee.

Conforms?

Section C: <u>SUMMARY</u>

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section D: SPECIMENS, SECURITY, AND CHAIN OF CUSTODY

D-1 The laboratory must make user agencies aware of their requirements on the following topics:

- **types and minimum amounts of specimens;**
- **specific requirements for the type and size of specimen containers;**
- **type and amount of preservative to be added, if appropriate;**
- **instructions for proper labeling of individual specimen containers;**
- **acceptable conditions for packing and transportation; and**
- **instructions on how to properly fill out all chain of custody documentation.**

The proper selection, collection, submission, and storage of specimens for toxicologic analysis are important if analytical results are to be accurate and their subsequent interpretation is to be scientifically sound.

Conforms?

D-2 The laboratory must compare the information on the specimen labels against that on the requisition and document any discrepancies.

Conforms?

D-3 The laboratory must assign unique identification number(s) to each individual container of specimen received.

The manner in which individual specimens are identified within a laboratory may vary. It is a common procedure for individual specimens to each be given a unique "accession number" upon receipt in the laboratory. Alternative procedures may be acceptable, providing that each individual container of specimen is uniquely identified in some way. For example, some medical examiner laboratories use the ME case number, plus a "specimen designator" (e.g., "Bl" for blood). This is acceptable providing that multiple specimens of the same type (e.g., multiple vials of blood from the same case) are uniquely identified. A "container": is defined as an individual tube or bottle, and does not refer to a package or box that may contain two or more individual specimens.

Conforms?

D-4 The laboratory must document the condition of specimens that appear atypical or volumes that are inadequate for testing.

An atypical specimen appearance may include blood that is "watery", fatty, or of unusual color, and urine or vitreous that appears "bloody", etc.).

Conforms?

D-5 The laboratory must control access during working hours by at least the following:

- **the Laboratory Director must authorize access;**
- **unauthorized persons must be escorted, and a record of the visit maintained;**
- **unauthorized entry must be detected;**
- **exterior ingress/egress points must be secured;**
- **all keys (or equivalent) must be accounted for; and**
- **exhibits/evidence must be secured when authorized personnel are not present.**

Conforms?

D-6 The laboratory must be secured by locks during non-working hours.

Additional security precautions may sometimes include monitoring devices (e.g., motion detectors) and security personnel in the building where the laboratory is located.

Conforms?

D-7 The laboratory must secure short- and long-term specimen storage areas when not in use.

Proper security can be achieved by storing specimens in locked cabinets, refrigerators or rooms. It is acceptable to leave storage rooms unlocked when authorized personnel are present.

Conforms?

D-8 The laboratory must secure long-term record storage areas. Access must be restricted to authorized personnel (e.g., personnel assigned to records management, appropriate supervisory and laboratory personnel).

Records have the same evidentiary importance as the specimens. Records can be stored in a secured room, area, or file cabinet. An example of long-term records might be completed case files.

Conforms?

D-9 "In use" toxicology records must be kept in a secure area.

"In use" records (e.g., incomplete files or those pending reporting or filing) may be, as a matter of convenience, temporarily stored at different locations prior to final disposition. Temporary storage of such files outside of a locked cabinet or storage room is acceptable, providing the laboratory is secured and access is limited to authorized laboratory personnel.

Conforms?

D-10 Where toxicology results and other confidential information are stored electronically, access must be password controlled and available only to authorized personnel. The ability to change laboratory results must be restricted to a small number of specific, approved staff once the data is finalized and locked.

Most toxicology laboratories use computers that are networked to other parts of the organization. Access to the forensic toxicology data and information should be appropriately restricted to those people that have access approved by, or on behalf of, the Laboratory Director. For example, some people (e.g., coroner, medical examiner etc.) may have "read-only" access to finalized toxicology reports, but do not have "write" access to the reports.

Conforms?

D-11 The laboratory must maintain the available external chain of custody, requisition, and/or shipping information.

Conforms?

D-12 The laboratory must contemporaneously maintain chain of custody records, including documentation of all persons handling the specimens. At a minimum, the records must include the date and identity of the individuals involved in the specimen transfer and laboratory identification number.

This document may be a logbook, worksheet, or other suitable means of recording the information and does not necessarily have to be a strict chronological "z-style" chain of custody document. Batch forms are acceptable if transfer involves multiple specimens.

Conforms?

D-13 The laboratory must store specimens in such a manner as to, as far as practical, preserve the analytical and toxicological integrity of the specimen. Specimens received in the laboratory must, as appropriate, be refrigerated or frozen as soon as possible after arrival.

Conforms?

D-14 The laboratory must have adequate space for the short- and long-term storage of specimens.

Conforms?

Section D: <u>SUMMARY</u>

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section E: QUALITY ASSURANCE, QUALITY CONTROL, AND REPORTING

E-1 One or more suitably qualified individuals must be assigned day-to-day responsibility for QA.

In a smaller laboratory, that individual might be the Laboratory Director. However, in most laboratories, although the Director will retain overall responsibility for QA, day-to-day responsibility will be delegated to a deputy, supervisor, or other responsible technical person. Suitability should be judged in the context of academic qualifications, experience, knowledge and job function, but does not necessarily require formal training in QA.

Conforms?

E-2 The quality assurance program of the laboratory must undergo a documented review annually for its appropriateness. The review must include a review of corrective actions taken and may be conducted by the Laboratory Director or a qualified designee (e.g., deputy director, QA supervisor, or equivalent), but it must undergo final review by the Laboratory Director.

Annual review ***of the entire Quality Assurance Program of the laboratory is required*** to ensure that it is up-to-date and effective. That review may be documented as a signed and dated review (or revision) of the QA section of the laboratory's SOP Manual. It should be noted that ***the annual review is <u>of the program as a whole</u> and does not apply to QC or other analytical data only.*** The review should include randomly selected casework.

Conforms?

E-3 For *qualitative* immunoassays, the laboratory must include, at a minimum, one positive control that challenges the assay decision point and one negative control with each batch of specimens for analysis, regardless of batch size. These controls must be carried through the procedure with the unknown specimens.

Where multiple positive controls are analyzed, a positive control should be included at or close to the end of the run. Inclusion of a positive and negative control mid-way through long immunoassay runs (e.g., 96-well ELISA plate) is good practice to determine if "drift" has occurred.

Conforms?

E-4 Unless the immunoassay is validated for alternate matrices, matrix-matched controls must be used for each specimen type in the batch and prepared by fortifying analyte-free matrices such as tissue homogenates, expired blood bank blood or plasma, or another appropriate matrix.

Conforms?

E-5 The laboratory must have appropriate written criteria for the acceptance of the qualitative immunoassay and other non-chromatographic controls.

It is acceptable to indicate simply that the positive control should test positive and the negative control should test negative.

Conforms?

E-6 For LC- or GC-based qualitative and quantitative procedures, the laboratory must:

- **analyze positive and negative controls concurrently with each batch of specimens;**
- **include at least one positive control or reinjected calibrator at or near the end of the batch; and**
- **include a control mid-run if the batch contains 20 or more test samples.**

Case specimens should never be assayed in isolation. For example, a sample that tests negative should be supported by a positive control that is extracted and run simultaneously to demonstrate that there were no analytical deficiencies. The mid-run and end-of-run control can be a reinjection of extracts run earlier in that same run, or may be additional extracts. (Re)injection of calibrators and/or controls is a valid way of demonstrating stability of analytical instrumentation (e.g., GC/MS). The negative control ("blank" sample) is not considered a calibrator.

Conforms?

E-7 The laboratory must have appropriate written criteria for the acceptance of qualitative controls for chromatography-based assays that includes an assessment of the minimum sensitivity of the assay.

The criteria should include some means of assessing minimum sensitivity of the assay, for example, detection of drugs contained in the control at a concentration approaching the LOD of the screen, or other criteria such as minimum peak height or peak area for positive controls or internal standards.

Conforms?

E-8 Quantitative control results must be listed or plotted and reviewed by the Laboratory Director or designee at least once every three months.

A variety of techniques can be used and include Levy-Jennings charts, cumulative sum (cusum) charts, or mean/range charts. For those analytes with relatively few QC results in a given reporting period, it is acceptable to simply list the results, as an alternate to charting them.

It is important for the QC summaries to list ALL positive control results for all assays where there is a valid calibration. Results outside of the usual acceptance criteria (e.g., ±20%) should be included unless the control was clearly invalid (e.g., unacceptable internal standard recovery or chromatography).

Signing and dating a paper QC record constitutes evidence of review. If the QC chart (or list) is electronic, the review can be documented by an electronic note or memo or other means. In some cases, the Director may designate this review to a laboratory manager or quality control supervisor. Monthly or more frequent review of plotted or listed QC results is encouraged, but should not be less frequent than once every 3 months.

Conforms?

E-9 The laboratory must have appropriate written criteria for the acceptance of quantitative controls.

The appropriateness of acceptable criteria is to some extent based on the assay. The use of two standard deviations for all quantitative assays is an accepted practice, providing that the absolute deviation from target is not unreasonable (e.g., > ±30% would normally be considered unacceptable) and providing there is an adequate number of data points. Other acceptable criteria include use of the mean or target value ±20%, or less, depending on the intended purpose of the assay. However, it is understood that for some assays insufficient data is generated to make an analysis of control precision meaningful. It may sometimes be appropriate to set less stringent quantitative criteria for a control which is close to the LOQ of the assay, compared with a mid-range control, especially where concentrations approaching the LOQ are of little toxicological or forensic significance.

Conforms?

E-10 Repeated QC or calibration failures must be thoroughly investigated to determine the root cause. The investigation and any corrective action must be documented and monitored.

Occasional QC or calibration failures may be due to occasional random errors and not necessarily due to an easily identifiable problem. However, repeated failures beyond that statistically expected, indicates a problem that warrants investigation. Causes may include a poor assay design, poor technique/training, bad or deteriorated reagents, deteriorated calibration standards or QC samples.

If a high (or low) calibrator fails, that is a strong indicator that the calibration range is too broad for the target drug and an indication that the assay should be redeveloped and revalidated. Similarly, positive controls that frequently fail are an indication that the assay is not robust. The duration of monitoring will depend on the frequency with which the assay is performed and to some extent on the nature of the issue (e.g., random failure or persistent issue).

Conforms?

E-11 The laboratory must have a policy that calibrators and controls are traceable to different stock solutions.

This can be accomplished by a separate weighing or initial dilution, or by obtaining or deriving the stock solution from different sources. If both the calibrator and control(s) are derived from the same source, the laboratory may introduce an undetectable bias into its results, since controls are used to verify the calibration. In some laboratories this may be done by a separate QA section or an individual assigned QA responsibility.

Conforms?

E-12 The preparation of calibrator and control solutions must be properly documented as to the source of the materials, how much was used, the identity of the preparer, and the date of preparation.

Conforms?

E-13 The laboratory must independently verify the identity and concentration of analytical standards that are not supplied with a certificate of analysis.

The verification may involve obtaining a full spectrum GC/MS analysis with comparison to library spectra and absence of additional/ interfering chromatographic peaks, measurement of a physical constant (e.g., melting point, refractive index), or use of other analytical techniques (e.g., HPLC, IR, UV/VIS).

Conforms?

E-14 The laboratory must verify the concentration of a reference material if it is used beyond its expiration date and set a new expiration or re-verification date.

Conforms?

E-15 The laboratory must have a procedure that delineates the appropriate action to take when a control fails and requires the action taken to be documented.

The appropriate action is dependent on the assay. For qualitative immunoassays it may be necessary to repeat all specimens in a batch (e.g., if the negative control tests positive).

Conforms?

E-16 Proficiency test (PT) samples must be tested in the same manner as client samples, to the extent possible and reasonable.

It is recognized that PT samples generally look different from client samples and the manner of reporting results may be very different from client samples. As far as possible, the range of testing and the criteria used for evaluation and acceptance of analytical results should be the same as that used for client samples.

Test results received from a reference laboratory should not be reported to the PT provider.

No staff member who would otherwise be handling routine case samples for the same tests at the time the proficiency test samples are received should be deliberately excluded from testing proficiency test samples.

Proficiency findings should never be shared or discussed with another laboratory before the results are reported to the PT provider and the PT provider's report is received by both laboratories.

Conforms?

E-17 Proficiency test scores received from the PT provider must undergo documented review by the Laboratory Director. At a minimum, the Director must review and sign-off on all proficiency test results received from the PT provider after results are submitted and scoring is complete and, where necessary, after appropriate corrective action has been taken.

Conforms?

E-18 Does the laboratory appropriately investigate quantitative results that are outside of the acceptable limits set by the ABFT Accreditation Program (within +/-10% or +/-2SD for ethanol, and within +/-20% or +/- 2SD for all other substances, based on the participant mean of the PT program)?

Note: The above ranges may differ from those published by PT vendors. However, the ABFT ranges take precedence for assessment to ABFT Standards See the separate document: Guidelines for Performing Corrective Action for Deviations in Proficiency Test Results for further information (refer to the ABFT website, http://ABFT.org, under Lab Accreditation).

Conforms?

E-19 Does the laboratory appropriately investigate false positive results?

Conforms?

E-20 Does the laboratory investigate false negative results appropriate for the mission of the laboratory?

Note: The extent of investigation and corrective action required for a false negative will depend on whether the analyte might ordinarily be expected to be detected by the laboratory at the spiked concentration, or whether detection is judged to be unimportant for the mission of the laboratory. For example, failure to report a drug metabolite that is not normally reported by the laboratory is not regarded as a "false negative"

Conforms?

~~False-positive results require the most rigorous investigation. Extensive and thorough investigation is expected. However, the error may be considered less serious if it is clerical in nature and unique to the way results are reported for the particular PT program (e.g., use of an incorrect analyte code). The extent of investigation and corrective action required for a false negative will depend on whether the analyte might ordinarily be expected to be detected by the laboratory at the spiked concentration, or whether detection is judged to be unimportant for the mission of the laboratory. For example, failure to report a drug metabolite that is not normally reported by the laboratory is not regarded as a "false negative".~~

~~The Laboratory Director should make his or her decision as to whether performance has been satisfactory, where practical, based on the following, or more stringent criteria: no false positives; ethanol within ±2 S.D. or ±10% of the participant mean; for drugs, the challenges should be within ±2 S.D. or ±20% of the participant mean. Corrective action or investigation (if only limited to an audit of the raw data) is sometimes appropriate, even if the results are within ±2 S.D. For example, the proficiency test S.D. range for some analytes is so large that ±2 S.D. can represent from near zero to at least double the weighed-in target or participant mean. Note: These ranges may differ from those published by PT vendors; the forgoing acceptable PT ranges take precedence.~~

E-21 The laboratory must label laboratory-prepared reagents with at least the following: the identity of the reagent, preparation date, expiration date, and identity of the preparer.

Conforms?

E-22 The laboratory shall label purchased reagents with at least the date received and date opened, or use another mechanism such as a bar code scanner, so long as the analyst is able to access the required information in real time, when the reagents are prepared or use.

Conforms?

E-23 The laboratory must validate and document new or freshly prepared reagents. The reagents that must be validated include, but may not be limited to:

- **organic solvents and mixtures for chromatography and extraction,**
- **pH-specific reagents and buffers, and**
- **hydrolysis reagents.**

There are two primary ways to validate new reagents. A laboratory can prepare separate validation batches containing only controls prepared with the new and current reagents. Alternatively, a laboratory can prepare routine batches of specimens, including controls, with the new reagents and compare the results of controls from preceding batches, prepared with the current reagents. Documentation may be by annotation in a reagent log or other method that cross references the analytical run in which the reagent was validated.

Conforms?

E-24 The laboratory must have a documented procedure to verify the accuracy of fluid dispensing devices (e.g., pipettes) used for critical volume applications at least annually.

Typically, gravimetric or colorimetric methods are used for verifying the accuracy of fluid dispensing devices. Where a pipette is not calibrated because it is intended solely to qualitatively dispense reagents, it should be labeled as such (e.g., "qualitative only").

Conforms?

E-25 The laboratory must have a preventive maintenance schedule and maintenance records for all instruments in routine use. These records must be readily available to the staff operating the instruments and located either near the instrument the records pertain to or in a known location.

All instruments require some type of routine maintenance. This can usually be divided into routine service that the operator performs (e.g., for GC, liner and septum changing, cutting columns, etc.), service that is performed less frequently (e.g., changing rough pump oil; MS source cleaning), in addition to ad hoc work performed by qualified service personnel. Records of scheduled service may be included as an integral part of the service log, or as part of a separate maintenance schedule for the laboratory, such that it is readily evident to users of the equipment and QA staff.

Conforms?

E-26 Equipment that is uncalibrated, broken, or otherwise out of service must be clearly marked as such.

Conforms?

E-27 The laboratory must regularly monitor and record temperatures on all equipment where temperature control is critical for the application.

Conforms?

E-28 Analytical balances must be cleaned, serviced, and calibrated at least annually by qualified service personnel. Documentation of such service must be maintained.

This applies to balances used for critical weighing (e.g., preparation of calibration solutions or QC material).

Conforms?

E-29 The laboratory must check the accuracy of balances when critical weighing is performed. Documentation of the checks must be maintained.

Conforms?

E-30 In-house computer programs, spreadsheets, and macros that are used to calculate or report analytical results must be:

- **validated prior to use;**
- **protected from change; and**
- **backed up securely.**

Backup copies of validated files should be kept secure from general use (e.g., physically secure, via password protection or read-only status). Spreadsheets in particular can easily have formulas in cells changed without it necessarily being obvious to the user. The extent of monitoring some macros or programs may simply be to ensure that it appears to do what it was written for, without any special checks (e.g., draw a set of 3 overlaid chromatograms). Validation of commercial software is not required.

Conforms?

E-31 The laboratory must have a procedure for the review of each toxicology report prior to issuance that requires a qualified individual to document the review of:

- **chain of custody documentation;**
- **all qualitative and quantitative data;**
- **relevant quality control;**
- **consistency between screening and confirmation data; and**
- **final report.**

Different aspects of the review may be conducted by different people. A "qualified" person is defined as someone with sufficient training and experience to perform the stated review.

Conforms?

E-32 If the laboratory chooses to include immunoassay results in the final report, a summary of the drugs typically detected by each immunoassay, the cut-off for each primary target drug, and the approximate cross-reactivity for the drugs commonly detectable by each kit must be made available to the client.

This information is important for proper interpretation of immunoassay results, especially for drug classes such as benzodiazepines and opiates/opioids and fentanyl. At a minimum that information may be obtained from the manufacturer's product insert, although ideally it would be determined experimentally in the matrix most commonly used (e.g., whole blood, urine). The information does not necessarily need to be included within the toxicology report.

Conforms?

E-33 Sufficient documentation from failed runs must be maintained (paper or electronic), to show a record of the testing performed, the volume of specimens used and who handled those specimens.

Conforms?

E-34 Technical review of all analytical data must be undertaken by at least one qualified person other than the analyst.

It is expected that the person who conducted an analysis will perform the initial technical verification of the data.

Conforms?

E-35 The laboratory must have a documented policy and procedure for determining the potential for carryover and whether carryover or contamination may have occurred in qualitative and quantitative assays.

Detection of carryover or contamination may sometimes require a careful review of the analytical results against the case history, and it may require the reanalysis of specimens, or analysis of multiple specimens. Where a laboratory routinely quantifies analytes in separate assays from that used to detect the substance, carryover or contamination (within the laboratory) may be easy to detect. However, extreme caution is warranted where a drug is simultaneously detected and quantitated in a single specimen analyzed in a single assay.

Conforms?

E-36 The laboratory must validate automatic pipetting/diluting equipment for potential carryover if the pipette tips are non-disposable.

Because these devices are used to analyze specimens that can contain large concentrations of analyte, it is important that the laboratory has validated the potential for carryover and modified the method/process to prevent or identify occurrence. An example of appropriate corrective action is reanalyzing consecutive positives with a negative control between them when the first positive specimen has a higher concentration than the carryover limit.

Conforms?

E-37 Where possible, the final report must be reviewed in the light of information provided with the case and supported by the available data.

This can be a valuable quality assurance check. For example, if a fatal concentration of a drug were found in an individual who appeared to be the innocent victim of an industrial accident, further review of the analytical data would be warranted.

Conforms?

E-38 If the laboratory is unable to test for certain drugs or toxicants that were requested, this must be stated in the report or the client informed by alternate means.

Conforms?

E-39 If reports use vague terms to report the possible presence of an analyte, such as “indicated”, these must be properly defined as part of the report.

Conforms?

E-40 If presumptive, unconfirmed results are reported (e.g., positive cannabinoids immunoassay screen where the finding has little or no forensic importance), the fact that the result is presumptive and unconfirmed must be clearly stated in the report.

Conforms?

E-41 Where test results obtained from another laboratory are included in the report, the name of the reference laboratory must be clearly stated.

Alternatively, the reference laboratory's report may simply be attached or forwarded separately.

Conforms?

E-42 Records of testing data, including laboratory accession numbers, specimen type, analyst, and date of analysis, must be maintained and easily retrievable for a minimum of 5 years or as otherwise mandated by local, state, or federal authority, whichever is longer.

Conforms?

Section E: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section F: SCOPE OF FORENSIC TOXICOLOGY TESTING AND PROFICIENCY TESTING PERFORMED

F-1 If the laboratory performs postmortem toxicology testing, they must have a full 12-month subscription to the CAP AL1 (blood alcohol) and CAP FTC (whole blood drugs) proficiency tests.

The CAP AL1 whole blood alcohol PT also includes acetone, isopropanol, and methanol, which are important volatiles for postmortem cases. The CAP FTC PT offers a broad range of illicit, prescription, and over-the-counter drugs and metabolites in whole blood.

Conforms?

F-2 If the laboratory performs toxicology testing on blood and/or urine for driving under the influence of drugs (DUID) cases, they must have a full 12-month subscription to the CAP AL1 (blood alcohol) and CAP FTC (whole blood drugs) proficiency tests.

Note, if the laboratory is not required to test for acetone, isopropanol, or methanol, subscription to an alternate whole blood-based ethanol proficiency test is acceptable, providing the number of challenges for ethanol per year is equivalent or greater.

Note, if the laboratory only analyses urine, subscription to the CAP UT (urine) proficiency test is acceptable.

Conforms?

F-3 If the laboratory performs toxicology testing on blood, serum/plasma or urine from drug facilitated crime cases (DFC, aka DFSA) they must additionally subscribe to a full 12-month subscription of the CAP DFC proficiency tests.

The CAP DFC PT survey is urine-based and differs from the FTC PT in that the drug concentrations are designed to mimic the often very low concentrations that may be found in urine of DFC victims, where the urine specimen may not have been collected until up to 24 hours after an assault. The drugs and concentrations used are based in part on the OSAC/ASB draft document "*Standard for the Analytical Scope and Sensitivity of Forensic Toxicology Urine Testing in Drug Facilitated Crime Investigations*".

Conforms?

Section F: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section G: CHROMATOGRAPHY AND CALIBRATION

G-1 **Quantitative calibrators or controls must be prepared in a matched matrix for the samples being analyzed, or shown to be equivalent through validation studies, or demonstrated to be equivalent through the use of matrix-matched controls, or shown to be valid through the use of standard addition or a recovery spike with pre-defined limits for performance.**

Where the matrix may be unique (e.g., decomposed tissues, bone, hair or nails), the laboratory should select a matrix similar to the specimen being analyzed.

Conforms?

G-2 The laboratory must report only quantitative results that are within a valid calibration range.

If the concentration of the specimen exceeds the nominal concentration of the highest calibrator, the specimen may be diluted and re-extracted or, alternatively, reported "greater than the X mg/L" where X is the highest calibrator. If the concentration is less than the lowest calibrator but greater than the limit of detection, it may be reported as "less than X".

Conforms?

G-3 Calibrators and controls must be analyzed in the same manner as unknowns.

Where case samples are hydrolyzed to liberate a drug from its glucuronide metabolite, at least one control containing the glucuronide should be included in the run.

Conforms?

G-4 A valid calibration for each quantitative assay must be established using a minimum of three positive calibrators for linear regression or four for a quadratic or polynomial regression curve fit. If the laboratory uses a greater number of calibrators, the SOP must clearly indicate how many points can be dropped and under what circumstances. The SOP must also address which results can be reported after calibrators are deleted.

Calibration points **cannot** be dropped solely to improve a curve fit or to get a control to pass.

Conforms?

G-5 For multi-point calibrations, criteria must be established for the acceptability of calibration linearity.

- **For linear regression acceptability using non-labelled internal standards, the coefficient of determination must be ≥ 0.98.**
- **For linear regression acceptability using matched labelled internal standards, the coefficient of determination must be ≥ 0.99.**

There are a variety of procedures for establishing the acceptability of calibration data, and these are often listed as options within data reduction software included with modern analytical instruments. A significant deviation from historical values indicates a problem with the assay.

Conforms?

G-6 For multi-point calibrations, criteria must be established for acceptability of calibrations and include evaluation of individual calibrators.

Calibrators should read-back values that are within ±20% of their nominal value. A slightly wider acceptance value (e.g., ±25% or ±30%) may be acceptable for calibrators that approach the LOQ of the assay.

Conforms?

G-7 If the laboratory uses historical calibration, controls must be run with each batch of specimens to verify validity of the high and low ends of the calibration range.

Conforms?

G-8 At least one internal standard must be included in qualitative chromatographic assays.

Use of an internal standard in qualitative assays can help monitor extraction recovery and also determine whether a dilution is necessary for the quantitative assay. An internal standard will also assist in identifying the unknown analyte, if the laboratory uses relative retention times for this purpose. Some screening methods, such as LC/MS/MS or LC/TOF, may require the use of multiple isotopically labeled internal standards.

Conforms?

G-9 Where possible, an internal standard with chemical and physical properties as similar to the analyte as possible must be used for chromatography-based quantitative assays. If the analyte is derivatized, the internal standard must form an analogous derivative.

Adequate method validation should allow for assessment of the adequacy of an internal standard. Use of an internal standard may not be feasible for certain analytes such as carbon monoxide run by GC-TCD.

Conforms?

G-10 Internal standard recovery must be monitored for quantitative assays and documented action taken for recovery less than 50% of that for the calibrators or controls.

Where internal standard recovery is substantially reduced, it may indicate possible quantitative inaccuracy depending on the appropriateness of the internal standard. Method validation will provide information on how sensitive the assay is to reduced internal standard recovery. This will usually depend on the appropriateness of the internal standard (e.g., isotopically labeled analogue of the target analyte or not). A spike recovery using an aliquot of that specimen may be used to determine whether or not the low internal standard recovery has had a significant effect on the quantitation of the target analytes(s) and therefore whether reporting a quantitative result is appropriate. The robustness of a matching deuterated internal standard may be determined during method validation and/or with subsequent investigation.

Conforms?

G-11 New assays must be appropriately validated before implementation. Validation will minimally include:

- **Qualitative assays:**
  - **LOD or decision point**
  - **Interferences**
  - **Carryover**
- **Quantitative assays:**
  - **Calibration model**
  - **Matrix effects (including ion suppression studies for MS-based LC assays)**
  - **Accuracy**
  - **Precision**
  - **Interferences**
  - **Carryover**
  - **Dilution integrity (when routinely performed)**

Laboratories are strongly encouraged to refer to the ANSI/ASB Standard 036 "Standard Practices for Method Validation in Forensic Toxicology" (http://www.asbstandardsboard.org/published-documents/toxicology-published-documents/) when performing assay validations.

Rarely performed quantitative assays (e.g., fewer than 3 times annually) may be regarded as "self-validating" if sufficient calibrators and controls are run to demonstrate linearity, precision, sensitivity, and specificity (e.g., mass spectrometry-based technology). For example, when a multi-point matrix-matched calibration is run, if each calibrator is acceptable when read against the graph (e.g., ±20% of nominal value), case results are only to be reported out within the calibrator range, and an independently prepared control is run and acceptable (e.g., ±20% of target), the assay may be regarded as "fit for purpose". For such assays, and subject to sample availability, it is good practice to include a "standard addition" tube where a known amount of standard has been added to the unknown in order to assess recovery and linearity.

Conforms?

G-12 Validation records must be summarized and the data maintained for at least 5 years after an analytical method is no longer in service.

The validation package should clearly summarize what was done, what results were obtained, and what the conclusions were. Laboratories will not be unduly penalized for failure to have available documentation of validation that occurred prior to their initial accreditation. However, the ABFT Accreditation Program reserves the right to request assay validation, or re-validation, where performance issues are evident. Analysis of proficiency test samples can serve to demonstrate ongoing validation of a method, especially when those analyses are performed frequently (e.g., ethanol).

Conforms?

G-13 For assays that have been in use for several years, data must be available in a summarized format that consistently supports validity and reliability for all analytes covered by the assay and the stated calibration range.

For quantitative assays, the data may include information on the linearity of calibrations and the performance of calibrators and/or controls over a specified period of time.

It is not sufficient to collate the data as evidence of satisfactory prior performance. Periodic QC or calibrator failures are to be expected. However, if a specific analyte has chronically poor performance (e.g., poor linearity, or frequently failing calibrators or QC), then that analyte cannot be considered validated in that assay. Similarly, if a high or a low calibrator is frequently failing criteria, then the calibration range for that analyte cannot be considered validated.

Conforms?

G-14 The laboratory must have documented criteria for designating a positive qualitative result.

Definition of a positive analytical result by chromatography may be based on retention time, relative retention time, or retention index. For LC-spectrophotometry or GC-mass spectrometry it may be based on comparison with reference library data and a statistically based “fit”. Identification may alternatively be based on a combination of retention time and selected ion monitoring ion ratios (GC/MS) or MS/MS transition ratios compared with those of the calibrator. Identification by LC/(Q)TOF and Orbitrap may involve a combination of retention time, accurate mass data, and sometimes MS/MS transition ratios.

Conforms?

G-15 Positive results from immunoassay screening tests must be confirmed by another, more specific method, such as mass spectrometry.

Quantitation of an analyte may serve as acceptable confirmation of its identity if it was initially detected by a significantly different method (e.g., mass spectrometry quantitation of a drug detected by immunoassay). Similarly, the identification of a unique metabolite may serve as confirmation of the parent drug. Use of one immunoassay test to confirm the results of another immunoassay test is not acceptable.

Conforms?

G-16 Determination of the presence of a drug or toxicant must not rely solely on a single extraction (e.g., liquid/liquid, SPE or solvent 'crash') from a single specimen or aliquot thereof.

Confirmation of the identity of an analyte in a different specimen from that used for the first test (e.g., urine or blood) is acceptable, as is confirmation in a second aliquot of the same specimen, from the same or a different container. However, confirmation of a drug or toxicant in the same original extract is not usually acceptable, as that would not rule out the possibility that the extraction vial or extraction tube used was contaminated

Conforms?

G-17 Ethanol must be determined using a 2-column GC method or alternate method of equivalent or greater forensic strength.

Conforms?

G-18 Sufficient documentation from failed runs must be maintained (paper or electronic), to show a record of the testing performed, the volume of specimens used and who handled those specimens.

Deviations from these retention time standards must be individually justified for each analyte.

Conforms?

Section G: <u>SUMMARY</u>

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section H: GAS CHROMATOGRAPHY-MASS SPECTROMETRY (GC/MS[MS]) and LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY (LC/MS[MS]), and HIGH-RESOLUTION MS

H-1 The laboratory must have a documented procedure for action if MS tuning results are outside predetermined limits.

Hard copies of all MS tuning records are typically kept in chronological order in a folder or binder for easy review if a problem subsequently develops. However, an electronic record is also satisfactory, particularly if the records are in a database format so that they may be searched or graphically displayed. Evidence of corrective action is sometimes indicated directly on the MS tuning records. Often, the corrective action is recorded in a logbook or service record.

Conforms?

H-2 If the laboratory uses GC/MS full scan for mass spectral identification, there must be written criteria for identifying a positive spectral match that ensures that:

- **all diagnostic ions present in the reference spectra are present in the unknown;**
- **relative abundances of the diagnostic ions are considered; and**
- **relative retention times are considered.**

This is a difficult area to define, particularly in terms of a mathematical fit or "quality match". There may be additional ions in the 'unknown' spectrum due to minor interferences that cannot be removed by background subtraction, but all of the diagnostic ions present in the reference spectrum should be present in the 'unknown' unless absent due to low absolute abundance.

Conforms?

H-3 If the laboratory uses LC/MS 'full' scan or related methods scan for mass spectral identification, there must be written criteria for identifying a positive match that includes retention time and at least one fragment ion.

LC/MS spectra (or first stage LC/MS/MS) tend to be relatively simple and often consist mainly of an M+1 or M-1 base peak, plus isotope and/or adduct ions. While such spectra may be useful for indicating the molecular weight of the analyte, the relative lack of spectral information limits the certainty of identifying the substance specifically. Additional use of retention time can increase the confidence of identification. Running scans at 4–6 different cone voltages can further improve the accuracy of identification if additional fragments can be generated. However, LC/MS scans are often only useful as a screen for tentative identification of an analyte or perhaps for confirmation together with another mass spectral method.

Conforms?

H-4 If the laboratory uses LC/TOF* data for mass spectral identification, there must be written criteria for identifying a positive match that includes acceptable retention time and mass deviation.

Like LC/MS spectra LC/TOF spectra tend to be relatively simple and often consist mainly of a M+1 or M-1 base peak, plus isotope and/or adduct ions. However, TOF data provides the additional information of mass accuracy to 3 or 4 decimal places, thereby considerably improving the chances of identifying the molecular formula of the analyte. Additional use of retention time can increase the confidence of identification significantly. However, LC/TOF scans are useful as a screen for tentative identification of analyte or perhaps for confirmation together with another mass spectral method. *Also applies to high resolution data not derived using TOF technology.

Conforms?

H-5 If the laboratory uses commercial software to assist in mass spectral identification (e.g., GC/MS[MS], LC/MS[MS], LC/TOF applications), there must be written criteria for identifying a positive match that includes review of the underlying mass spectral data to confirm the general basis for the software match and that does not rely solely on the software algorithm.

Conforms?

H-6 If the laboratory uses GC/MS selected ion monitoring (SIM) for identification, ion ratios and retention times between calibrators, controls, and unknowns must be compared.

- **A minimum of three ions must be monitored for the analyte and two ions for the internal standard. C-13 Isotope ions are not suitable as qualifier ions.**
- **Qualifying ions must be no more than ±20% of the target, relative to a calibrator, unless the laboratory has documented that ±20% of the target cannot be reliably achieved for specific analytes, in which case ion ratios no greater than ±30% are acceptable.**
- **Retention times must be within ±2% or ±0.1 minutes relative to a calibrator or control in the same run.**

Conforms?

H-7 If the laboratory uses LC/MS[MS] multiple reaction monitoring (MRM) for identification, ion ratios and retention times between calibrators, controls, and unknowns must be compared.

- **Two transition ions must be monitored for the analytes. If a second transition cannot be reliably used for confirmation of specific analytes, those exceptions and reasoning must be documented.**
- **For all quantitative assays developed and validated after April 1, 2021, two transition ions must be monitored for each internal standard. If a second transition ion cannot be reliably used, those exceptions and reasoning must be documented.**
- **Transition ratios must be no more than ±20% of target, relative to a calibrator, unless the laboratory has documented that ±20% of the target cannot be reliably achieved for specific analytes, in which case transition ratios no greater than ±30% are acceptable.**
- **Transition ratios no greater than ±30% are acceptable if the laboratory can document that ±20% cannot be reliably achieved for specific analytes.**
- **Retention times must be within ±3% or ±0.1 minutes relative to a calibrator or control in the same run.**

Conforms?

H-8 If the laboratory uses Orbitrap technology for mass spectral identification, there must be written criteria for identifying a positive match.

The Orbitrap may be run in multiple modes (e.g., single MS analysis, MS/MS with full scan collection, or MS/MS with multiple reaction monitoring). It can also be run in ion trap mode (unit mass resolution) or at various high-resolution settings (typically 7500–60,000, depending on the instrument). The criteria for identification should be appropriate to the type of analysis performed.

Conforms?

Section H: <u>SUMMARY</u>

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section I: OTHER ANALYTICAL TECHNIQUES

I-1 For each of the techniques utilized by the laboratory not covered elsewhere in this accreditation checklist, the laboratory must have in place appropriate policies and procedures to ensure that reported results are supported.

It is recognized that, depending on a given laboratory's scope of testing, various instrumental and non-instrumental techniques that are not covered in other sections of this accreditation checklist may be used. While not comprehensive, the following are other techniques that may be found in forensic toxicology laboratories, including more common techniques for the detection and measurement of carboxyhemoglobin or carbon monoxide and cyanide:

- Inductively-coupled Plasma Mass Spectrometry (ICP-MS)
- Optical Emission Spectroscopy (OES)
- Atomic Absorption Spectroscopy (AAS)
- Capillary Electrophoresis (CE)
- Thin-layer Chromatography (TLC)
- Laser Diode Thermal Desorption Mass Spectrometry (LDTD-MS)
- Direct Analysis in Real Time Mass Spectrometry (DART-MS)

It is not feasible or practical to establish checklist questions for such techniques. However, it is incumbent upon laboratories to have similar policies and procedures covered within other sections of this checklist as they apply. These include:

- Administrative and Procedural SOPs
- Method Validation
- Quality Control
- Instrument Performance Logs to include Records of Routine and Unscheduled Maintenance
- Reporting Criteria
- Proficiency Testing, as available

Conforms?

List Applicable Techniques:

_____

_____

_____

_____

_____

Section I: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section J: BIOCHEMISTRY INCLUDING IMMUNOASSAY

Some toxicology laboratories are periodically asked to perform certain biochemistry tests on postmortem specimens such as vitreous humor or partially hemolyzed blood. Examples include glucose, sodium, chloride, urea, and creatinine. Results of such testing may assist forensic pathologists in the determination of cause of death. It is also recognized that performance of biochemistry tests on postmortem specimens may not be practical in all clinical laboratories.

J-1 The laboratory instrumentation must be maintained and serviced regularly, according to the manufacturer's recommended protocol.

In addition to containing instrument specifications and routine testing procedures, the instrument operator's manual contains recommended maintenance procedures to be performed daily, weekly, monthly, etc. and troubleshooting diagrams or flow charts and directions for equipment servicing that can be performed by the operator. Many operator's manuals contain service log sheets and maintenance checklists that can be copied and used in the laboratory.

Conforms?

J-2 Maintenance records must be maintained and readily available to the technical staff operating the equipment and supervisory personnel responsible for review.

They are indicators that the instrument is operating properly. Changes in instrument and reagent performance with time can be noted.

Conforms?

J-3 If a commercial methodology is applied to specimens that have not been approved by the manufacturer the application must be validated by the laboratory.

The vast majority of biochemical analyses include immunoassays as well as sodium, potassium, chloride, urea, creatinine, and glucose in vitreous humor, performed using commercial equipment and reagents designed for clinical testing of serum or plasma. It is necessary for the laboratory to validate any modification to a commercially available assay, such as running a different specimen than that which the commercial assay was designed (e.g., vitreous instead of serum or plasma) or running a specimen of a very different condition (e.g., badly hemolyzed blood versus serum or plasma).

Conforms?

J-4 Adequate matrix-matched controls must be included in each analytical run.

For vitreous electrolytes, preparing a positive vitreous electrolyte control may be as simple as pooling multiple specimens to obtain an adequate volume, fortifying with glucose as necessary. The control material may be tested multiple times in order to establish an acceptable QC range. As necessary, such a pool may be augmented with additional analyte such as glucose to establish a useful QC range. ‘Normal’ vitreous electrolyte ranges may be established by running a large enough number of vitreous samples and establishing a mean and standard deviation for the lab’s own instrumentation, or published ranges can be used (e.g., CAP: www.cap.org/apps/docs/newspath/0812/vitreous_postmortem_chemical_analysis.pdf).

Conforms?

Section J: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section K: OTHER EXHIBITS

Forensic toxicology laboratories may periodically be asked to qualitatively, and occasionally quantitatively, analyze non-biological exhibits for the presence of drugs and other toxicants. Such exhibits include drug abuse paraphernalia such as syringes, spoons, pipes, etc., as well as powders, pills, capsule contents, and possible drug residues (e.g., dry residue or fluid in drinking vessels). Analysis of such exhibits is generally well within the capability of any competent forensic toxicology laboratory, and the findings may assist forensic pathologists in determining the cause or manner of death.

K-1 Analysis of drugs in non-biological samples must be performed in a manner that prevents cross-contamination with assays used to perform testing on biological samples.

Analysis of high-concentration exhibits such as pills, powder, and drug paraphernalia should ideally be performed in an area that is separate from that used for biological samples such as blood and urine and, ideally, using different analytical equipment. Where it is not practical to do so, care should be taken to avoid any cross-contamination or carryover. Use of disposable glassware to minimize cross-contamination is important. Also, post-analysis checks such as the analysis of negative control material can demonstrate the absence of contamination once the analysis is complete.

Conforms?

K-2 Determination of the identity and/or concentration of a drug or other toxicant must be performed following a validated method, as prescribed for biological sample testing.

Conforms?

K-3 Where a laboratory chooses to perform testing on non-biological samples, procedures used must be clearly outlined in an SOP, supplemented as necessary by bench notes that are retained with the analytical record or case file.

Conforms?

Section K: <u>SUMMARY</u>

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

Section L: SAFETY

L-1 The laboratory must follow good laboratory safety practices.

- **Have a documented safety training program to include general laboratory safety practices and bloodborne pathogens.**
- **Proper equipment must be available to render first aid to a victim and prevent harm to others.**
- **There must be a safety manual that at a minimum abides by local, state, and federal regulations and addresses the following:**
  - **specimen handling, including infectious material and the disposal of biological specimens;**
  - **handling and disposal of solvents, reagents, and other chemicals;**
  - **handling and disposal of laboratory glassware;**
  - **responses to personal injuries;**
  - **responses to spillage of biological specimens, chemicals, solvents, reagents or radioactive materials;**
  - **evacuation procedures; and**
  - **regulations governing protective clothing, eating, drinking, or smoking in the laboratory.**

It is essential that the laboratory personnel work in a safe and healthy environment. Safety is the collective responsibility of the individual and all laboratory personnel.

Conforms?

L-2 The laboratory must have a documented procedure for all laboratory staff to review the safety manual, at a minimum on commencement of initial employment.

The manual may be owned and controlled by the institution that the forensic toxicology laboratory is a part of (e.g., larger laboratory system or hospital).

Conforms?

L-3 The laboratory's work areas must be clean and free of clutter.

Conforms?

L-4 The laboratory must have proper general ventilation and adequate heating, cooling, and humidity control. Adequate and proper lighting must be provided for personnel to carry out assigned tasks.

Conforms?

L-5 The laboratory must have adequate room to accommodate all technical work and safe storage of laboratory and supplies to include:

- **space for each employee to accomplish assigned tasks;**
- **space for each instrument to facilitate its use and operation;**
- **space for personnel for the writing of reports and other official communications;**
- **space for general supplies and materials intended for immediate use; and**
- **space for laboratory and clerical supplies that are in excess of short-term use.**

Inadequate space reduces the efficiency of laboratory operations and increases the risk of mishandling or contaminating evidence and poses a potential safety risk to personnel. Inadequate space also reduces personnel morale and thus adversely affects productivity. The physical design of the laboratory should enhance the flow of work from the time of specimen receipt to final disposal. Interrelationship of functional areas should be laid out in a manner that will facilitate the use of equipment and instruments.

Conforms?

Section L: SUMMARY

General Comments (if any):

Non-conformities (list the standard numbers here and explain any non-conformities under each standard):

Suggestions for improvement (non-mandatory suggestions that are not required program standards):

CONCLUDING SUMMARY COMMENTS

Start here…

Team Lead/Lab Director:_____ Date:_____